U.S. Food and Drug Administration

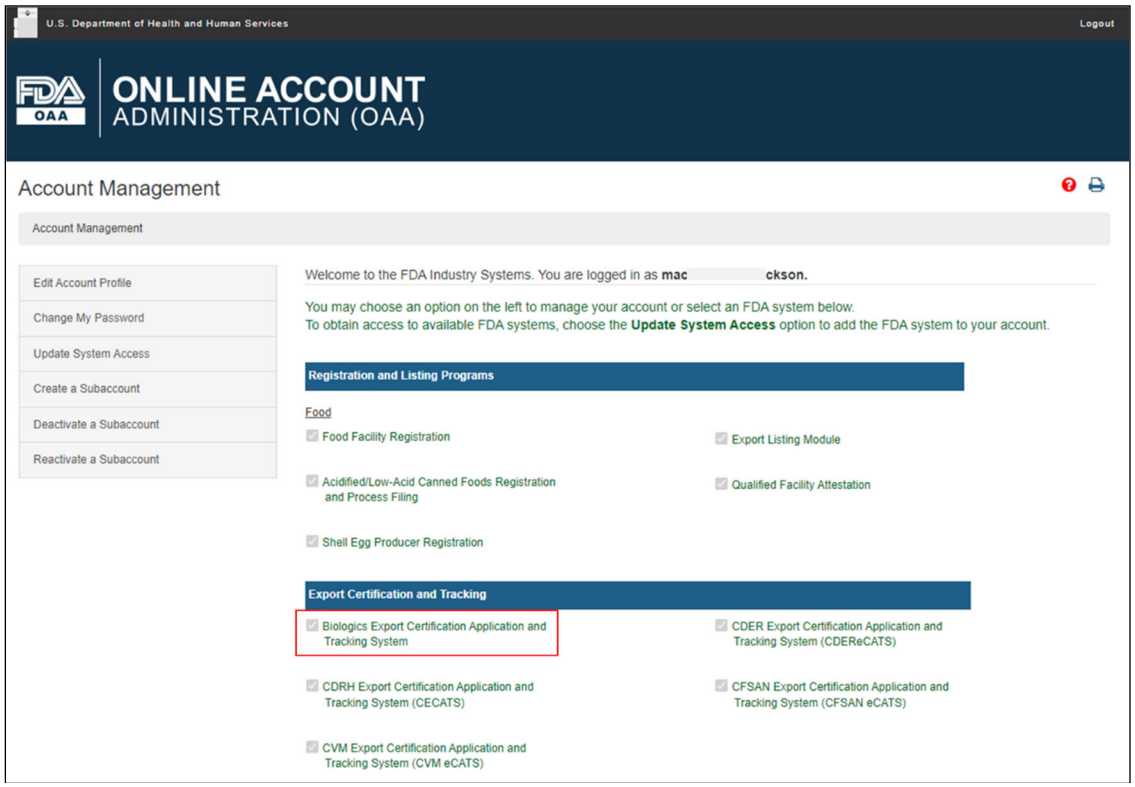
BECATS External User Guide – Enter a Certificate of a Pharmaceutical Product (CPP) Application Step-by-Step Instructions

Table of Contents

Accessing BECATS

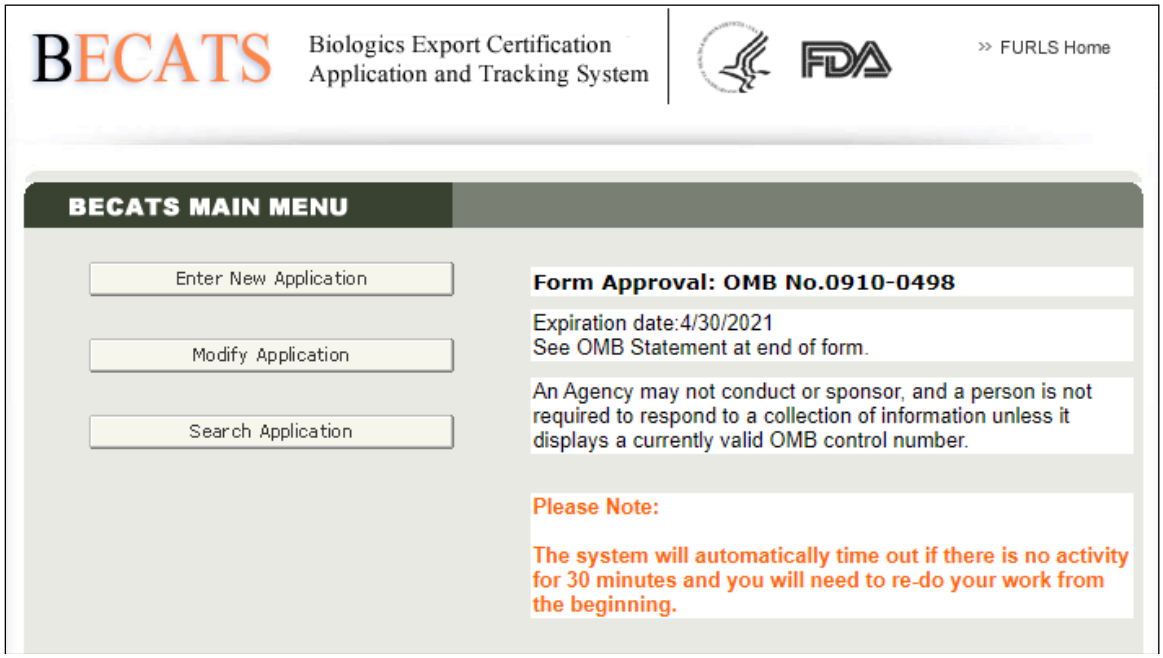
After you have logged into the FDA Industry Systems, select 'Biologics Export Certification Application & Tracking System' (BECATS) from the list of systems available on the FURLS Home Page as shown in **Figure 1** below.

Figure 1: FDA Industry Systems Page



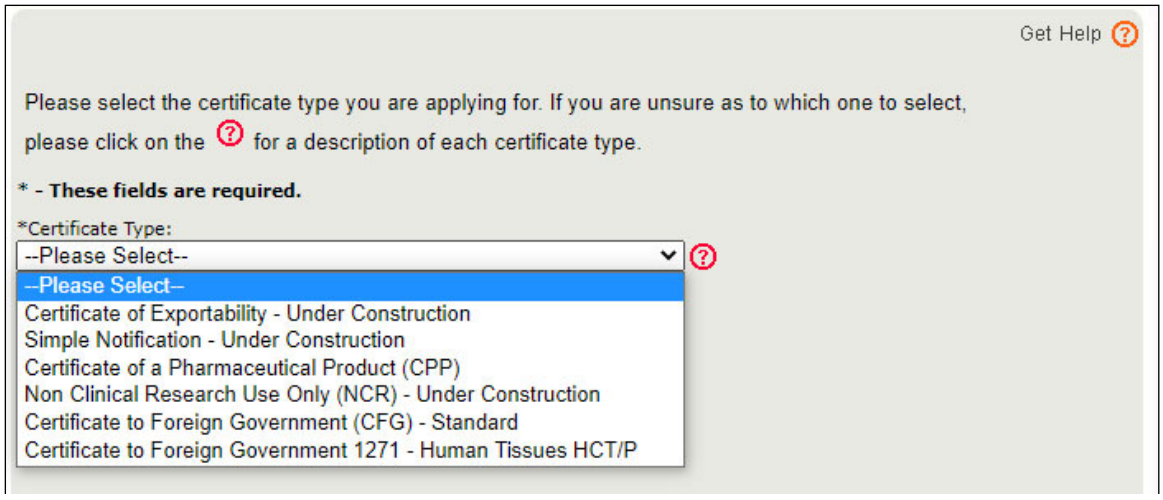
Once you have selected 'Biologics Export Certification Application and Tracking System', the system will direct you to the BECATS Main Menu page as shown in **Figure 2** below.

Figure 2: BECATS Main Menu



The Center for Biologics Evaluation and Research (CBER) issues several Export Certificate Types. When creating a new application, you will need to first select which certificate type you are requesting as shown in **Figure 3** below.

Figure 3: Certificate Types



NOTE: Currently the Certificate to Foreign Government (CFG) Standard, 1270, 1271, and the Certificate of a Pharmaceutical Product (CPP) are the only certificate type that can be requested online. The online applications for the other certificate types (which include the Non-Clinical Research and Certificate of Exportability) will be available in the near future. For all other certificate types, please fill out and send the appropriate application form to the following address:

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Case Management
10903 New Hampshire Avenue
Silver Spring, MD 20993
CBERBECATS@fda.hhs.gov

Description of Certificate Types:

CFG - Standard	Certificate to Foreign Government (export of product legally marketed in the U.S.)
CFG - 1270	Certificate to Foreign Government (For Tissue Procured Prior to May 25, 2005)
CFG - 1271	Certificate to Foreign Government (For HCT/Ps Procured After May 25, 2005)
CPP	Certificate of a Pharmaceutical Product, World Health Organization (Labeling required)
NCR	Non-Clinical Research Use Only Certificate (Export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the U.S.)
COE (801(e)/802)	Certificate of Exportability (For Export of products not approved for marketing in the U.S.)
Simple Notification	Simple Notification (Requires persons exporting a drug or device under section 802(b)(1) of the Act to provide a "simple notification identifying the drug or device when the exporter first begins to export such drug or device" to any country listed in section 802(b)(1) of the Act. If the product is to be exported to an unlisted country, section 802(g) of the Act requires the exporter to provide a simple notification "identifying the drug or device and the country to which such drug or device is being exported.)

To view the definitions of the product types for which you can request an Export Certificate in BECATS, click on the red question icon located next to the certificate type list. The system will display in a new window with a description of each certificate type as shown in **Figure 4** below**.**

Figure 4: Certificate Type Description

Certificate Type:

Certificate to Foreign Government (CFG):

Certificate to Foreign Government (export of product legally marketed in the U.S.)

Certificate to Foreign Government 1270 - Tissues for Transplant:

Certificate to Foreign Government (For Tissue Procured Prior to May 25, 2005)

Certificate to Foreign Government 1271 - Human Tissues HCT/P:

Certificate to Foreign Government (For HCT/Ps Procured After May 25, 2005)

Certificate of a Pharmaceutical Product (CPP):

Certificate of a Pharmaceutical Product, World Health Organization (Labeling required)

Navigation

At the top of every page during the Enter New Application process, a status bar will track your progress through each step of the online application process as shown in **Figure 5** below.

Figure 5: Navigation Bar

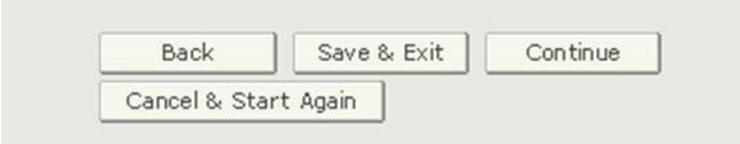
A ‘Get Help’ icon, located at the top right of each step, will provide page specific help. For an overview of online help files available, please refer to the FDA Industry Systems Index of Help Pages at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/BiologicsImportingExporting/default.htm

The ‘FURLS Home’ link, located at the top right corner of each page, will take you to the FURLS Home Page. The ‘BECATS’ link, located below the ‘FURLS Home’ link, will

take you to the BECATS Main Menu Page (Refer to **Figure 1** and **Figure 2**). To log out of the system, select 'FURLS Home' and click on logout.

At the top and bottom of each screen are navigation buttons as shown in **Figure 6** below.

Figure 6: General Navigation Buttons



- **Back** - Go back one screen and continue entering application information. Information entered on the current screen will NOT be saved.

- **Save & Exit** - Information entered up to this point will be saved. The system will provide you with an application number and your application will be in a 'Draft' status in the system for 60 days. After 60 days the application will be deleted from the system. When you log into the BECATS system, any applications that are in a 'Draft' status will be displayed after selecting the 'Enter New Application' option from the main menu.

- **Continue** - Go to the next screen and continue entering the application form.

- **Cancel & Start Again** - The system will return you to the screen where you enter your selected Certificate Type. Any information you have entered will NOT be saved.

Enter a Certificate of a Pharmaceutical Product (CPP) Application

To begin the application process, select 'Enter New Application' from the list of options from the Main Menu. You may also select 'Modify Application' or 'Search Application' from the main menu.

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

Figure 7: Account Applications

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

- If you wish to continue working on an application that has been saved, select the desired application radio button and click on 'Complete Draft Application'.
- If you wish to copy an existing application, select the desired application radio button and click on 'Clone Application'. Please refer to 'Create an application based on the existing application' section under the Modify Application of this document for more details.
- If you wish to create a new application, click on 'Enter New Application'.

Step 1 - Requestor Information

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

Most of the fields in Section 1 are automatically populated based on the information from your Online Administration Account (OAA) and cannot be edited in BECATS. If the information is incorrect, you can click on the '**OAA**' hyperlink and login into your OAA.

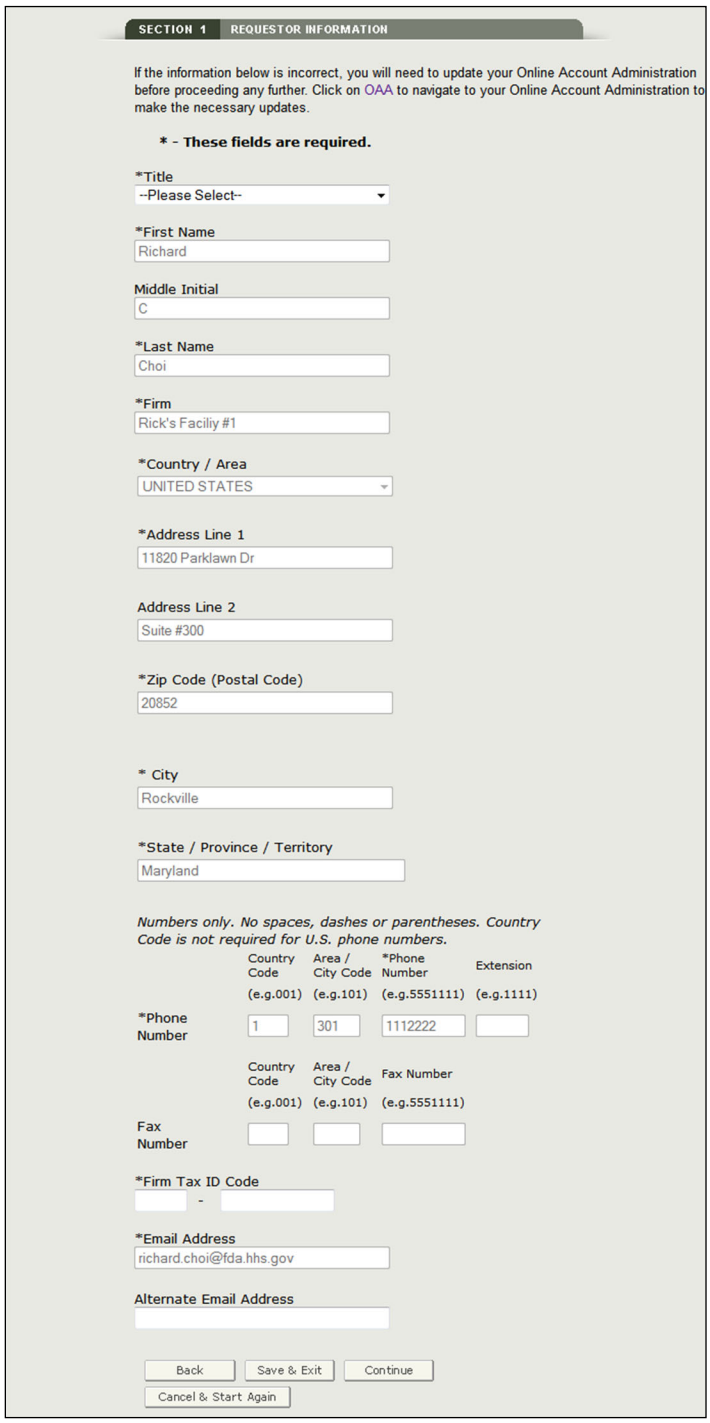
You can also click on the 'FURLS Home' link, located in the top right corner. Then select 'Edit Account Profile' on the left-hand side and update your account profile accordingly. Once you have updated your account, navigate back to BECATS and verify your changes.

Fields marked with an asterisk (*) are mandatory.

You may also enter an optional alternate email address to be included on all email notifications for this application.

Once you have completed these fields, click on Continue. See **Figure 7** below.

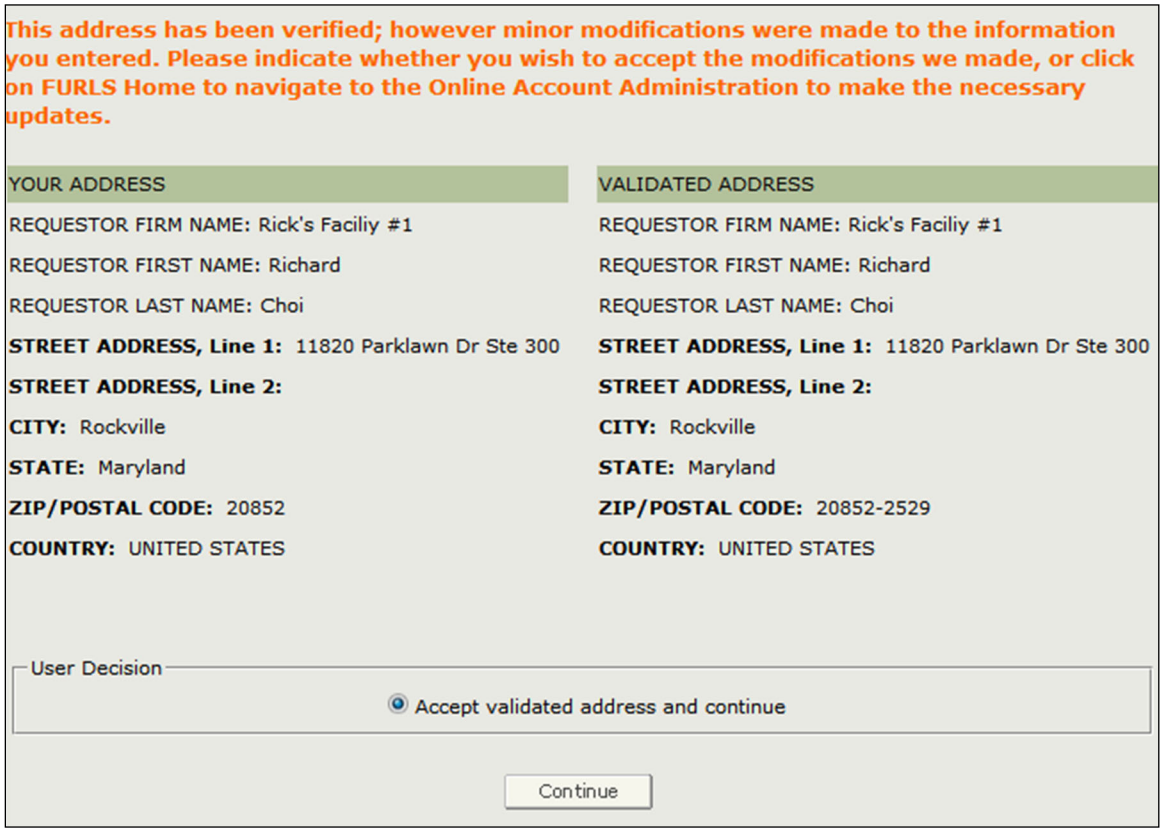
Figure 7: Requestor Information



Address Validation

The system will perform an address validation. The system will display the 'Validated Address' if there are minor differences to the requestor address. If the address is incorrect, you will need to exit the application and make the necessary updates to your Online Account Administration. Otherwise, select the 'Accept validated address and continue' radio button and click on Continue to proceed to Step 2. See **Figure 8** below.

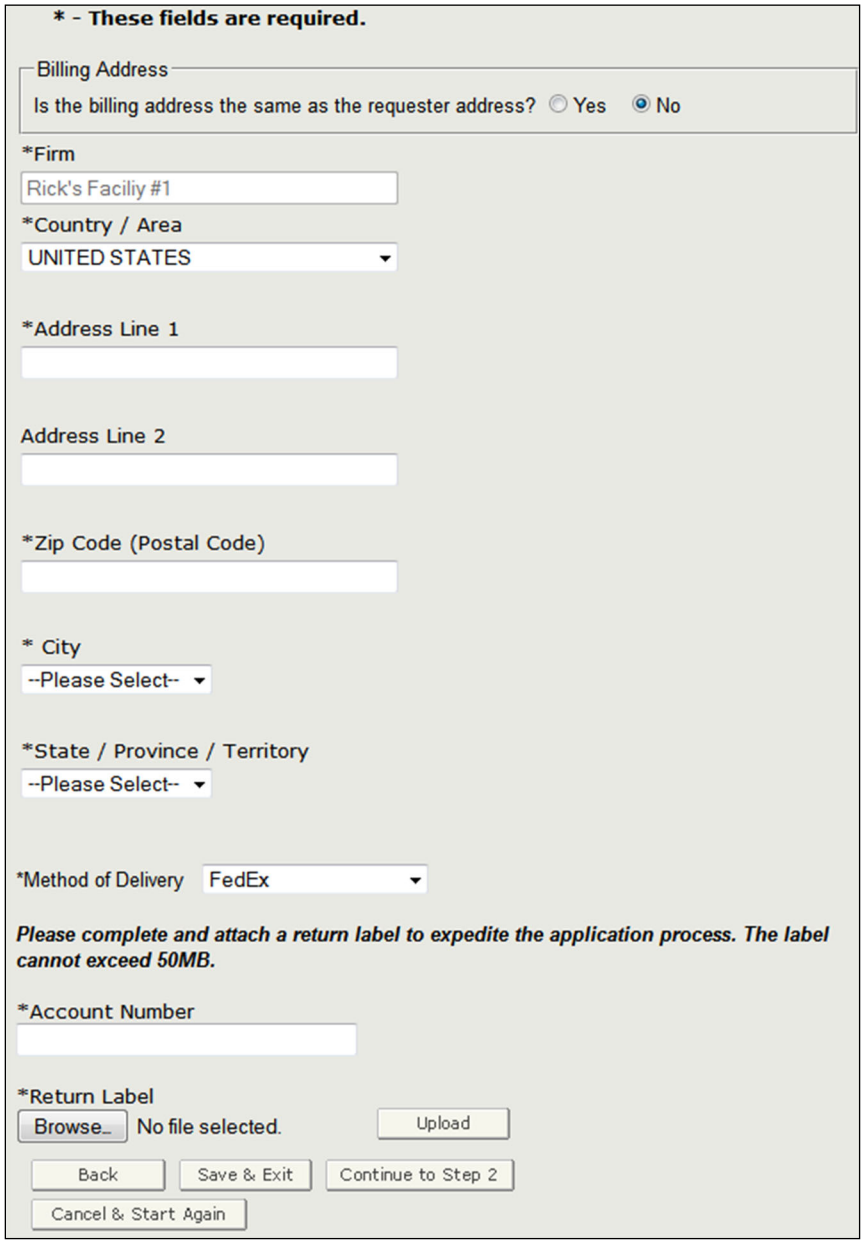
Figure 8: Address Validation



Billing Address / Method of Delivery

Before proceeding to step 2, you will need to verify if the billing address is the same as the requestor address. If it is NOT the same as the requestor address, select 'No' and enter the billing address. You will also be able to select the method of delivery. You have the option to select from USPS (Regular Mail), FedEx, or UPS. If you select FedEx or UPS, you will need to provide an account number and attach a filled-out return label as shown in **Figure 9** below.

Figure 9: Billing Address / Method of Delivery



Once you have completed this section, click on 'Continue to Step 2'.

NOTE: The system will perform an address validation check if you entered a new billing address. The system will display the 'Validated Address' if there are minor differences to the billing address. If the address is incorrect, you will need to update the billing address from the previous screen. Otherwise, select the 'Accept validated address and continue' radio button and click on 'Continue' to proceed to Step 2.

Step 2: Product Information

Section 1.1 - Proprietary Name, Dosage Form, and Foreign Brand Name

Please enter the Proprietary name and Dosage form exactly as you want it to be printed on the certificate. If a Foreign Brand name is available, enter the information. This is optional.

If you need to add ™, © and ® as part of the product name, please enter it as '(TM)', '(C)' and '(R)' respectively. When previewing the certificate, the ™, ©, ® will be displayed.

Section 1.2 - Active Ingredient and Amount per Unit Dose

Please enter the Active ingredient and Amount per unit dose exactly as you want it to be printed on the certificate.

If you need to add ™, © and ® as part of the product name, please enter it as '(TM)', '(C)' and '(R)' respectively. When previewing the certificate, the ™, ©, ® will be displayed.

NOTE: There is a limit on the number of characters that you can enter for each freeform text field for Sections 1.1 and 1.2. If you exceed that limit (calculated by the width of each character), you will receive an error message and will need to adjust your entry. If this situation occurs, please abbreviate as much as possible to reduce the number of certificates.

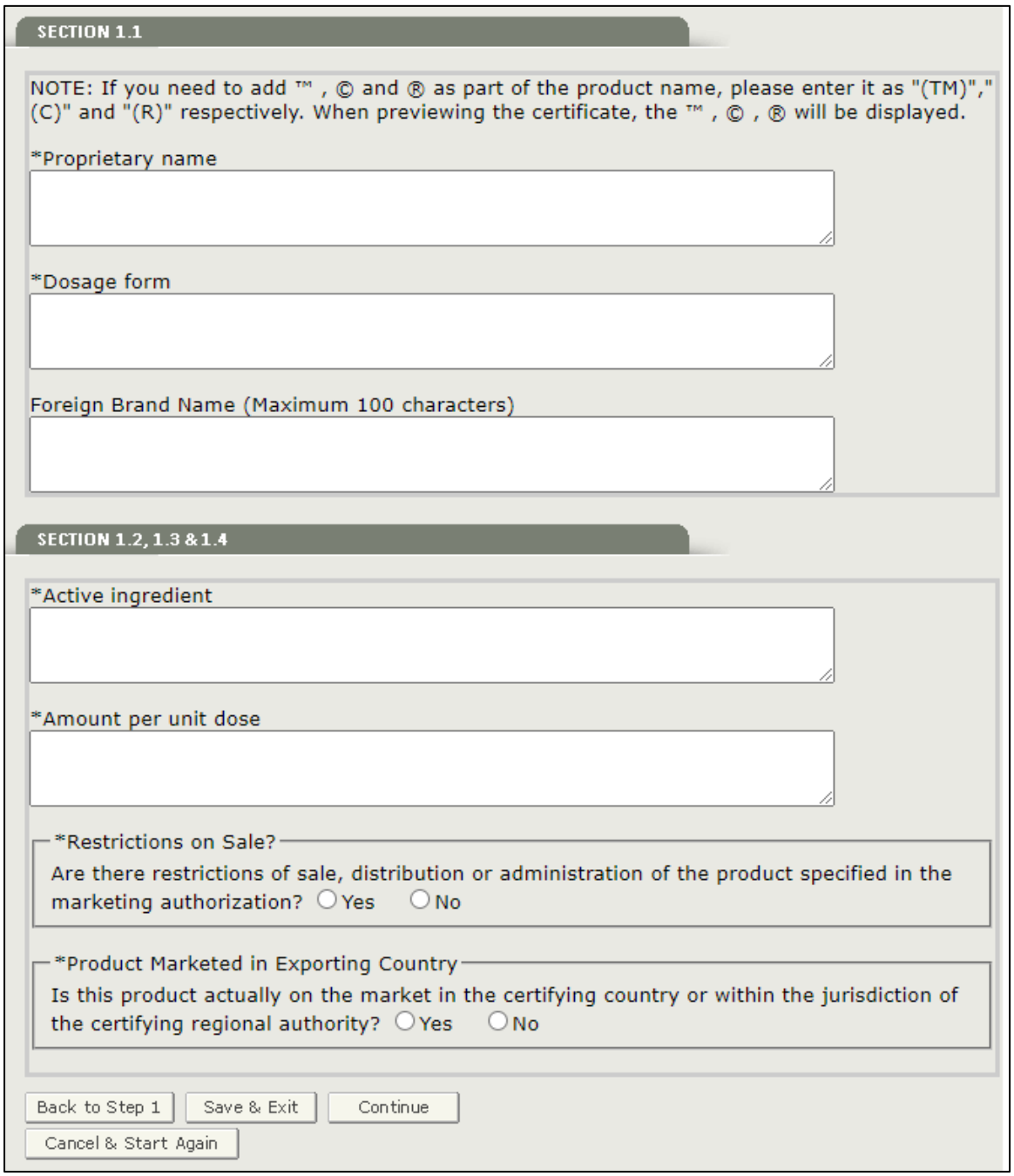
Section 1.3 and 1.4 Sales and Product Marketed

Provide a response to the following questions:

- Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority?
- Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization?
- Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority?

Fill out all fields that have be marked with an asterisk (*) as shown in **Figure 10** below.

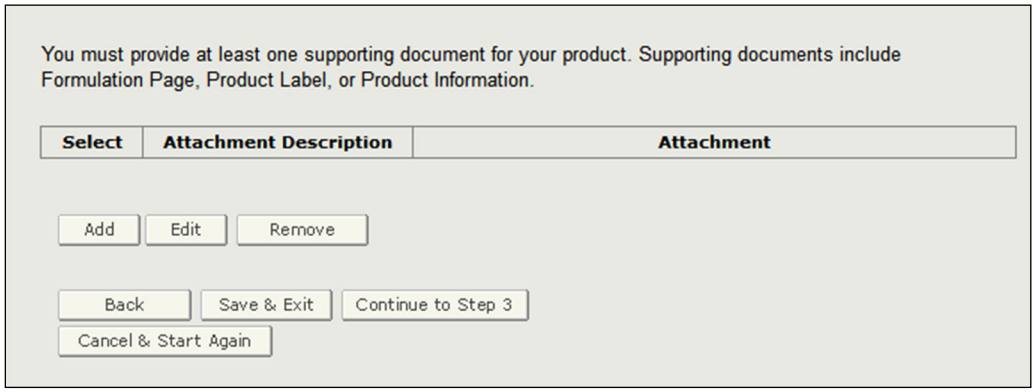
Figure 10: Section 1.1, 1.2 1.3 and 1.4 Information



Supporting Document for your Product

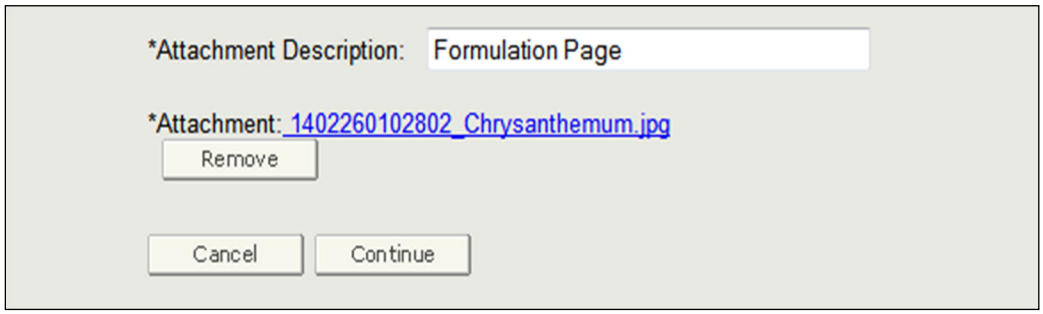
The FDA requires at least three supporting documents that must be accompanied with this application for the product to be exported. Supporting documents include the Formulation Page, Product Label, or any Product Information. To add a supporting document, click on the 'Add' button as shown in **Figure 11** below.

Figure 11: Supporting Document



You must enter a description of the attached file in the Attachment Description field. After entering a description, click on the 'Browse' button and select the file you wish to upload. Once you have selected the file, click on 'Upload'. If the system displays the uploaded file in a hyperlink format, then you have successfully attached the file to the application as shown in **Figure 12** below.

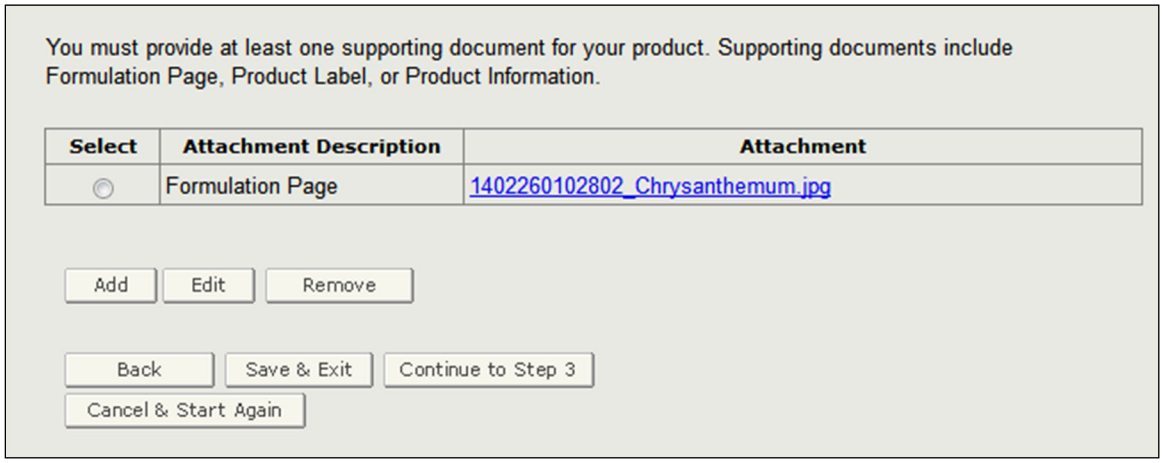
Figure 12: Browse for a File and Upload



Click on 'Continue'

The system displays the Attachment Description along with the uploaded file. If you wish to add additional documents, please click on 'Add' and repeat the steps as shown above. You may also remove any existing attached documents by clicking on the radio button next to the Attachment Description and click on 'Remove' as shown in **Figure 13** below.

Figure 13: Supporting Document Summary Page



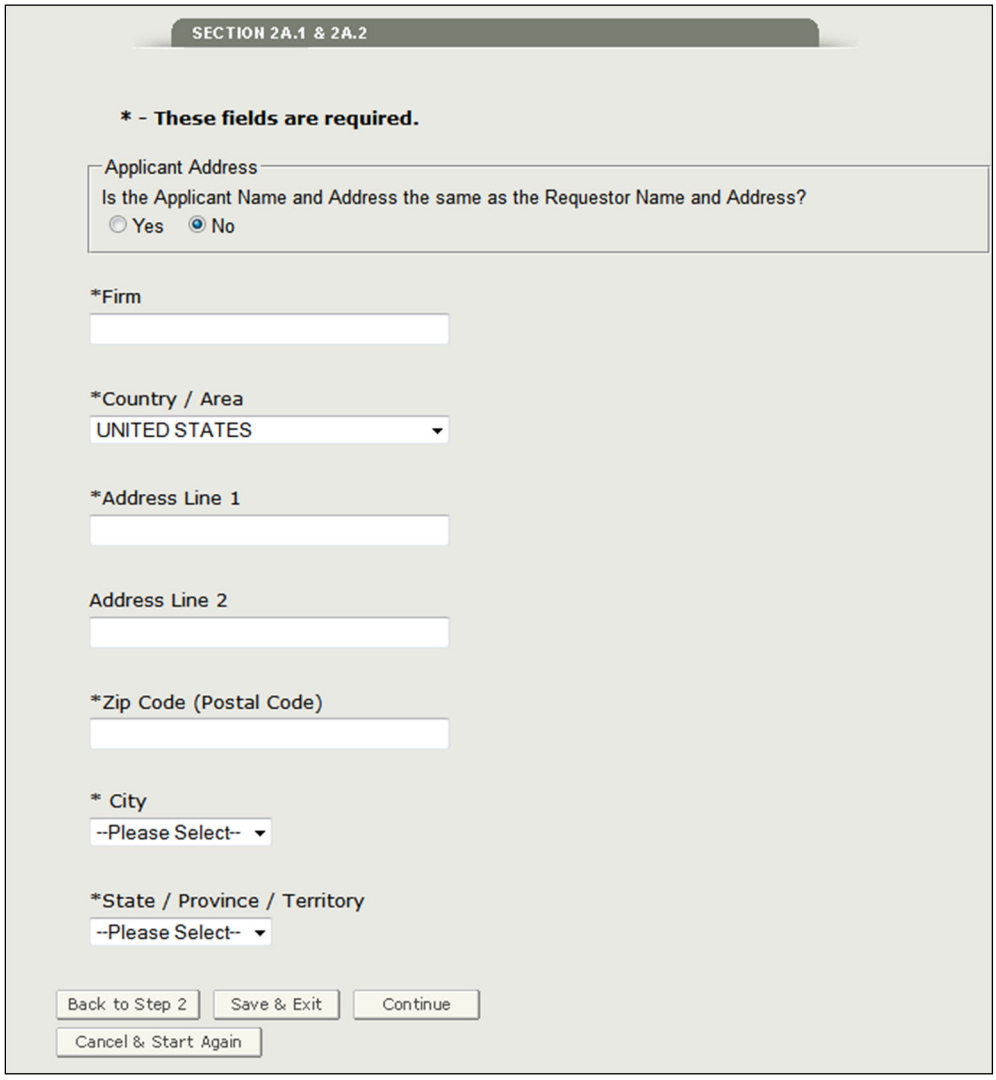
Once you have completed this step, proceed to the next step by clicking on 'Continue to Step 3'.

Step 3: Applicant Information

Section 2A.1 & 2A.2 - Applicant Address and Marketing Authorization Number

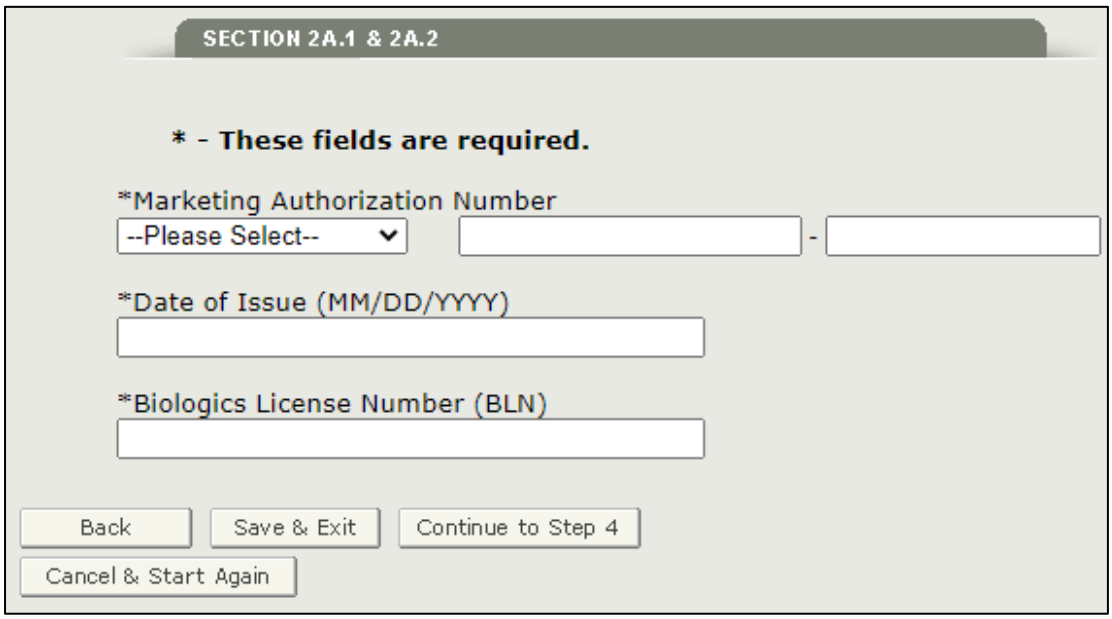
In section 2A.1 you will need to verify if the applicant's name and address is the same as the requestor name and address. If it is NOT the same as the requestor name and address, select 'No' and enter the applicant's name and address as shown in **Figure 14** below.

Figure 14: Applicant Address



In Section 2A.2, you must enter the type of product in the dropdown menu and the corresponding Marketing Authorization Number, Date of Issue, and the Biologics License Number (BLN) as shown in **Figure 15** below.

Figure 15: Marketing Authorization Number



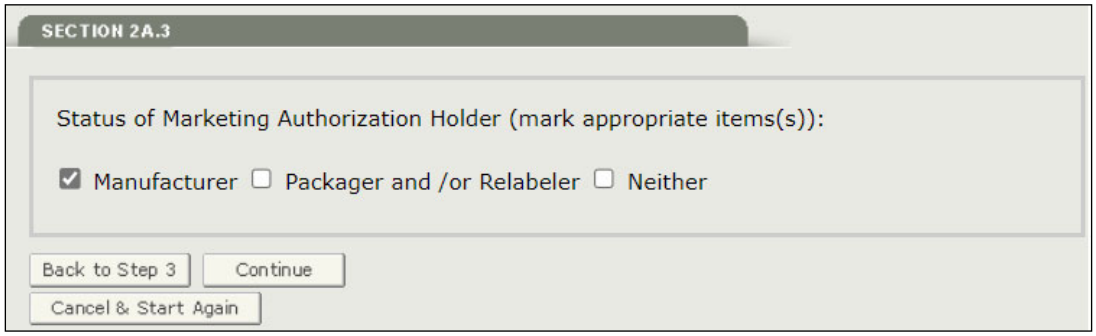
Once you have entered all of the fields, click on 'Continue to Step 4'.

Step 4: Marketing Authorization Holder Information

Section 2A.3 - Status of the Marketing Authorization Holder

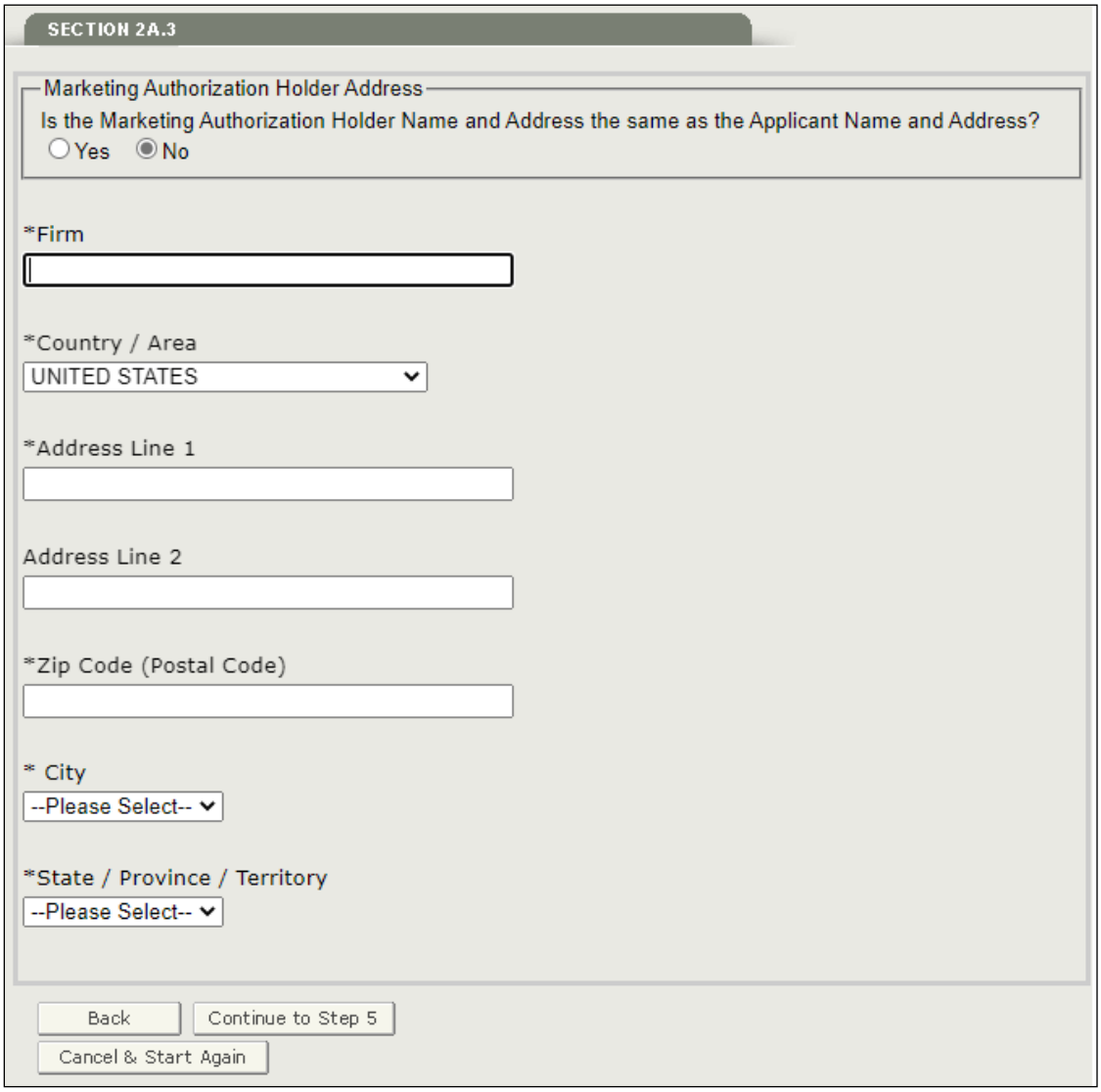
Please select the status of the product license holder. You have the option to select Manufacturer, Packager and/ or Relabeler, Manufacturer and Packager and/or Relabeler, or Neither as shown in **Figure 16** below.

Figure 16: Status of Marketing Authorization Holder



In section 2A.3 you will also need to verify if the product license holder name and address is the same as the applicant's name and address. If it is NOT the same as the applicant's name and address, select 'No' and enter the product license holder name and address as shown in **Figure 17** below.

Figure 17: Marketing Authorization Holder Name and Address



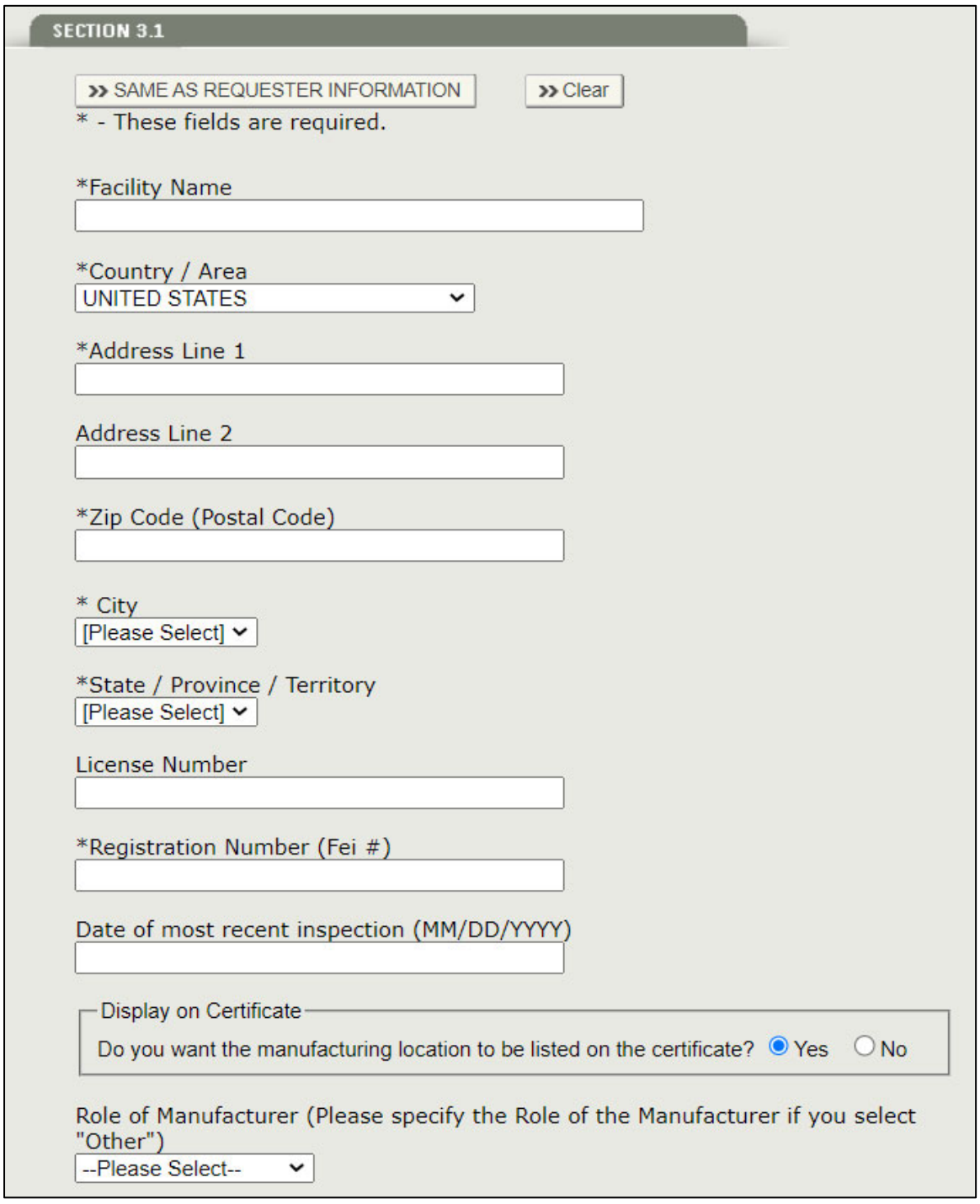
Step 5: Facility Information

Section 3.1 - Facility Information

In this section, you are required to enter at least one facility on the application. Please enter the facility name, address, and registration number as shown in **Figure 18** below.

NOTE: If you select the 'SAME AS REQUESTOR INFORMATION' button, the system will populate all required fields except the registration number and role of manufacturer.

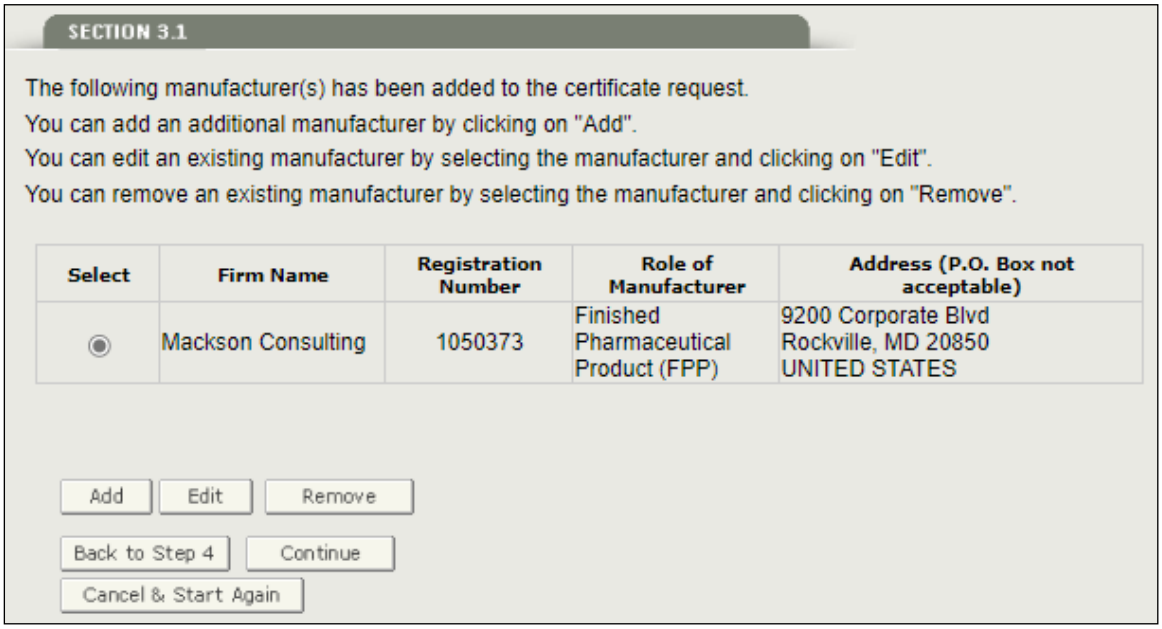
Figure 18: Facility Information



Once you have entered the Firm Name, address, and registration number fields, you must select whether you want the address to be printed on the certificate. You must then select the role of the manufacturer.

Click on ‘Add’ to add the facility to the application. The system displays the first facility added to your application as shown in **Figure 19** below.

Figure 19: Facility List



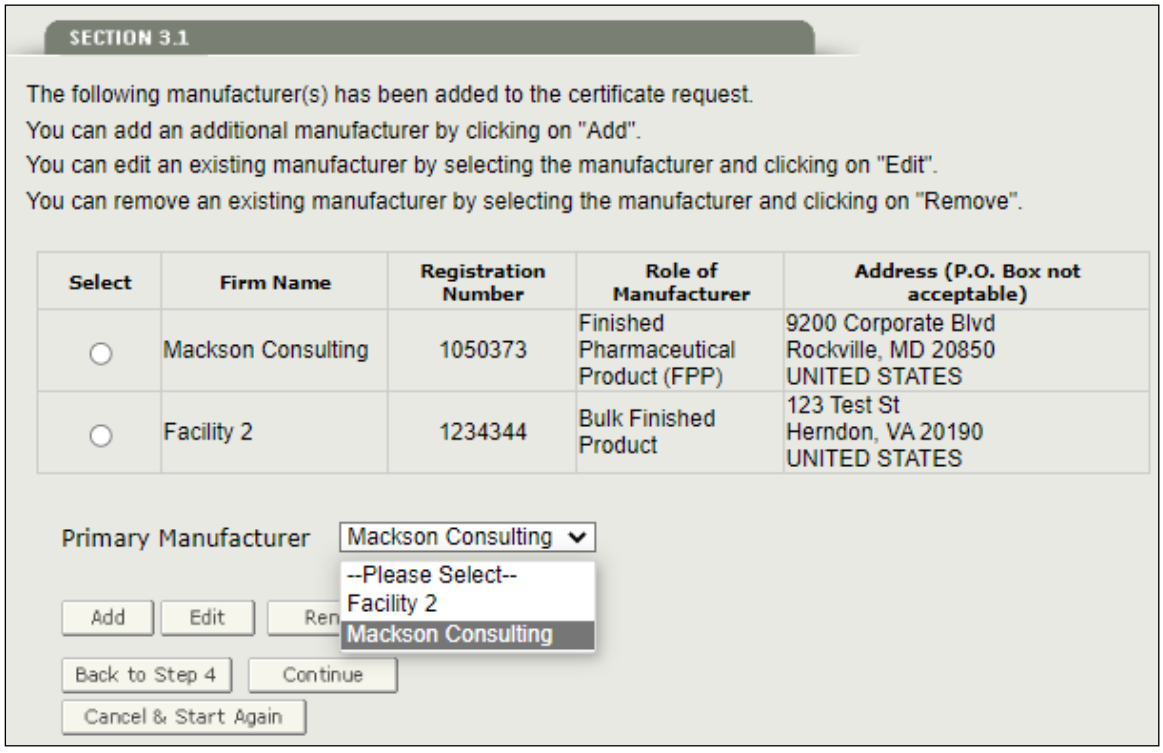
NOTE: You can add up to five facilities per application.

Add Facility

To add an additional facility, click on the Add button. Enter the required fields and when finished, click on ‘Add’. The system will display the facility added to the facility list.

If more than one facility is added and more than one facility will be listed on the certificate, the “Primary Manufacturer” field is displayed, as shown in Figure 20. This is the manufacturer that will be listed on the first page of the certificate. Additional manufacturers will be displayed on a second certificate page.

Figure 20: Select Primary Manufacturer



Edit Facility

To edit a facility, select the radio button next to the facility you wish to edit and click on 'Edit' as shown in **Figure 20** above. The system will re-display the facility information and allow you to edit any of the fields displayed.

Remove Facility

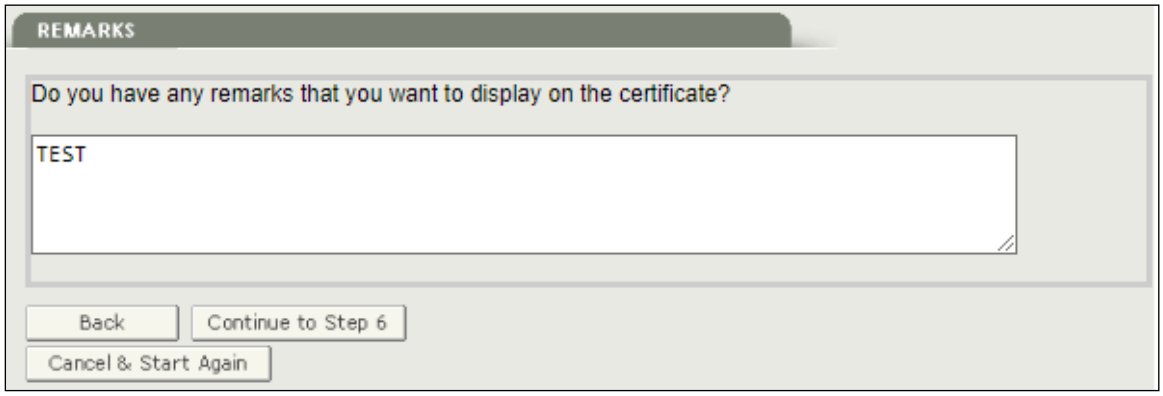
To remove a facility, select the radio button next to the facility you wish to remove and click on 'Remove' as shown in **Figure 20** above. The system will display the facility information and a warning message. Click on the 'Continue' button to remove the facility from the facility list. You may also select the 'Cancel' button if you do not wish to remove the facility.

Once all facilities have been added to the facility list, click on 'Continue'.

Add Remarks

As part of the "REMARKS" section, you have the option to add any remarks you would like to display on the certificate. Please enter any remarks in the freeform text field as shown in **Figure 21** below.

Figure 21: Remarks



Note: If the entered remarks are greater than 200 characters, a second certificate page will display the complete Remarks entered.

Click on 'Continue to Step 6' to proceed.

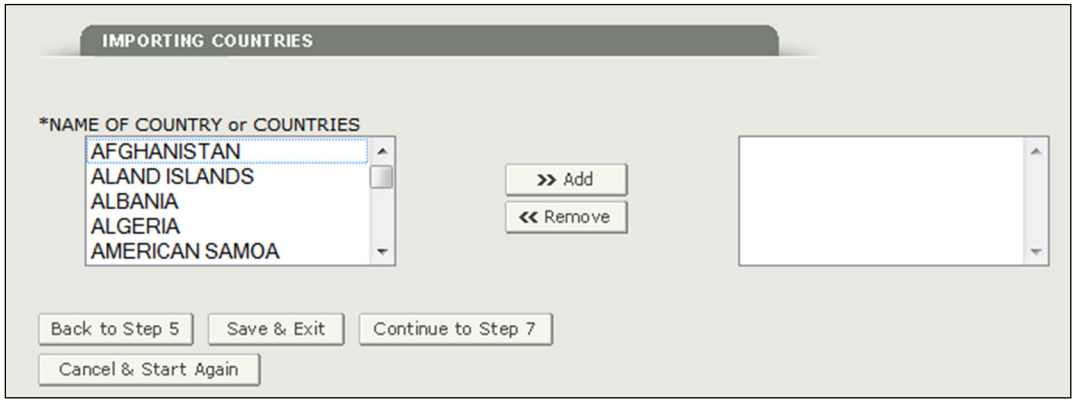
Step 6 – Importing Countries

This section is required.

***NAME OF COUNTRY or COUNTRIES** - Select one or more countries to indicate the product destination as shown in **Figure 22** below.

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

Figure 22: List of Countries



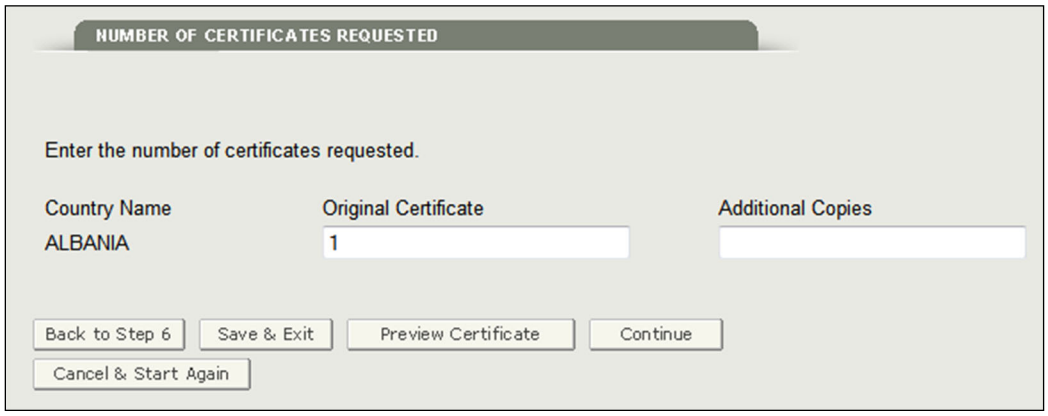
Once you have selected, click on the 'Continue to Step 7' button to proceed.

Step 7 - Number of Certificates Requested

This section is required.

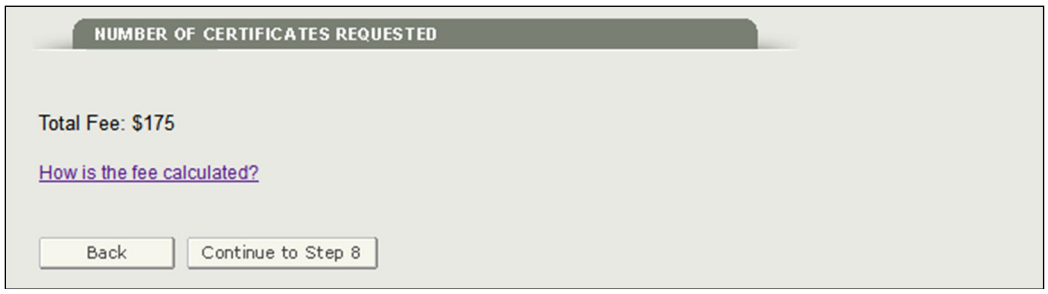
The system will display the selected country or countries (from step 6) where you will be able to enter additional copies of certificates by country as shown in **Figure 23** below.

Figure 23: Number of Certificates Requested by Country



Next, the system displays the total fee that will be billed to you as shown in **Figure 24** below.

Figure 24: Total Amount



For more information on how the fee is calculated, click on the 'How is the fee calculated' hyperlink.

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

Preview Certificate

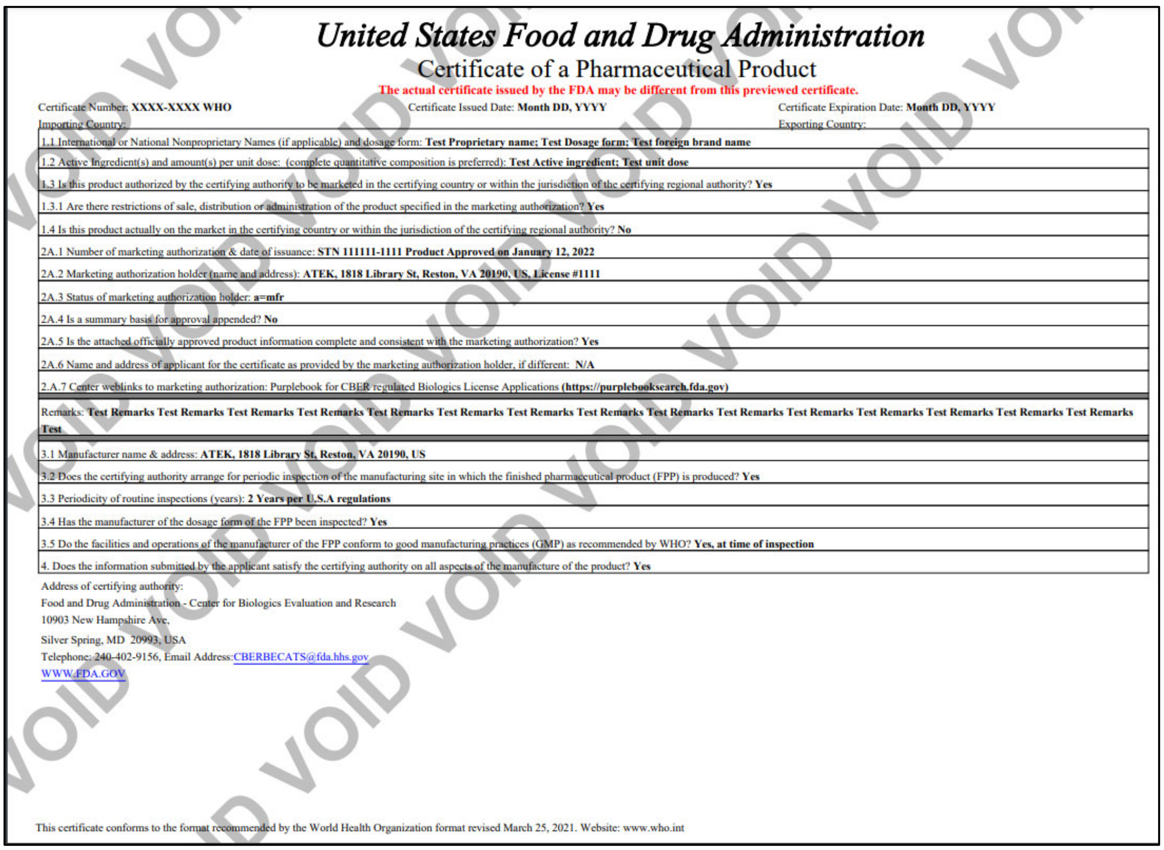
Prior to navigating to the next step, the system provides a 'Preview Certificate' button. This will allow you to view the certificate (assuming the FDA approves your application). You will be able to view how the certificate will look and, if necessary, make modifications to your application prior to submitting if it is not the expected output.

NOTE: If you find that it is not the desired output, you can modify your application. Specifically, you can perform one or all of the following to your application that will have a direct impact on the display of the certificate:

- Update the facility or facilities to be displayed on the certificate in section 5
- Update the remarks to be displayed on the certificate in section 5
- Update the country or countries to be displayed on the certificate in section 6 (please note that you can only list one country per certificate)

Below is an example of previewing a certificate as shown in **Figure 25** and **Figure 26** below.

Figure 25: Preview Certificate


United States Food and Drug Administration

Certificate of a Pharmaceutical Product

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

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

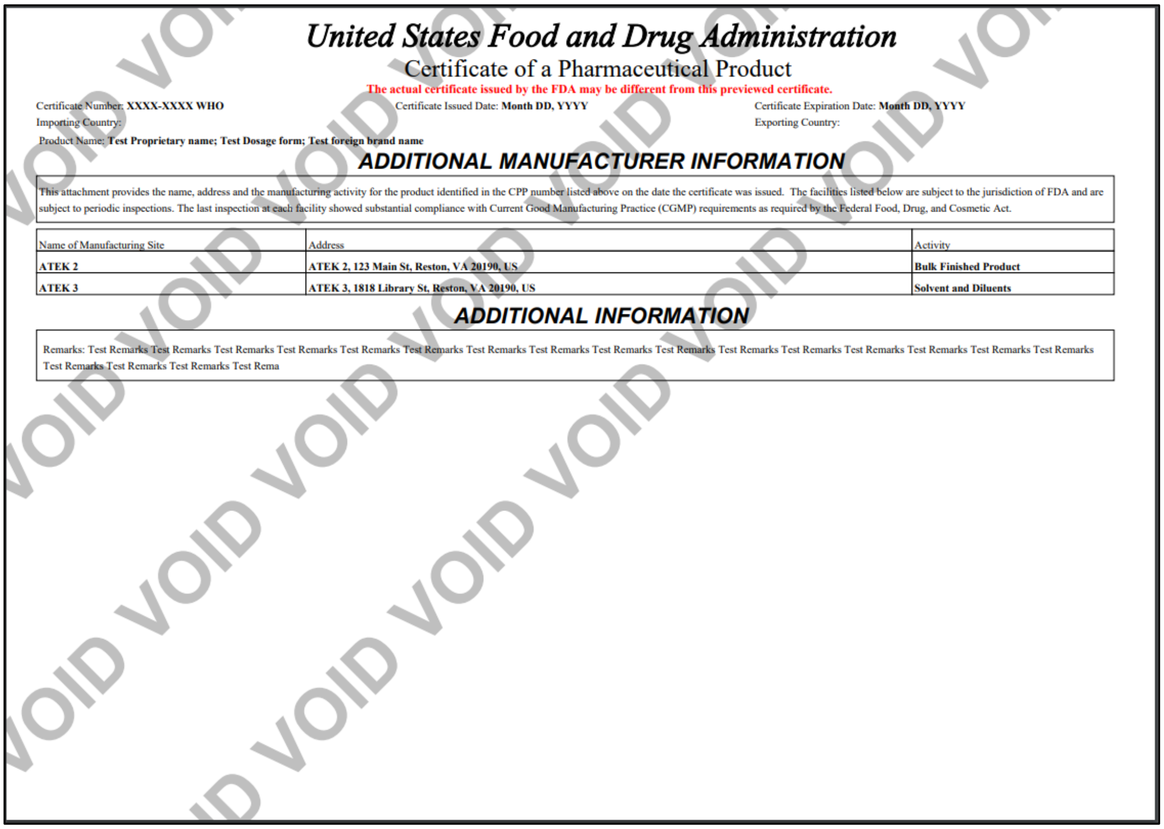
Importing Country: Exporting Country:

1.1 International or National Nonproprietary Names (if applicable) and dosage form: **Test Proprietary name; Test Dosage form; Test foreign brand name**
1.2 Active Ingredient(s) and amount(s) per unit dose: (complete quantitative composition is preferred): **Test Active ingredient; Test unit dose**
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**
1.3.1 Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization? **Yes**
1.4 Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? **No**
2A.1 Number of marketing authorization & date of issuance: **STN 111111-1111 Product Approved on January 12, 2022**
2A.2 Marketing authorization holder (name and address): **ATEK, 1818 Library St, Reston, VA 20190, US, License #1111**
2A.3 Status of marketing authorization holder: **a=mfr**
2A.4 Is a summary basis for approval appended? **No**
2A.5 Is the attached officially approved product information complete and consistent with the marketing authorization? **Yes**
2A.6 Name and address of applicant for the certificate as provided by the marketing authorization holder, if different: **N/A**
2.A.7 Center weblinks to marketing authorization: Purplebook for CBER regulated Biologics License Applications **(https://purplebooksearch.fda.gov)**
Remarks: **Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test**
3.1 Manufacturer name & address: **ATEK, 1818 Library St, Reston, VA 20190, US**
3.2 Does the certifying authority arrange for periodic inspection of the manufacturing site in which the finished pharmaceutical product (FPP) is produced? **Yes**
3.3 Periodicity of routine inspections (years): **2 Years per U.S.A regulations**
3.4 Has the manufacturer of the dosage form of the FPP been inspected? **Yes**
3.5 Do the facilities and operations of the manufacturer of the FPP conform to good manufacturing practices (GMP) as recommended by WHO? **Yes, at time of inspection**
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? **Yes**

Address of certifying authority:
Food and Drug Administration - Center for Biologics Evaluation and Research
10903 New Hampshire Ave,
Silver Spring, MD 20993, USA
Telephone: 240-402-9156, Email Address:CBERBECATS@fda.hhs.gov
WWW.FDA.GOV

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

Figure 26: Preview Certificate – Second Page



United States Food and Drug Administration

Certificate of a Pharmaceutical Product

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

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

Importing Country: Exporting Country:

Product Name: **Test Proprietary name; Test Dosage form; Test foreign brand name**

ADDITIONAL MANUFACTURER INFORMATION

This attachment provides the name, address and the manufacturing activity for the product identified in the CPP number listed above on the date the certificate was issued. 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) requirements as required by the Federal Food, Drug, and Cosmetic Act.

Name of Manufacturing Site	Address	Activity
ATEK 2	**ATEK 2, 123 Main St, Reston, VA 20190, US**	**Bulk Finished Product**
ATEK 3	**ATEK 3, 1818 Library St, Reston, VA 20190, US**	**Solvent and Diluents**

ADDITIONAL INFORMATION

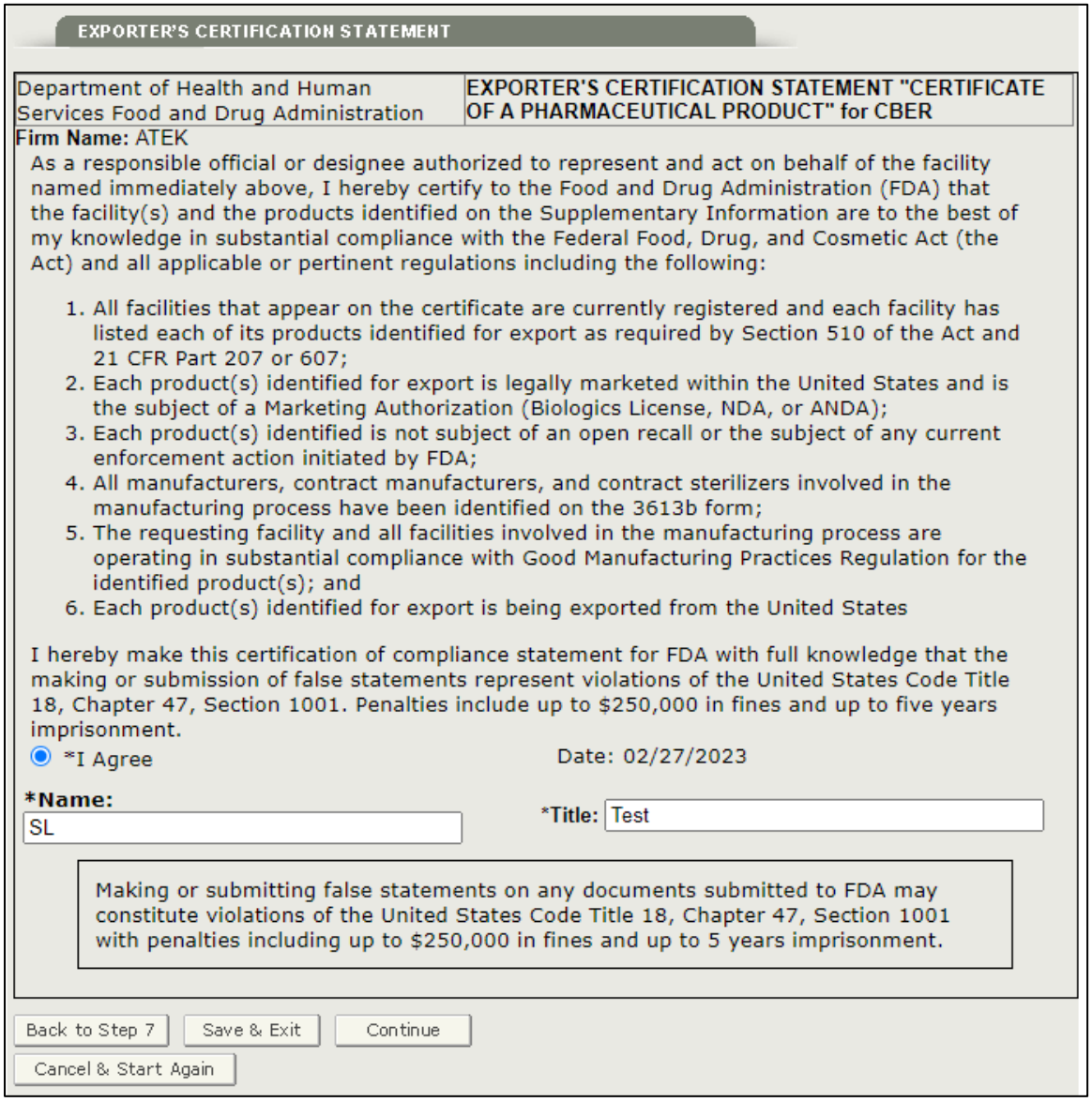
Remarks: Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Rema

Step 8 - Exporter’s Certification Statement (ECS)

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

Click on the ‘I Agree’ button located at the bottom of this section and enter your name and title. You will not be able to continue with the application until these fields have been completed. See **Figure 27** below.

Figure 27: Exporter's Certification Statement

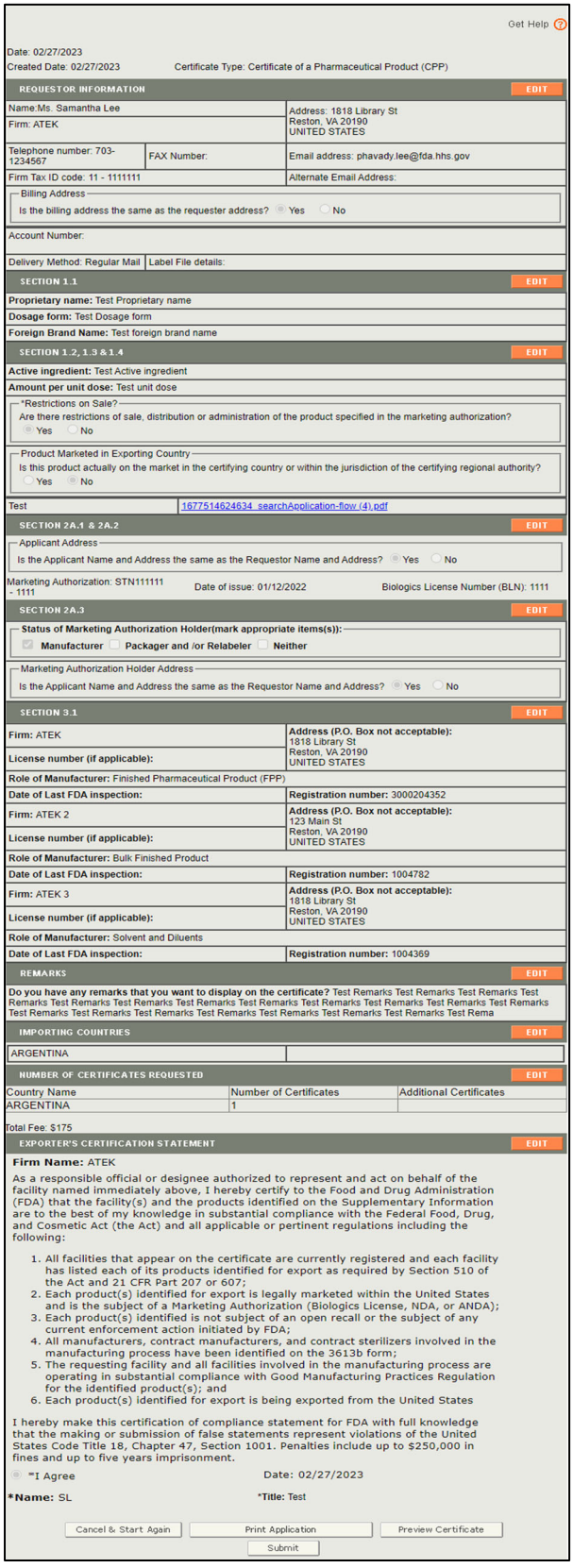


Once you have completed this step, click on the 'Continue' button to proceed to the Final Review Page.

Final Review Screen

The system will display the entire application broken out by section as shown in **Figure 28** below. You may choose to modify a section by selecting the 'Edit' button next to the step to be updated. The system will re-display the data entry screen corresponding to your chosen section. You may make changes as needed.

Figure 28: Final Review Page



Get Help

Date: 02/27/2023
Created Date: 02/27/2023 Certificate Type: Certificate of a Pharmaceutical Product (CPP)

REQUESTOR INFORMATION EDIT

Name:Ms. Samantha Lee Firm: ATEK	Address: 1818 Library St Reston, VA 20190 UNITED STATES
Telephone number: 703-1234567 FAX Number:	Email address: phavady.lee@fda.hhs.gov
Firm Tax ID code: 11 - 1111111	Alternate Email Address:

Billing Address
Is the billing address the same as the requester address? Yes No

Account Number:

Delivery Method: Regular Mail | Label File details:

SECTION 1.1 EDIT

Proprietary name: Test Proprietary name
Dosage form: Test Dosage form
Foreign Brand Name: Test foreign brand name

SECTION 1.2, 1.3 & 1.4 EDIT

Active ingredient: Test Active ingredient
Amount per unit dose: Test unit dose

*Restrictions on Sale?
Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization?
Yes No

Product Marketed in Exporting Country
Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority?
Yes No

Test 1677514624634_searchApplication-flow (4).pdf

SECTION 2A.1 & 2A.2 EDIT

Applicant Address
Is the Applicant Name and Address the same as the Requestor Name and Address? Yes No

Marketing Authorization: STN111111 - 1111 Date of issue: 01/12/2022 Biologics License Number (BLN): 1111

SECTION 2A.3 EDIT

Status of Marketing Authorization Holder(mark appropriate items(s)):
Manufacturer **Packager and /or Relabeler** **Neither**

Marketing Authorization Holder Address
Is the Applicant Name and Address the same as the Requestor Name and Address? Yes No

SECTION 3.1 EDIT

Firm: ATEK **License number (if applicable):**	**Address (P.O. Box not acceptable):** 1818 Library St Reston, VA 20190 UNITED STATES
Role of Manufacturer: Finished Pharmaceutical Product (FPP)	
Date of Last FDA inspection:	**Registration number:** 3000204352
Firm: ATEK 2 **License number (if applicable):**	**Address (P.O. Box not acceptable):** 123 Main St Reston, VA 20190 UNITED STATES
Role of Manufacturer: Bulk Finished Product	
Date of Last FDA inspection:	**Registration number:** 1004782
Firm: ATEK 3 **License number (if applicable):**	**Address (P.O. Box not acceptable):** 1818 Library St Reston, VA 20190 UNITED STATES
Role of Manufacturer: Solvent and Diluents	
Date of Last FDA inspection:	**Registration number:** 1004369

REMARKS EDIT

Do you have any remarks that you want to display on the certificate? Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Rema

IMPORTING COUNTRIES EDIT

ARGENTINA

NUMBER OF CERTIFICATES REQUESTED EDIT

Country Name	Number of Certificates	Additional Certificates
ARGENTINA	1	

Total Fee: $175

EXPORTER'S CERTIFICATION STATEMENT EDIT

Firm Name: ATEK

As a responsible official or designee authorized to represent and act on behalf of the facility named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the facility(s) and the products identified on the Supplementary Information are to the best of my knowledge in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations including the following:

1. All facilities that appear on the certificate are currently registered and each facility has listed each of its products identified for export as required by Section 510 of the Act and 21 CFR Part 207 or 607;
2. Each product(s) identified for export is legally marketed within the United States and is the subject of a Marketing Authorization (Biologics License, NDA, or ANDA);
3. Each product(s) identified is not subject of an open recall or the subject of any current enforcement action initiated by FDA;
4. All manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process have been identified on the 3613b form;
5. The requesting facility and all facilities involved in the manufacturing process are operating in substantial compliance with Good Manufacturing Practices Regulation for the identified product(s); and
6. Each product(s) identified for export is being exported from the United States

I hereby make this certification of compliance statement for FDA with full knowledge that the making or submission of false statements represent violations of the United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to five years imprisonment.

*I Agree Date: 02/27/2023

***Name:** SL ***Title:** Test

Cancel & Start Again | Print Application | Preview Certificate

Submit

You may choose to print your application prior to submission. Select the 'Print Application' button located at the bottom of the review page. A new browser window will open which will allow you to print the application. **NOTE:** Printing the application will print the contents of the application itself and not a final certification letter. When you are finished, close the browser window in order to return to the BECATS application.

When your application is ready for submission, click on the 'Submit' button also located at the bottom of the review page. The system will display a message that your application was successfully submitted as shown in **Figure 29** below. The system will provide you with an application number. Please save this number for future reference. The application number will be required to check the status of your application. You will also receive an email confirmation that your application has been successfully received along with the application number.

Figure 29: Submission Page