



U.S. FOOD & DRUG
ADMINISTRATION

U.S. Food and Drug Administration

**Center for Veterinary Medicine Export Certification
Application and Tracking System (CVM eCATS)**

Step-by-Step Instructions for Industry Applicants

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Abbreviations

ANADA	Abbreviated New Animal Drug Application
CNADA	Conditional New Animal Drug Applications
CVM	Center for Veterinary Medicine
eCATS	Export Certification Application and Tracking System
FDA	U.S. Food and Drug Administration
FEI	FDA Establishment Identification (number)
FGO	Foreign Government Official
FIS	FDA Industry Systems
FURLS	FDA's Unified Registration and Listing System
NADA	New Animal Drug Application
NDC	National Drug Code
OAA	Online Account Administration

Standardized Icons

Standardized icons are used throughout the system. Each icon performs a specific system function. The icon description and system function are described below:

Icon Description	Icon	System Function
Eye		View the associated item.
Pencil		Edit the associated item.
X		Cancel or Delete the associated item.
Document		Associate label or document to certificate.
Printer		Print the associated item.

1 Introduction

This document is intended for use by stakeholders of the Center for Veterinary Medicine Export Certification Application and Tracking System (CVM eCATS).

This document provides instructions on:

- Creating an account in the FIS;
- Filling out an application;
- Saving an application;
- Submitting an application;
- Viewing an application;
- Canceling an application;
- Cloning (Copying) an application;
- Responding to a returned application;
- Printing or obtaining certificates;
- Reviewing system notifications;
- Validating the authenticity of CVM-Issued Export Certificates (by Foreign Government Official (FGO)).

2 Overview of CVM eCATS.

The FDA Center for Veterinary Medicine (CVM) Export Certification Application and Tracking System (CVM eCATS) facilitates the submission of the following CVM certificate types:

- Current Good Manufacturing Practice (CGMP) certificate;
- Certificate to Foreign Government (CFG);
- Certificate of Free Sale (COFS);
- Certificate of Exportability (COE);
- Certificate of a Pharmaceutical Product (CPP).

FDA Industry Systems (FIS)

The FIS is an electronic portal which facilitates submissions to the FDA. It includes registration, listing, export certification, and other online submissions. The FIS is available 24 hours a day, seven days a week. It provides general entry to a series of systems which enable electronic submissions to the Food and Drug Administration (FDA).

FDA's Unified Registration and Listing System (FURLS)

The FURLS is a specific component of FIS. Persons with an account ID and password for the FIS electronic portal can use FURLS to submit information to the Agency. The FURLS system described in this document is for submissions of export certification applications to the Center for Veterinary Medicine.

Supported Browsers

The FURLS can be accessed using Firefox, Chrome, or Internet Explorer. Please visit the "Systems Requirements" section of the FURLS page for a list of approved browsers and browser versions. The "Systems Requirements" section can be found by navigating to <https://www.access.fda.gov/>.

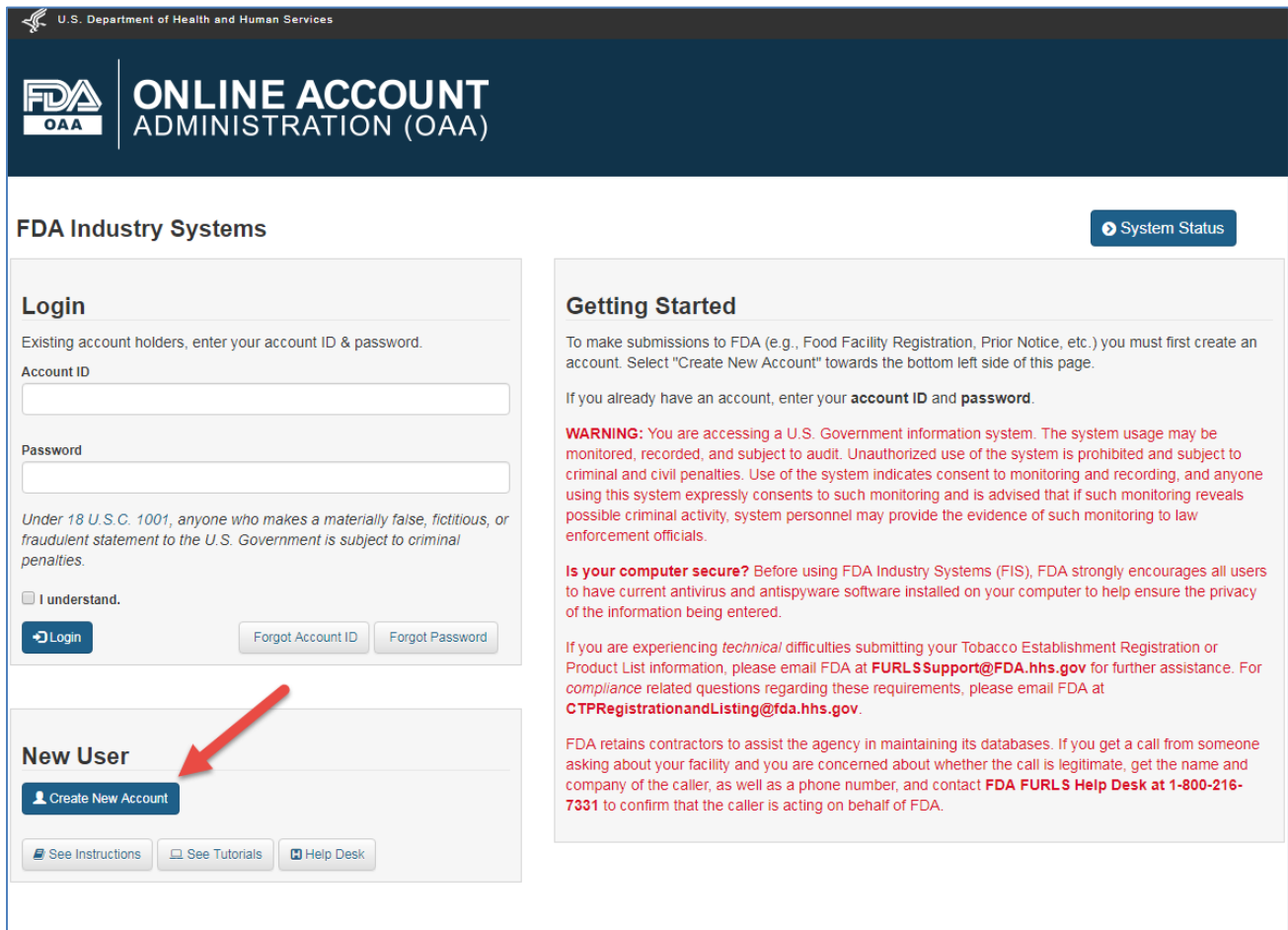
3 Applying for Login Credentials using FIS

All users must obtain an account through the FDA Industry Systems (FIS) Electronic Portal. From this portal you will receive a personal account ID and password to use with your submissions.

Step 1: Access FIS Electronic Portal.

To access the FIS electronic portal, go to <https://www.access.fda.gov/>. Click the **Create New Account** button as shown in Figure 1.

Figure 1: Create New Account in FDA FIS Electronic Portal FDA Industry System



U.S. Department of Health and Human Services

FDA
OAA

ONLINE ACCOUNT
ADMINISTRATION (OAA)

FDA Industry Systems

[System Status](#)

Login

Existing account holders, enter your account ID & password.

Account ID

Password

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I understand.

[Login](#) [Forgot Account ID](#) [Forgot Password](#)

New User

[Create New Account](#)

[See Instructions](#) [See Tutorials](#) [Help Desk](#)

Getting Started

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page.

If you already have an account, enter your **account ID** and **password**.

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

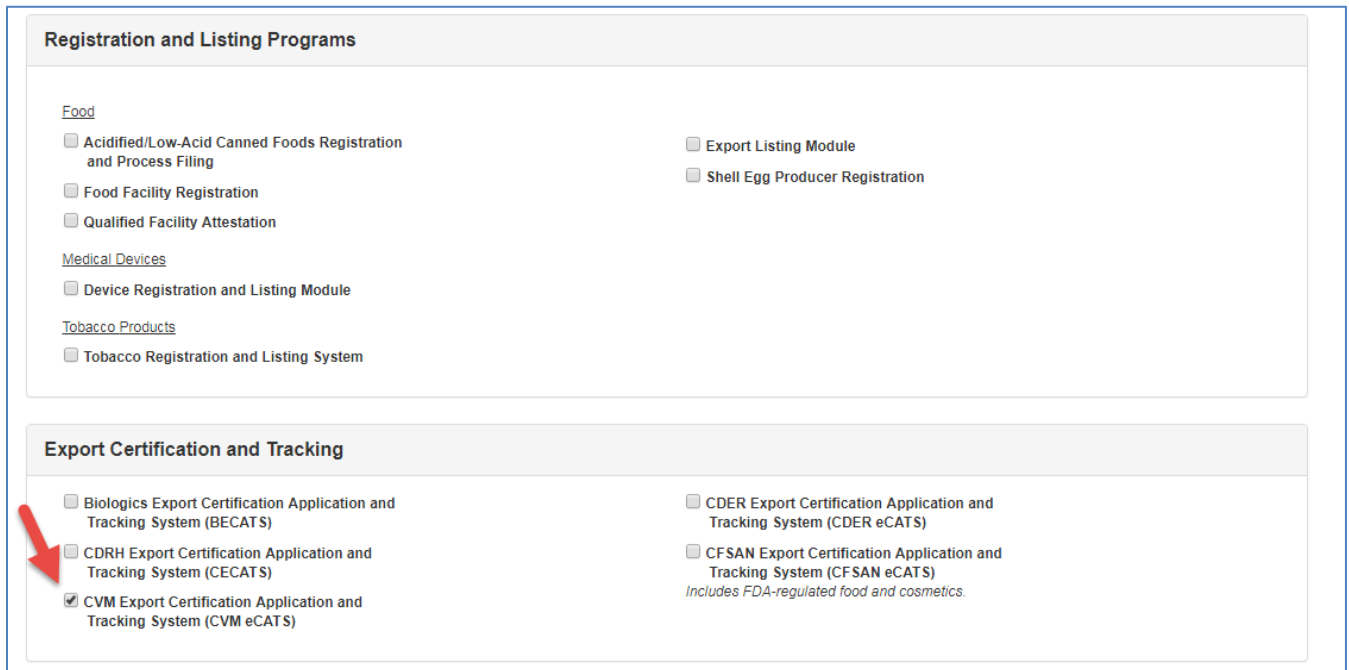
If you are experiencing *technical* difficulties submitting your Tobacco Establishment Registration or Product List information, please email FDA at FURLSsupport@FDA.hhs.gov for further assistance. For *compliance* related questions regarding these requirements, please email FDA at CTPRegistrationandListing@fda.hhs.gov.

FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact **FDA FURLS Help Desk at 1-800-216-7331** to confirm that the caller is acting on behalf of FDA.

Step 2: Select CVM Export Certification Application and Tracking System

Under the Export Certification and Tracking section, click the checkbox for “CVM Export Certification Application and Tracking System (CVM eCATS)” as shown in Figure 2. Then click the **Continue** button at the bottom of the screen.

Figure 2: Click CVM eCATS Checkbox in FIS Electronic Portal



The screenshot displays a web interface with two main sections. The top section, titled "Registration and Listing Programs", contains three sub-sections: "Food" with checkboxes for "Acidified/Low-Acid Canned Foods Registration and Process Filing", "Food Facility Registration", "Qualified Facility Attestation", "Export Listing Module", and "Shell Egg Producer Registration"; "Medical Devices" with "Device Registration and Listing Module"; and "Tobacco Products" with "Tobacco Registration and Listing System". The bottom section, titled "Export Certification and Tracking", contains three checkboxes: "Biologics Export Certification Application and Tracking System (BECATS)", "CDRH Export Certification Application and Tracking System (CECATS)", and "CVM Export Certification Application and Tracking System (CVM eCATS)". The "CVM eCATS" checkbox is checked and highlighted with a red arrow. To the right of the "CVM eCATS" checkbox, there is a note: "Includes FDA-regulated food and cosmetics." Other checkboxes in this section include "CDER Export Certification Application and Tracking System (CDER eCATS)" and "CFSAN Export Certification Application and Tracking System (CFSAN eCATS)".

Step 3: Fill out your contact information.

Fill out the contact information, including name, address, phone number, and email address in the fillable boxes as shown in Figure 3. FURLS uses the email address for all communication purposes including notifications about your export certification application.

Figure 3: Fill out Contact Information in FIS Electronic Portal

? 🖨

Create New Account

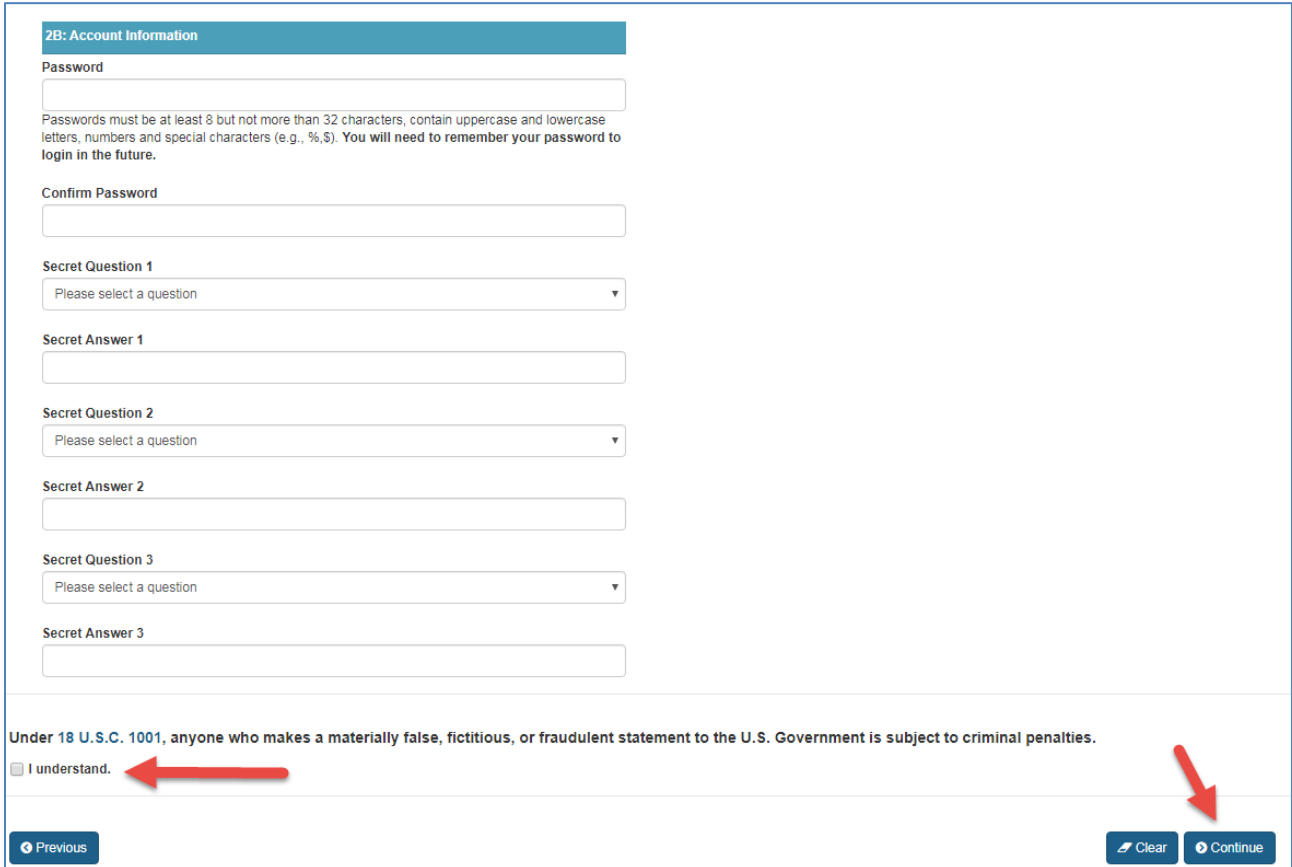
Step 2: Enter Your Account Information

2A: Point of Contact Information	2C: Physical Address (Business) of Account Holder								
First Name <input style="width: 95%;" type="text"/>	Country / Area <input style="width: 95%;" type="text" value="Please Select Country"/>								
Middle Initial (Optional) <input style="width: 95%;" type="text" value="Optional"/>	Address Line 1 <input style="width: 95%;" type="text"/>								
Last Name / Surname <input style="width: 95%;" type="text"/>	Address Line 2 (Optional) <input style="width: 95%;" type="text" value="Optional"/>								
Job Title <input style="width: 95%;" type="text"/>	City <input style="width: 95%;" type="text"/>								
Company Name <input style="width: 95%;" type="text"/>	State / Province / Territory <input style="width: 95%;" type="text" value="Please Select"/>								
Web Address (Optional) <input style="width: 95%;" type="text"/> <small>(Example: http://www.name.domain or http://name.domain)</small>	Zip Code (Postal Code) <input style="width: 95%;" type="text"/>								
Phone Number <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid #ccc; padding: 2px; width: 15%;">Country</td> <td style="border: 1px solid #ccc; padding: 2px; width: 15%;">Area</td> <td style="border: 1px solid #ccc; padding: 2px; width: 40%;">Telephone</td> <td style="border: 1px solid #ccc; padding: 2px; width: 10%;">Ext</td> </tr> <tr> <td style="font-size: 8px;">Country</td> <td style="font-size: 8px;">Area</td> <td style="font-size: 8px;">Phone Number</td> <td style="font-size: 8px;">Extension</td> </tr> </table> <p style="font-size: 8px; margin-top: 5px;">Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country code is not required for US phone numbers.</p>	Country	Area	Telephone	Ext	Country	Area	Phone Number	Extension	Do you have preferred mailing address other than the physical address mentioned above? <input type="radio"/> Yes <input type="radio"/> No
Country	Area	Telephone	Ext						
Country	Area	Phone Number	Extension						
FAX Number (Optional) <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid #ccc; padding: 2px; width: 15%;">Country</td> <td style="border: 1px solid #ccc; padding: 2px; width: 15%;">Area</td> <td style="border: 1px solid #ccc; padding: 2px; width: 40%;">Fax Number</td> </tr> <tr> <td style="font-size: 8px;">Country</td> <td style="font-size: 8px;">Area</td> <td style="font-size: 8px;">Fax Number</td> </tr> </table>	Country	Area	Fax Number	Country	Area	Fax Number			
Country	Area	Fax Number							
Country	Area	Fax Number							
E-mail Address <input style="width: 95%;" type="text"/>									
Confirm E-mail Address <input style="width: 95%;" type="text"/>									

Step 4: Enter Security Information and Submit.

Enter a password and select and answer secret questions, check the “I understand” checkbox after reading the statement, and click the **Continue** button at the bottom of the screen, as shown in Figure 4.

Figure 4: Complete Contact Information (password and secret questions) in FIS Electronic Portal



2B: Account Information

Password

Passwords must be at least 8 but not more than 32 characters, contain uppercase and lowercase letters, numbers and special characters (e.g., %, \$). You will need to remember your password to login in the future.

Confirm Password

Secret Question 1

Please select a question ▼

Secret Answer 1

Secret Question 2

Please select a question ▼

Secret Answer 2

Secret Question 3

Please select a question ▼

Secret Answer 3

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I understand.

[Previous](#) [Clear](#) [Continue](#)

After you clicked the **Continue** button, the system asks you to review your contact information and complete the submission by clicking on the **Submit** button. If you need to modify your information, you can click the **Modify** button. Upon submission, the system will provide you with an account ID and password. You can then use these to log into your account on to the “Online Account Administration” (OAA) home page.

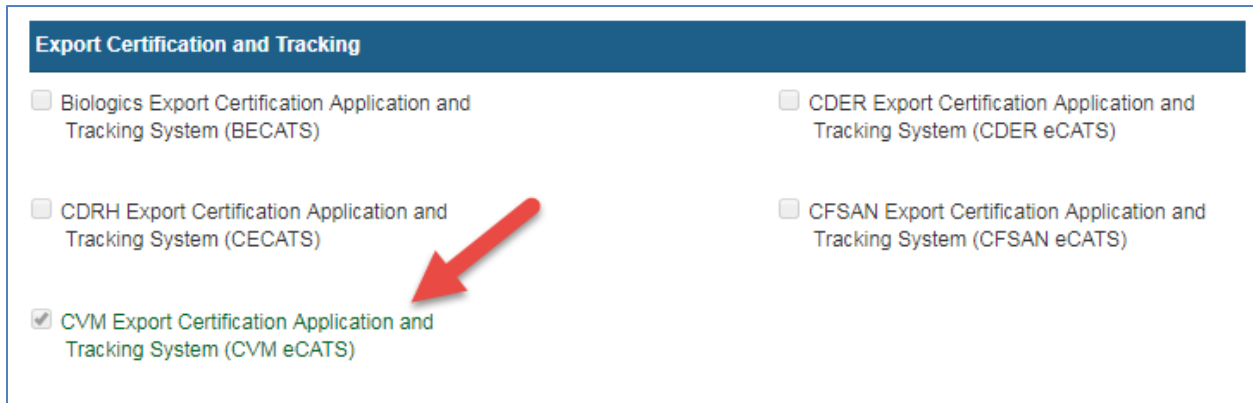
4 Submitting an Application for a Certificate

Applying for a certificate is a four-step process, followed by a formal attestation signoff and submission.

Step 1: Access CVM eCATS

After you logged on to FURLS, click the “**CVM Export Certification Application and Tracking System (CVM eCATS)**” link as shown in Figure 5.

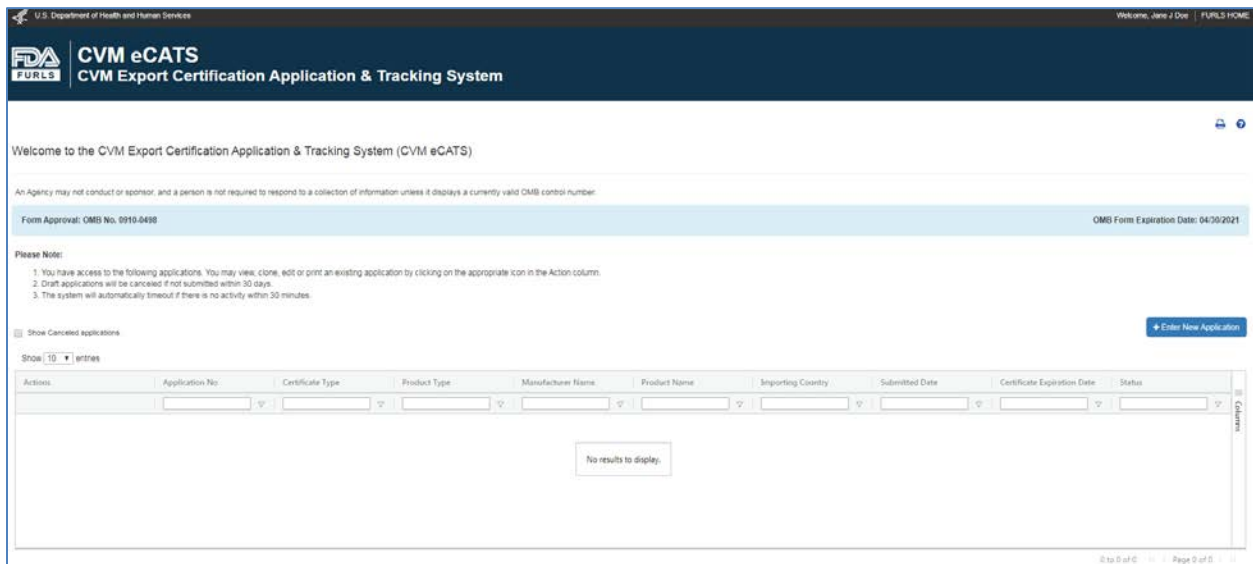
Figure 5: Click the CVM eCATS Link on FURLS Home Page



Step 2: Review Dashboard Contents.

The FURLS displays the CVM eCATS Welcome page, also known as the “Dashboard”, showing your existing application(s). If you have not created or submitted any electronic applications, the Dashboard contains no data, an empty Dashboard is shown in Figure 6. The Dashboard is where you can view, edit, cancel or clone applications. It is also where you can update your application if CVM returned your application for follow-up action(s).

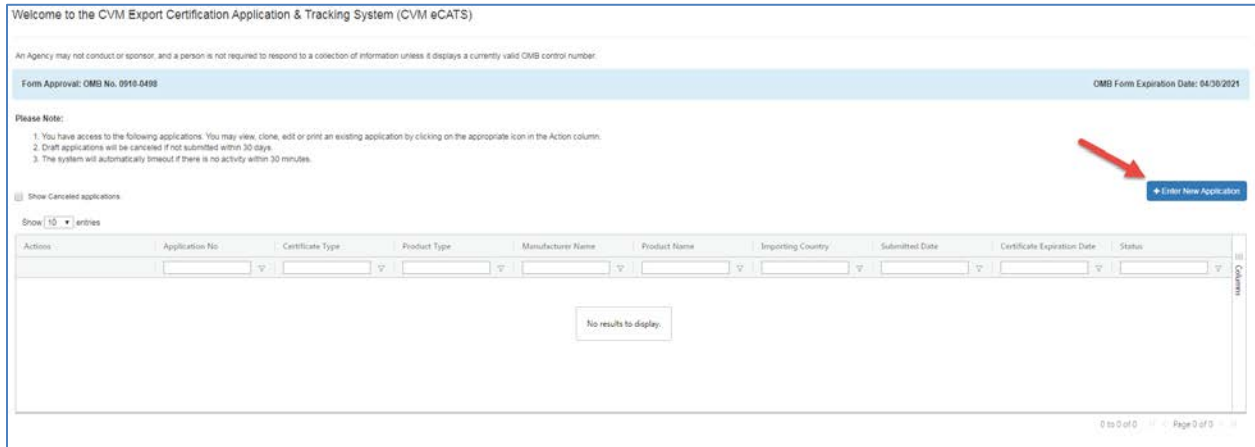
Figure 6: Accessing the CVM eCATS User Dashboard



Step 3: Enter New Application.

To create a new application, click the **Enter New Application** button shown in Figure 7.

Figure 7: Click the Enter New Application Button



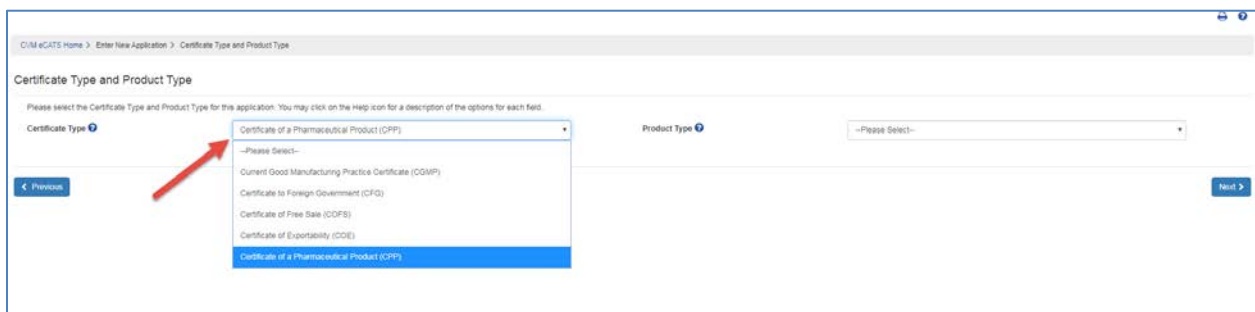
Step 4: Select the Certificate Type.

The system displays the **Certificate Type and Product Type** section.

From the dropdown menu, as shown in Figure 8, select the Certificate Type for the application you're applying for. Certificate Type choices include:

- Current Good Manufacturing Practice (CGMP) certificate;
- Certificate to Foreign Government (CFG);
- Certificate of Free Sale (COFS);
- Certificate of Exportability (COE);
- Certificate of a Pharmaceutical Product (CPP).

Figure 8: Select Certificate Type

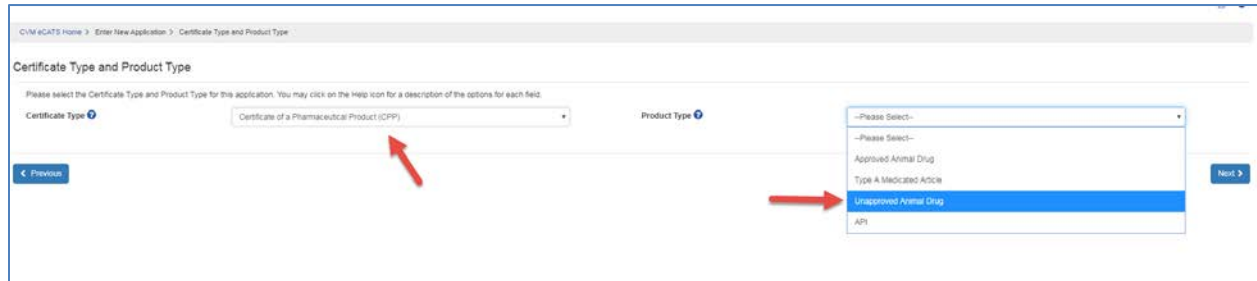


Step 5: Select the Product Type.

From the dropdown menu, as shown in Figure 9, select the Product Type. Product Type options vary for each certificate type. Then click **Next**.

Note: The CGMP certificate type does not have product types. Therefore, the system disables the Product Type field if you selected CGMP.

Figure 9: Select Product Type



Step 6: Enter Requestor Information.

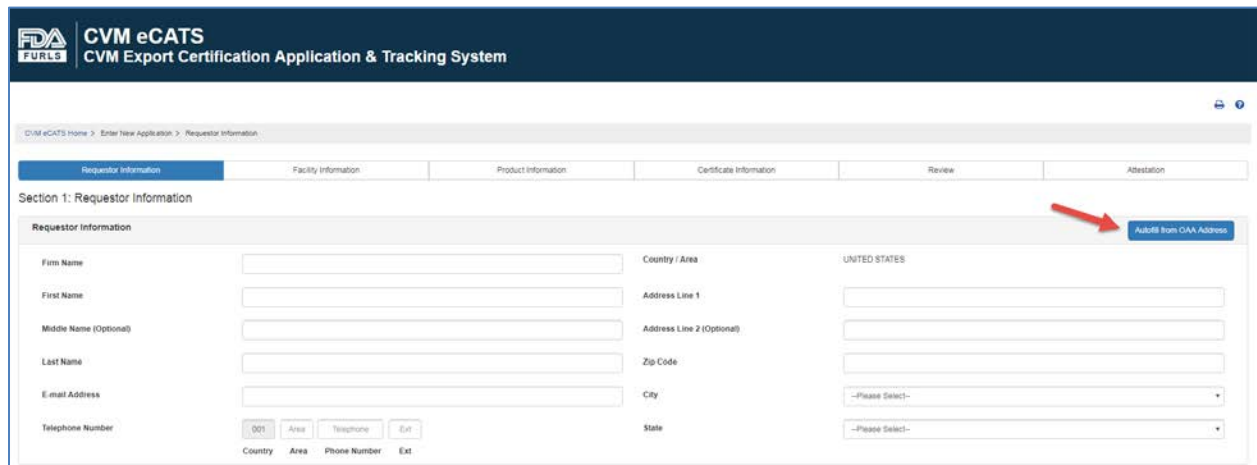
The system displays the **Requestor Information** section as shown in Figure 10. From here you:

1. Enter the contact information of the Requestor;
2. Enter the contact information for Billing purpose;
3. Upload delivery labels (UPS/FedEx) for CPP certificate applications.

To begin, enter the Firm Name and contact information for the Requestor. If this information is the same as that of your FDA FIS account, you can select the **Autofill from OAA Address** button, indicated by the red arrow in Figure 10, to auto-populate this information.

Note: The requestor address must be in the United States, with the exception of CGMP.

Figure 10: Enter Requestor Address Information



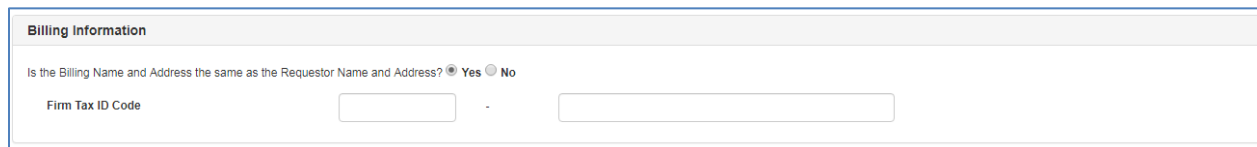
Step 7: Enter Billing Information.

Enter the Firm Name and contact information for Billing. If the billing contact information is the same as that of the requestor contact information, select “Yes” to the following question: “Is the Billing Name and Address the same as the Requestor Name and Address?”, as shown in Figure 11. Then enter your Firm Tax ID Code.

Note 1: The billing address must be in the United States.

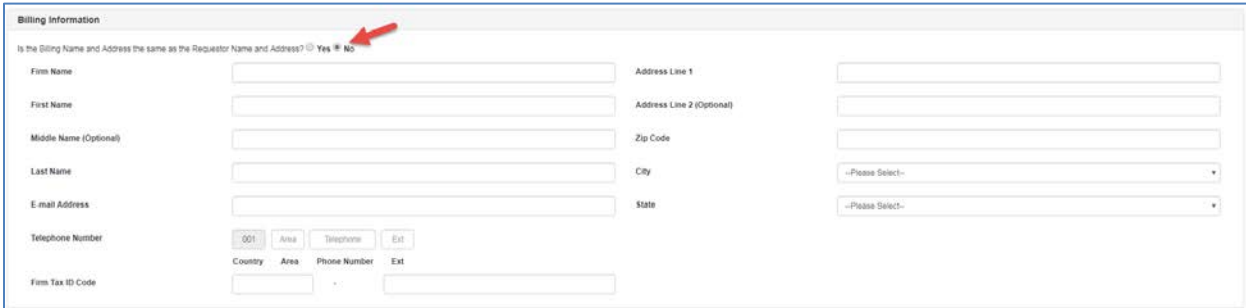
Note 2: The CGMP certificate type does not have a billing information section. For CGMP, you only need to fill in the Requestor information.

Figure 11: Answer Question - Billing Address is Same as Requestor Address



If the billing contact information is not the same as the requestor contact information, select “No”, as shown in Figure 12. Enter the billing contact address information, and the Firm Tax ID Code.

Figure 12: Answer Question - Billing Address is Not the Same as Requestor Address

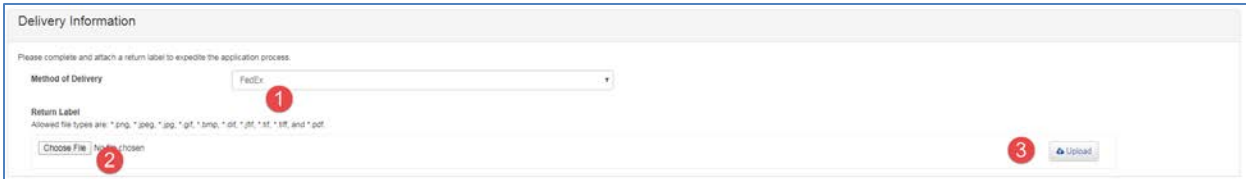


Step 8: For CPP Certificate, Upload a Delivery Label.

If you selected CPP as Certificate Type for the application, the system displays a section called “**Delivery Information**” for you to upload a FedEx or UPS mailing label for CVM to mail the certificate. You do this as follows:

1. Select the Method of Delivery (FedEx or UPS) choice, see number 1 denoted on Figure 13.
2. Under the Return Label section, click on the **Choose File** button and select a label file type (png, jpeg, jpg, bmp, dif, jfif, tif, tiff, or pdf), see number 2 denoted on Figure 13.
3. Click on the **Upload** button to upload the label, see number three denoted on Figure 13.

Figure 13: Upload a FedEx or UPS Label – CPP Only

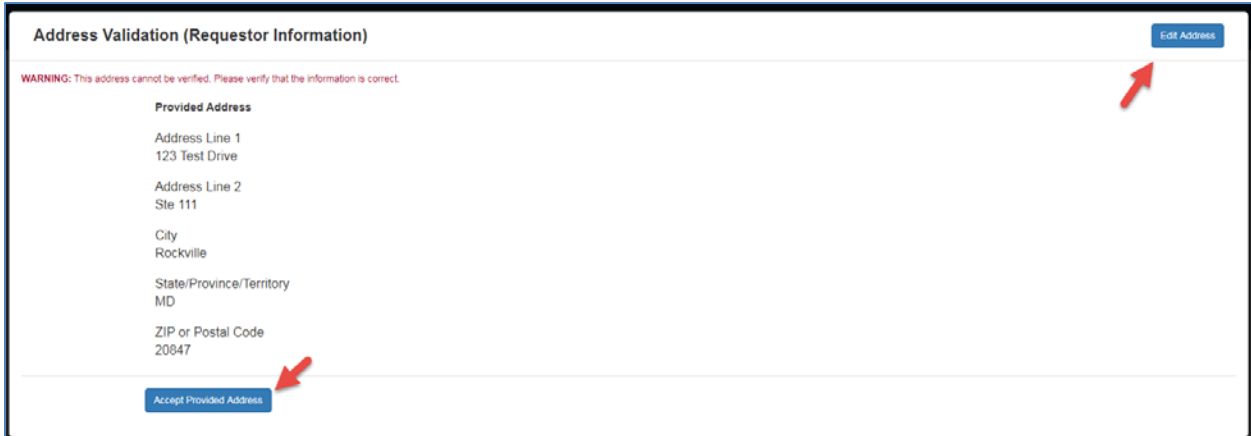


Step 9: Review Address Validation.

When you are done entering the Requestor, Billing, and Delivery (CPP) Information, click **Next**. The system validates the addresses that you have provided against the standard USPS addresses. If the address(es) is invalid, the system displays an error message. Otherwise, the system asks you to accept your provided requestor and billing addresses or accept the system’s validated addresses. The system’s validated addresses may include minor changes to your provided address, such as the four-digit extension to the Zip or Postal Code. You always have the option of returning to the Requestor and Billing information to modify your address by clicking on the **Modify** button. You must click **Accept Provided Address** or **Accept Validated Address** to proceed to next step, as shown in Figure 14.

Note: Address validation is only applicable to United States addresses.

Figure 14: Address Validation

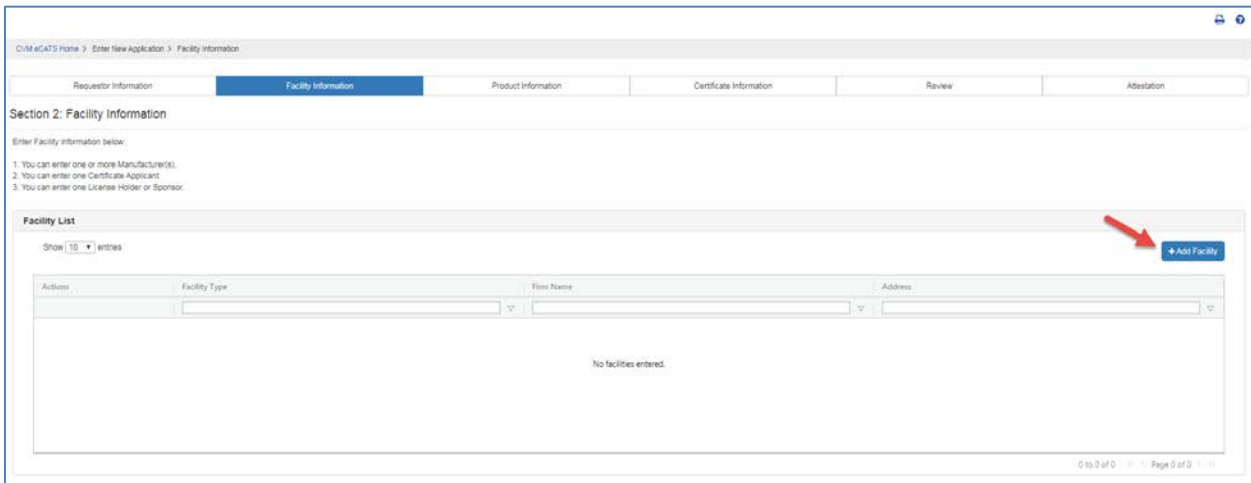


Step 10: Access the Facility Information Section.

After address validation, the system displays the **Facility Information** section, shown in Figure 15. From here you:

1. Add a facility such as a manufacturer or distributor;
2. Edit or delete a facility.

Figure 15: Access the Facility Information section



Step 11: Enter Facility Information.

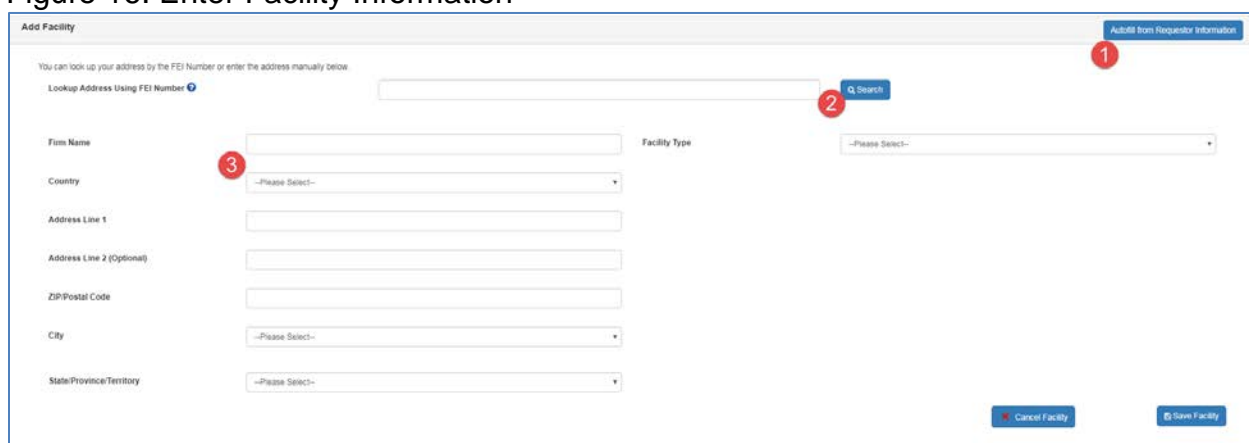
To add a facility, click the **Add Facility** button, indicated by the red arrow in Figure 15.

Note: A Facility that is a distributor must have a United States address.

You can enter facility information in one of three ways:

1. Click **Autofill** button from the Requestor Information section. This automatically populates the fields with the same information from the Requestor Information section. See number one denoted on Figure 16.
2. Enter the facility FEI (FDA Establishment Identification) number in the “Lookup Address Using FEI Number” field and click on the **Search** button. See number two denoted on Figure 16.
3. Manually enter the information, including Firm Name and address information. See number three denoted on Figure 16.

Figure 16: Enter Facility Information



The screenshot shows the 'Add Facility' form. At the top right, there is a blue button labeled 'Autofill from Requestor Information' with a red circle '1' next to it. Below this, there is a text input field for 'Lookup Address Using FEI Number' with a blue 'Search' button to its right, marked with a red circle '2'. The form contains several other input fields: 'Firm Name' (marked with a red circle '3'), 'Country' (a dropdown menu), 'Address Line 1', 'Address Line 2 (Optional)', 'ZIP/Postal Code', 'City' (a dropdown menu), and 'State/Province/Territory' (a dropdown menu). There is also a 'Facility Type' dropdown menu with the text '--Please Select--'. At the bottom right, there are two buttons: 'Cancel Facility' and 'Save Facility'.

Note 1: For Manufacturer and depending on the certificate type, you must either enter the FEI Number (by entering and using the **Search** button) or enter an address that the system can use to find the FEI number in the FDA databases. Table 17 indicated FEI Number requirements based on certificate type selected.

Note 2: Distributor does not require a FEI Number association.

Note 3: You can also use the FDA FEI Search Portal at <https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login> to locate the FEI number for the address you intended to use.

Table 17: FEI Number Requirements for Manufacturer

Certificate Type	FEI Number required
CGMP	Yes
CFG	Yes
COFS	No
COE	No
CPP	Yes

Step 12: Select Facility Type.

Select the Facility Type from the drop down, as shown in Figure 18. The options available will differ, depending on the certificate type. Table 19 shows facility limitations depending on certificate type selected.

Figure 18: Select Facility Type

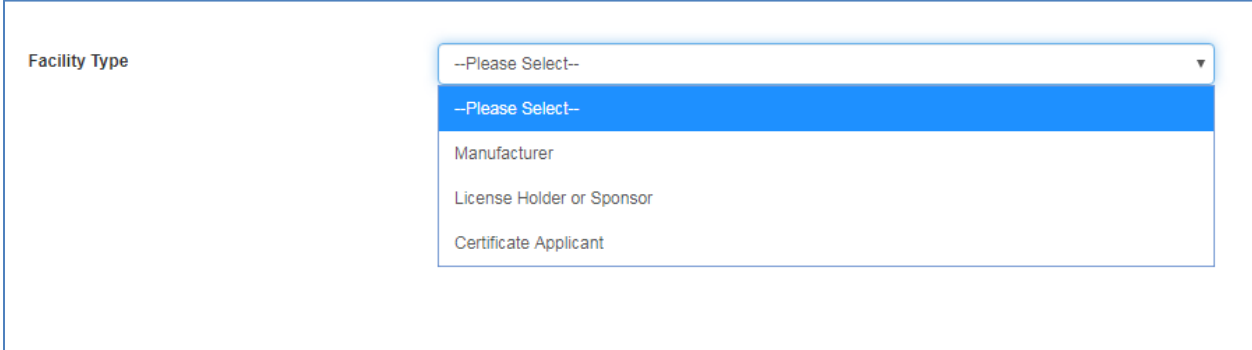


Table 19: Facility Limitations

Certificate Type	Facility Type Options	Number Allowed	Required or Optional	Exceptions and Notes
CGMP	Manufacturer	One	Required	None
CFG	Manufacturer	One	Required	You must enter at least one facility designated as manufacturer.
CFG	Distributor	One or Multiple	Optional	None
COFS	Manufacturer	One	Required	None
COFS	Distributor	One or Multiple	Optional	None
COE	Manufacturer	Multiple	Required	None
CPP	Manufacturer,	One or Multiple	Required	None
CPP	Certificate Applicant License Holder	One	Required	Certificate Applicant License Holder applicable to Approved Animal Drug and Type A medicated article.
CPP	Sponsor	One	Required	Sponsor only applicable to Approved Animal Drug and Type A medicated article.

Step 13: For CPP Only – Answer Certificate Applicant Address Question and select Statuses.

If you're applying for CPP certificate and you selected "Certificate Applicant" as the Facility Type, the system requires you to answer the following question: "Is the Certificate Applicant name and address the same as the License Holder or Sponsor name and address?", as shown in Figure 20.

Figure 20: Answer Certificate Applicant Question – For CPP Only

Is the Certificate Applicant name and address the same as the License Holder or Sponsor name and address? Yes No

If you're applying for CPP certificate and you selected "Certificate Applicant" or "License Holder or Sponsor" as Facility Type, the system also requires you to specify the License Holder or Sponsor Status, as shown in Figure 21.

Figure 21: Select Status for License Holder or Sponsor – For CPP Only

Facility Type: License Holder or Sponsor

License Holder or Sponsor Status: --Please Select--

- Please Select--
- Manufacturer
- Packager and/or Relabeler
- Neither

Step 14: Save Facility.

Click the **Save Facility** button to add the facility to the application. The system displays all facilities added onto the Facility List Table, from which you can either modify (or edit) or delete the facility entry, if necessary. The edit and delete options are noted by the red arrows in Figure 22.

Figure 22: Save Facility to Facility Table, Edit and Delete Facilities.

CIMeCATS Home > Enter New Application > Facility Information

Requestor Information | **Facility Information** | Product Information | Certificate Information | Review | Abatement

Section 2: Facility Information

Enter Facility information below:

- You can enter one or more Manufacturer(s).
- You can enter one Certificate Applicant.
- You can enter one License Holder or Sponsor.

Facility List

Show 10 entries

[Add Facility](#)

Action	Facility Type	Firm Name	Address
	Manufacturer	Test Facility Name Data Inc.	Test Facility Street Address Line 1, Rockville, Maryland 20852 United States
	Certificate Applicant	Test Facility Name Data Inc.	Test Facility Street Address Line 1, Rockville, Maryland 20852 United States

1 to 2 of 2 | Page 1 of 1

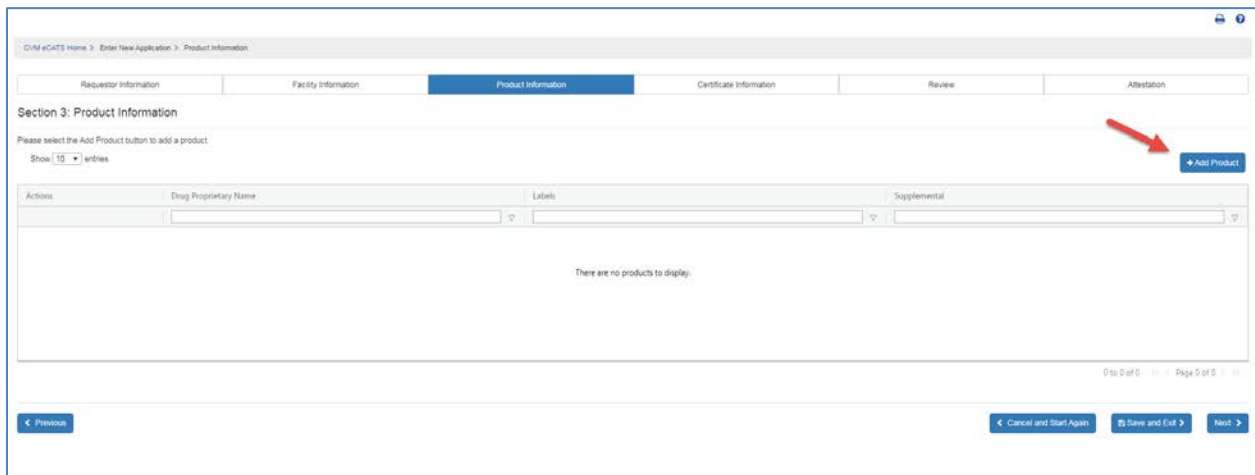
Step 15: Enter Product Information.

When you are done with entering the facility information, click **Next**.

The system displays the **Product Information** section, as shown in Figure 23. From here you:

1. Add a product;
2. Upload an English-language label;
3. Add optional supplemental documents.

Figure 23: Access the Product Information Section



Step 16: Add a Product.

Click the **Add Product** button, indicated by the red arrow in Figure 23. Please note the product number limitations described in Table 24 below.

Table 24: Product Number Limitations

Certificate Type	Number of Products Allowed	Exceptions and Notes
CGMP	Multiple	None
CFG	One or Multiple	Animal Device allows multiple products.
COFS	One or Multiple	Animal Food allows multiple products.
COE	One or Multiple	Unapproved Animal Drug limited to one product. Animal Food allows multiple products.
CPP	One	None

Note: In the case of Animal Devices Only, you may enter “See Attached List of Products” for Product Trade Name, Proper Name, and details of products provided as label or supplemental attachments.

Figure 25: Add a Product

The fillable information fields as shown on Figure 25 vary depending on the certificate type and product type. Refer to the Table 26 for the list of data entry fields applicable to each certificate and product type combination:

Table 26: Applicable Product Fields

Certificate Type(s)	Fields
CGMP	Product Name
CFG for Animal Food and Animal Device	Product Trade Name Product Proper Name Note: for Animal Devices only, you can enter "See Attached List of Products" on the Product Trade Name and Proper Name and attach the details of products as a label/supplemental attachments
CFG for Approved Animal Drug, Type A medicated article, Type B medicated feed, and Type C medicated feed	Product Trade Name Product Proper Name Drug Application Type (NADA, ANADA, CNADA) Drug Approval License Number FDA Product Listing Number (NDC)
CFG for Unapproved Animal Drug and API	Product Trade Name Product Proper Name FDA Product Listing Number (NDC)
COFS for Animal Food	Product Trade Name Product Proper Name Note: for Animal Devices only, you can enter "See Attached List of Products" on the Product Trade Name and Proper Name and attach the details of products as a label/supplemental attachments
COFS for Approved Animal Drug, Type A medicated article, Type B medicated feed, and Type C medicated feed	Product Trade Name Product Proper Name Drug Application Type (NADA, ANADA, CNADA) Drug Approval License Number FDA Product Listing Number (NDC)

Certificate Type(s)	Fields
COFS for Unapproved Animal Drug and API	Product Trade Name Product Proper Name FDA Product Listing Number (NDC)
COE for Animal Food	Product Name
COE for Unapproved Animal Drug and API	Product Name FDA Product Listing Number (NDC)
CPP for Approved Animal Drug and Type A medicated article	Drug Proprietary Name FDA Date of Approval Drug Application Type (NADA, ANADA, CNADA) Drug Approval License Number FDA Product Listing Number (NDC) Dosage Form Drug Active Ingredients Amount per Unit Dose Question: Is this product approved/licensed to be on the market for use in the United States? Question: Is this product currently on the market in the United States?
CPP for Unapproved Animal Drug and API	Drug Proprietary Name FDA Product Listing Number (NDC) Dosage Form Drug Active Ingredients Amount per Unit Dose Question: Is this product approved/licensed to be on the market for use in the United States? Question: Is this product currently on the market in the United States?

In addition, each field may be required, or optional, or not applicable, depending on the Certificate and Product Type combinations, these are described in Table 27.

- O = Optional
- R = Required
- NA = Not Applicable

Table 27: Required Fields for Products

Certificate Type	Product Type	Product Name	NDC Number	NADA Number	Product Type
CGMP	NA	O	NA	NA	CGMP US applicant
CGMP	NA	O	NA	NA	CGMP International applicant
COE	Animal Food	R	NA	NA	COE Animal Food
COE	API	R	O	NA	COE API
COE	Unapproved Animal Drug	R	R	NA	COE Unapproved Animal Drug
CPP	Approved Animal Drug	R	R	R	CPP Approved

Certificate Type	Product Type	Product Name	NDC Number	NADA Number	Product Type
CPP	Type A Medicated Article	R	R	R	CPP Type A
CPP	API	R	O	NA	CPP API
CPP	Unapproved Animal Drug	R	R	NA	CPP Unapproved
COFS	Animal Food	R	NA	NA	COFS Animal Food
COFS	Approved Animal Drug	R	R	R	COFS Approved
COFS	Type A Medicated Article	R	R	R	COFS Type A
COFS	Type B Medicated Feed	R	O	R	COFS Type B
COFS	Type C Medicated Feed	R	O	R	COFS Type C
COFS	API	R	O	NA	COFS API
COFS	Unapproved Animal Drug	R	R	NA	COFS Unapproved
CFG	Animal Food	R	NA	NA	CFG Animal Food
CFG	Approved Animal Drug	R	R	R	CFG Approved
CFG	Type A Medicated Article	R	R	R	CFG Type A
CFG	Type B Medicated Feed	R	O	R	CFG Type B
CFG	Type C Medicated Feed	R	O	R	CFG Type C
CFG	API	R	O	NA	CFG API
CFG	Unapproved Animal Drug	R	R	NA	CFG Unapproved
CFG	Animal Device	R	NA	NA	CFG Animal Device

Note: For CPP certificate, you must answer two questions displayed at the bottom of the Information section.

- Is this product approved/licensed to be on the market for use in the United States? and,
- Is this product currently on the market in the United States?

For Approved Animal Drug and Type A medicated article products, the first question above requires a “Yes” answer.

For Unapproved Animal Drug and API, the first question above requires a “No” answer.

Step 17: Add Labels and Supplemental Documents.

Click the **Add file(s)** button to add a product label, as shown in Figure 28. Except for CGMP certificates, you must provide at least one product label in English for FDA review purpose. Navigate to where you stored your label(s), select the label(s), and click the **Start Upload** button to add to the application.

Although optional, you can provide Supplemental documents as part of the application. You can upload supplemental documents by accessing the Supplemental Documents section as shown in Figure 28, clicking on the **Add file(s)**, selecting the documents, and then clicking on **Start Upload**:



When you have finished adding labels and supplemental documents, click the **Save** button. Valid file types are jpg, jpeg, doc, docx, txt, xls, xlsx, pdf, gif, png, or rtf. File size not to exceed 50 MB.

Figure 28: Add Labels and Supplemental Documents

<p>Label</p> <p>Please upload at least one product label in English for each product for review purposes, otherwise your application will not be approved. Valid file types are .jpg, .jpeg, .doc, .docx, .txt, .xls, .xlsx, .pdf, .gif, .png or .rtf. File size may not exceed 50 MB.</p> <p>+ Add file(s)</p>
<p>Supplemental Documents (Optional)</p> <p>Please upload supplemental documents, as needed. An example of a supplemental document is a label in a foreign language. Valid file types are .jpg, .jpeg, .doc, .docx, .txt, .xls, .xlsx, .pdf, .gif, .png or .rtf. File size may not exceed 50 MB.</p> <p>+ Add file(s)</p>

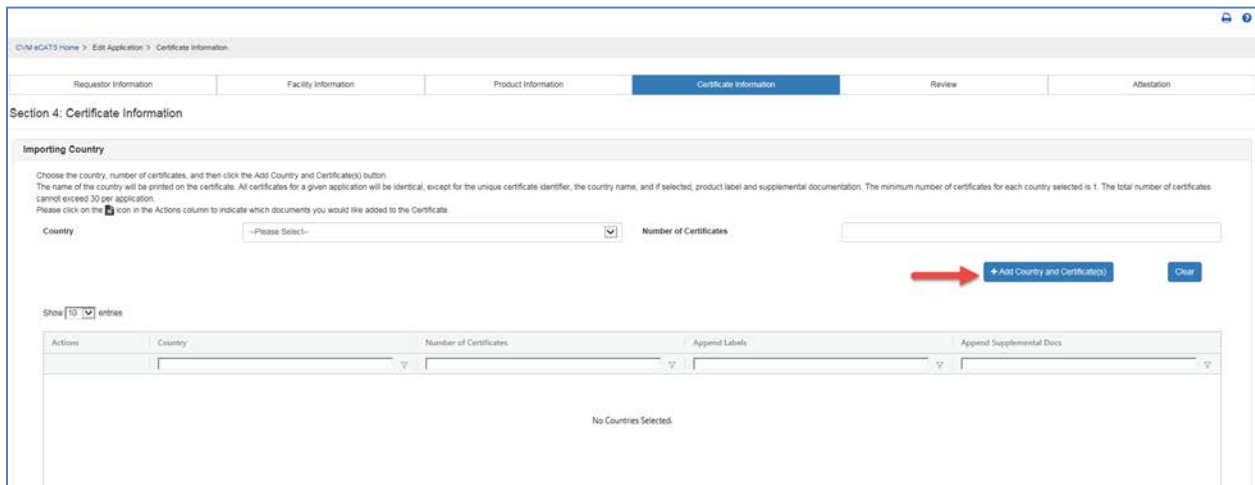
Step 18: Enter Certificate Information.

Click **Next** when the *Product Information* section is completed.

The system displays the **Certificate Information** section, as shown in Figure 29. From here you:

1. Select the importing country and the number of certificates you want;
2. Associate the labels and supplemental documents to each certificate (optional);
3. Add additional information to the certificate;
4. Review your fees.

Figure 29: Access the Certificate Information Section



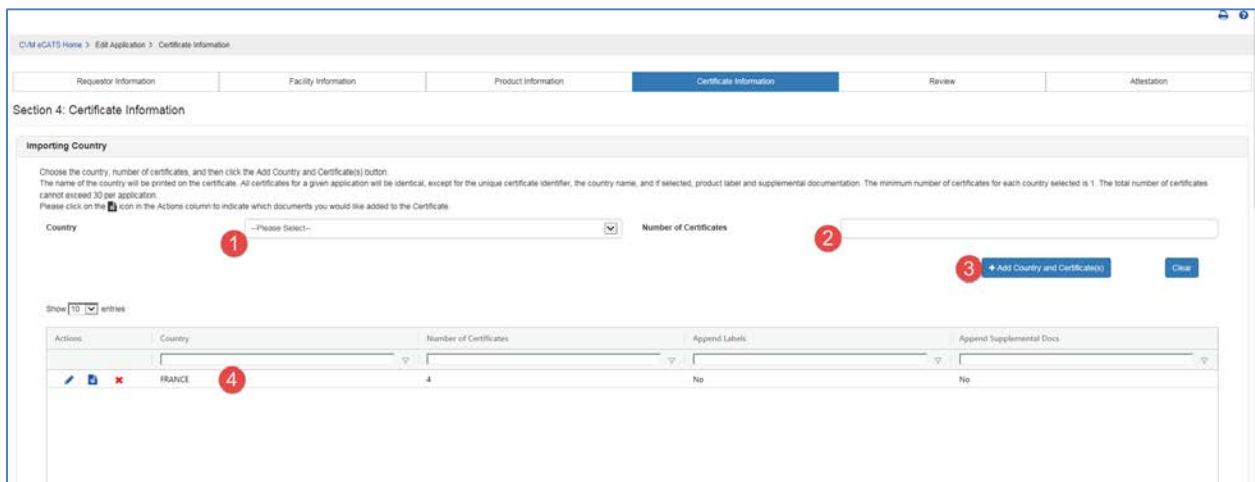
Step 19: Add Importing Country and Certificates.

Use the Country dropdown field to select a country. Then enter the number of certificates in the Number of Certificates field. Click the **Add Country and Certificates** button, to add the country and number of certificates needed. The system adds the country and the number of certificates showing them in the list, example of added country and certificates shown in Figure 30.

You can enter multiple importing countries, and you can add up to 30 certificates total per application.

Note: A country on the U.S. Embargo List cannot be added to the application.

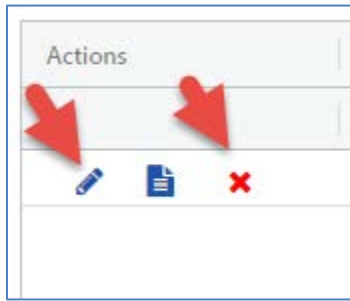
Figure 30: Add a Country and Certificates



Step 20: Edit and Delete Country and Certificates

From the country and certificate table, you can change the number of certificates using the pencil icon if necessary. Or you can delete your entry using the delete icon, as shown in Figure 31.

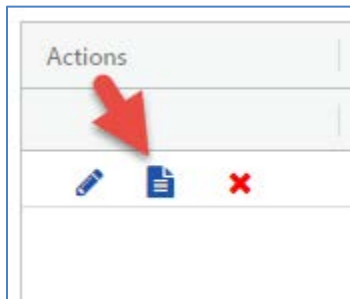
Figure 31: Edit and Delete Country and Certificates



Step 21: Associate labels and supplemental documents to Certificates.

Associate the labels and supplemental documents to your certificates by clicking on the **Document** (paper) icon, as shown in Figure 32.

Figure 32: Associate labels and documents to Certificates



When you click the **Document** icon, the system displays the Product Label(s) and Supplemental Document(s) screen. From here, you can indicate each label and supplemental document that you want to add to your certificate by clicking the requisite checkboxes, as shown in Figure 33. When you have made the associations, click the **Save** button.

Figure 33: Associate labels and documents to Certificates

Product Label(s)

Select any product label(s) to append to your certificate(s).

Select	Product Name	Product Label
<input checked="" type="checkbox"/>	RSTT	Label 1.pdf

1 to 1 of 1 Page 1 of 1

Supplemental Documents (Optional)

Select any supplemental document(s) to append to your certificate(s).

Select	Product Name	Supplemental Document Name
<input type="checkbox"/>	RSTT	submit.doc

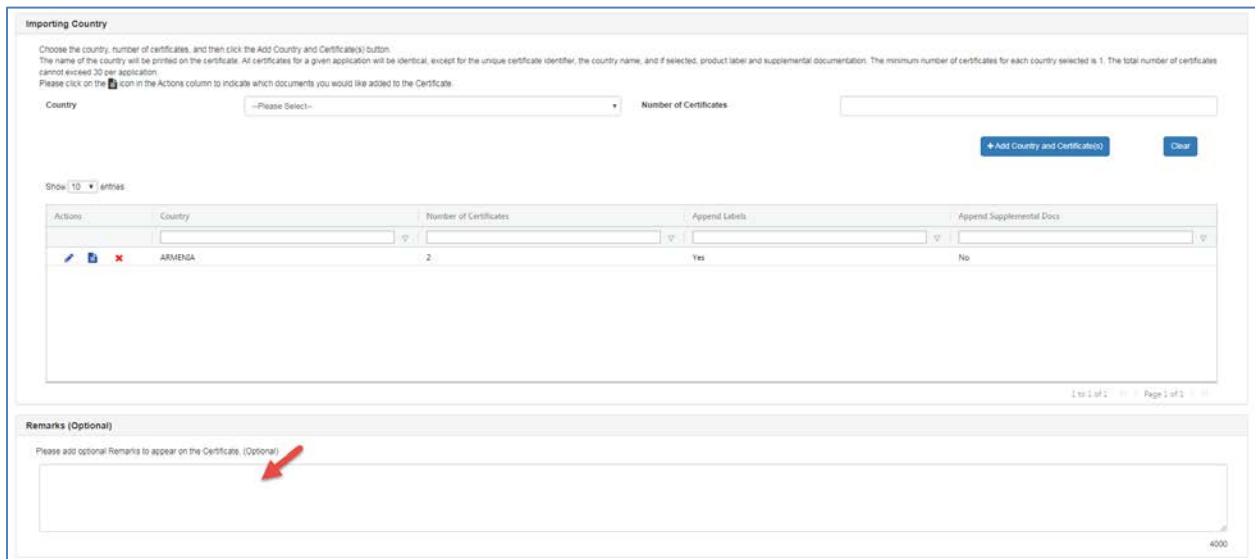
1 to 1 of 1 Page 1 of 1

Cancel
Save


Step 22: Add Optional Remarks or Additional Information to appear on Certificate.

From the **Remarks** (for CPP) or **Additional Information** (non-CPP certificates) section, you can add remarks or additional information to appear on the certificate, as shown in Figure 34. Remarks and Additional Information are optional.

Figure 34: Add Optional Remarks to Certificate






Importing Country

Choose the country, number of certificates, and then click the Add Country and Certificate(s) button. The name of the country will be printed on the certificate. All certificates for a given application will be identical, except for the unique certificate identifier, the country name, and if selected, product label and supplemental documentation. The minimum number of certificates for each country selected is 1. The total number of certificates cannot exceed 20 per application. Please click on the  icon in the Actions column to indicate which documents you would like added to the Certificate.

Country: Number of Certificates:

Show 10 entries

Actions	Country	Number of Certificates	Append Labels	Append Supplemental Docs
  	ARMENIA	2	Yes	No

1 to 1 of 1 Page 1 of 1

Remarks (Optional)

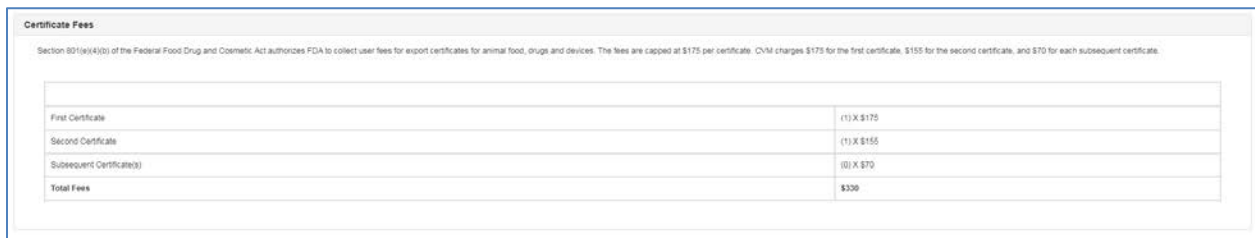
Please add optional Remarks to appear on the Certificate. (Optional)

4000

Step 23: View the Certificate Fees.

On the **Certificate Fees** section, the system displays the fees for the requested total number of certificates, an example shown in Figure 35.

Figure 35: View Certificate Fees



Section 801(a)(4)(B) of the Federal Food, Drug, and Cosmetic Act authorizes FDA to collect user fees for export certificates for animal food, drugs and devices. The fees are capped at \$175 per certificate. O/M charges \$175 for the first certificate, \$155 for the second certificate, and \$70 for each subsequent certificate.

First Certificate	(1) X \$175
Second Certificate	(1) X \$155
Subsequent Certificate(s)	(0) X \$70
Total Fees	\$330

Click **Next** when you finished viewing the Certificate Fees information.

Step 24: Review.

The system displays the **Review** section. This section allows you to review your data prior to submitting to the FDA. Review the data in each section to verify accuracy. If you need to change the data in any section, you can click the **Edit** button to the right of each section, as shown in Figure 36.

Figure 36: Review Application Prior to Submission

Step 25: Attestation.

Click **Next** when you have reviewed your data for accuracy and are ready to submit your application.

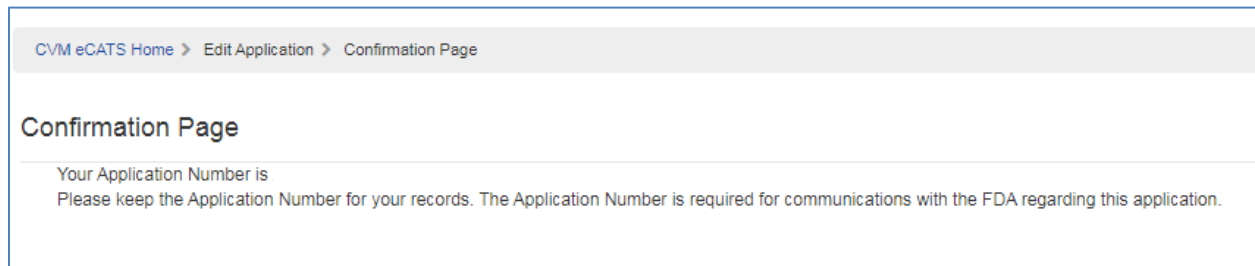
The system displays the **Attestation** section, as shown in Figure 37. Review the attestation information and warning. Enter your name and title. Your title is optional. Then click the **I agree** button and then the **Submit** button to submit your application.

Figure 37: Fill out Attestation Section

Step 26: Submission Confirmation.

After you submitted the application, the system displays a Confirmation message with your application number, which is required for any communications with the FDA regarding the application, as shown in Figure 38.

Figure 38: View Confirmation and Application Number



When you return to the Dashboard, your application will be displayed with a status of “Submitted.”

As part of the confirmation, the system also sends you an email notification to inform you of FDA receipt of your submission.

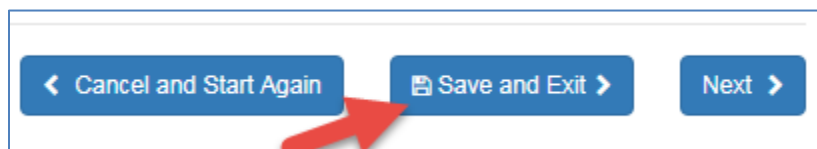
5 Saving and Editing an Application

You may “save” your application prior to submission. You may also “save” your application if it is in a “Return for Action” status. Saving the application allows you to return to the application later to complete your entries and then to submit the application.

Step 1: Click Save and Exit Button

On each page of the workflow, with the exception of the first page and the Attestation page, you can save your application by clicking on the **Save and Exit** button, as shown in Figure 39. You may also cancel your work and start again by clicking the **Cancel and Start Again** button.

Figure 39: Saving an Application



















Step 2: Click Edit Application button

If you saved your application prior to submission, the system saves the application with a status of “Incomplete”. You can view the incomplete application on the Dashboard. “Incomplete” means the application has not been submitted to the FDA.

Important: You must submit your application within 30 days of your first save, or the application will be automatically cancelled. You will not be able to edit or work with a cancelled application.

To edit your application, locate it on the Dashboard, and click the **Edit Application** button (pencil), as shown in Figure 40. You can then update and submit your application to the FDA or save your application again for later edits.

Figure 40: Edit an Application

Actions	Application No	Certificate Type	Product Type
	<input type="text"/>	<input type="text"/>	<input type="text"/>
   	TEST000145	Certificate of Free Sale (COF...	Approved Animal Drug
   	TEST000144	Certificate to Foreign Gover...	Type A Medicated Article
   	TEST000147	Certificate of a Pharmaceuti...	Approved Animal Drug
   	TEST000146	Certificate of Exportability (...)	Animal Food

















6 Viewing an Application

You can “view” your application from the Dashboard at any time.

Step 1: Click the View Button

You can view your application from the Dashboard by clicking the **View Application** button (Eye), as shown in Figure 41. You cannot modify your application when you’re in View mode.

Figure 41: View an Application

Actions	Application No	Certificate Type	Product Type
	<input type="text"/>	<input type="text"/>	<input type="text"/>
   	TEST000145	Certificate of Free Sale (COF...	Approved Animal Drug
   	TEST000144	Certificate to Foreign Gover...	Type A Medicated Article
   	TEST000147	Certificate of a Pharmaceuti...	Approved Animal Drug
   	TEST000146	Certificate of Exportability (...)	Animal Food





7 Canceling an Application

You can “cancel” your application from the Dashboard when the status is “Incomplete” or “Return-for-Action”.

Step 1: Click the Cancel Button

Locate the application that you want to cancel from the Dashboard and click the **Cancel Application** button (Red X), as shown in Figure 42.

Figure 42: Cancel an Application

Actions	Application No	Certificate Type	Product Type
   	<input type="text"/>	<input type="text"/>	<input type="text"/>
	TEST000145	Certificate of Free Sale (COF...	Approved Animal Drug
	TEST000144	Certificate to Foreign Gover...	Type A Medicated Article
	TEST000147	Certificate of a Pharmaceuti...	Approved Animal Drug
	TEST000146	Certificate of Exportability (...)	Animal Food

The system displays the Confirmation message for you to proceed. Click **OK** if you want to continue with the cancellation or click **Go Back** if you wish to back out of the cancel action, as shown in Figure 43.

Figure 43: Acknowledge Cancel Warning

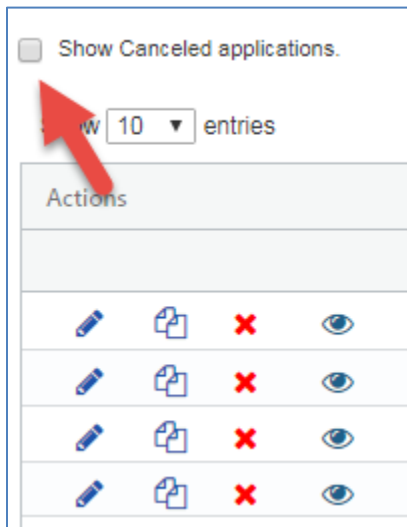
Cancel Application ✕

WARNING: Are you sure you want to cancel this application?

Step 2: View Canceled Applications.

By default, the system does not show your cancelled applications. If you want to view the canceled applications on your Dashboard, click the **Show canceled applications** checkbox, as shown in Figure 44.

Figure 44: View Canceled Applications on Dashboard



8 Cloning an Application

To save time, you can “clone” your existing application from the Dashboard. This allows you to “copy” an existing application and make modifications in support of a new application.

Step 1: Click the Clone Button

You can clone your application from the Dashboard by clicking the **Clone Application** button (Copy document), as shown in Figure 45. All data from the existing application is copied into the new application except for the Attestation section. You can then edit the new application, fill in the Attestation data, and submit as a new application.

Note: In Clone mode, you cannot change the Certificate Type or Product Type.

Figure 45: Clone an Application

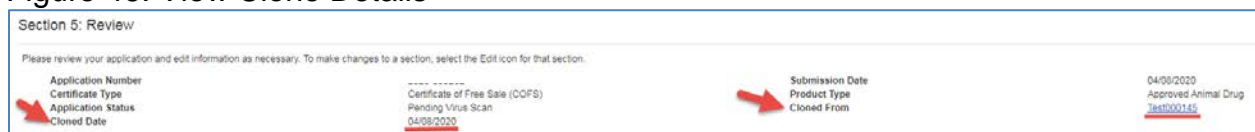
Actions	Application No	Certificate Type	Product Type
	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
	TEST000145	Certificate of Free Sale (COF...	Approved Animal Drug
	TEST000144	Certificate to Foreign Gover...	Type A Medicated Article
	TEST000147	Certificate of a Pharmaceuti...	Approved Animal Drug
	TEST000146	Certificate of Exportability (...)	Animal Food

Note: You cannot “clone” an application in Rejected or Canceled status. You also cannot clone an application immediately after submission, until the system has completed its virus scanning on the uploaded documents.

Step 2: View Clone Source in View Application

After you submitted a cloned application, you can see the “source” application from which this application was cloned. The system displays this information when you open the application in “View Application” mode, with values in the “Cloned From” and “Clone Date”, as shown in Figure 46.

Figure 46: View Clone Details



Section 5: Review

Please review your application and edit information as necessary. To make changes to a section, select the Edit icon for that section.

Application Number	Certificate of Free Sale (COFS)	Submission Date	04/08/2020
Certificate Type	Pending Virus Scan	Product Type	Approved Animal Drug
Application Status	<u>04/08/2020</u>	Cloned From	<u>Test000145</u>
Cloned Date			

9 Responding to Return for Action

The FDA Reviewer may return the application to you for modification.

Step 1: Review the email notification

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

Step 2: Select the application on the Dashboard

Locate on the Dashboard the application that has the status of “Returned for Action”. Click the **Modify Application** button.

Step 3: Make the requested change and submit

Make the required change described in your email notification. Then resubmit the application after filling out the Attestation section.

Note: You must complete and submit your return-for-action application within 3 business days of receipt. A return-for-action application is automatically canceled if it is not corrected and resubmitted within 3 business days from the time it is returned for action by the FDA reviewer to the applicant.

10 Printing or Obtaining the Certificate

If your application is approved, the system sends you an email notification to inform you of the approval status. You can view and print your certificate using the following steps:

- a) Log on to FURLS and access the CVM eCATS function
- b) On the Dashboard, locate the approved application. You can sort the listing of the dashboard in ascending order on the “Status” column to display applications with Approved status to be on top of the listing
- c) Click on the **Printer** icon of the application that you want to print the certificate
- d) Click on **Save** if you want to save the certificate on your file directory; or click on **Open** if you want to view the certificate
- e) Depending on whether you saved or viewed the certificate, you can then print it on your network or locally attached printer.

Note: For CPP certificates, if you have uploaded the FedEx/UPS label for mailing, CVM uses that to mail the printed certificate to you. As such, the system does not display the **Printer** icon next to the approved CPP application.

11 Obtaining and Responding to Notifications

The system provides automated notifications to your email address whenever:

- You save an application to draft prior to submittal.
- You submit your application.
- You cancel your application.
- You modify and re-submit your application based on a Return for Action request from the FDA.
- Your application is approved by the FDA.
- Your application is cancelled by the FDA.
- Your application is rejected by the 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 3 business days.

12 Validating the Authenticity of CVM-Issued Export Certificate

As a foreign government official (FGO), you can validate the authenticity of the CVM-issued certificate using the following steps:

- a) Navigate to the FDA Export Certificate Validation web site ([URL: to-be-provided](#))
- b) Enter **at least two** of the following certificate identifying information:
 - o Certificate Number
 - o Facility Name
 - o Dates of Certificate Expiration
 - o Product Name
- c) Click the **Search** button

If the provided information is correct, the system displays additional information about the certificate to include the following:

- Certificate number
- Certificate type
- Facility name and address
- Expiration date
- Product name
- Importing Country

Using the data displayed, you can verify against the certificate that a US Exporter has provided to you.