



U.S. FOOD & DRUG
ADMINISTRATION

U.S. Food and Drug Administration

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

**Step-by-Step Instructions for Industry
Applicants**

December 2024

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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 descriptions and system functions are described below:

Icon Description	Icon	System Function
Eye		View the associated item.
Pencil		Edit the associated item.
Clone		Clone 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 industry users of the Center for Veterinary Medicine (CVM) 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 the certificates;
- Reviewing system notifications;
- Validating the authenticity of CVM-Issued Export Certificates (by Foreign Government Officials).

2 Overview of CVM eCATS

FDA's 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 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 FDA.

FDA's Unified Registration and Listing System (FURLS)

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 CVM.

Supported Browsers

FURLS can be accessed using Firefox, Chrome, or Microsoft Edge browsers. Please visit the **Systems Requirements** section of the [FIS Home page](#) for a list of browser versions.

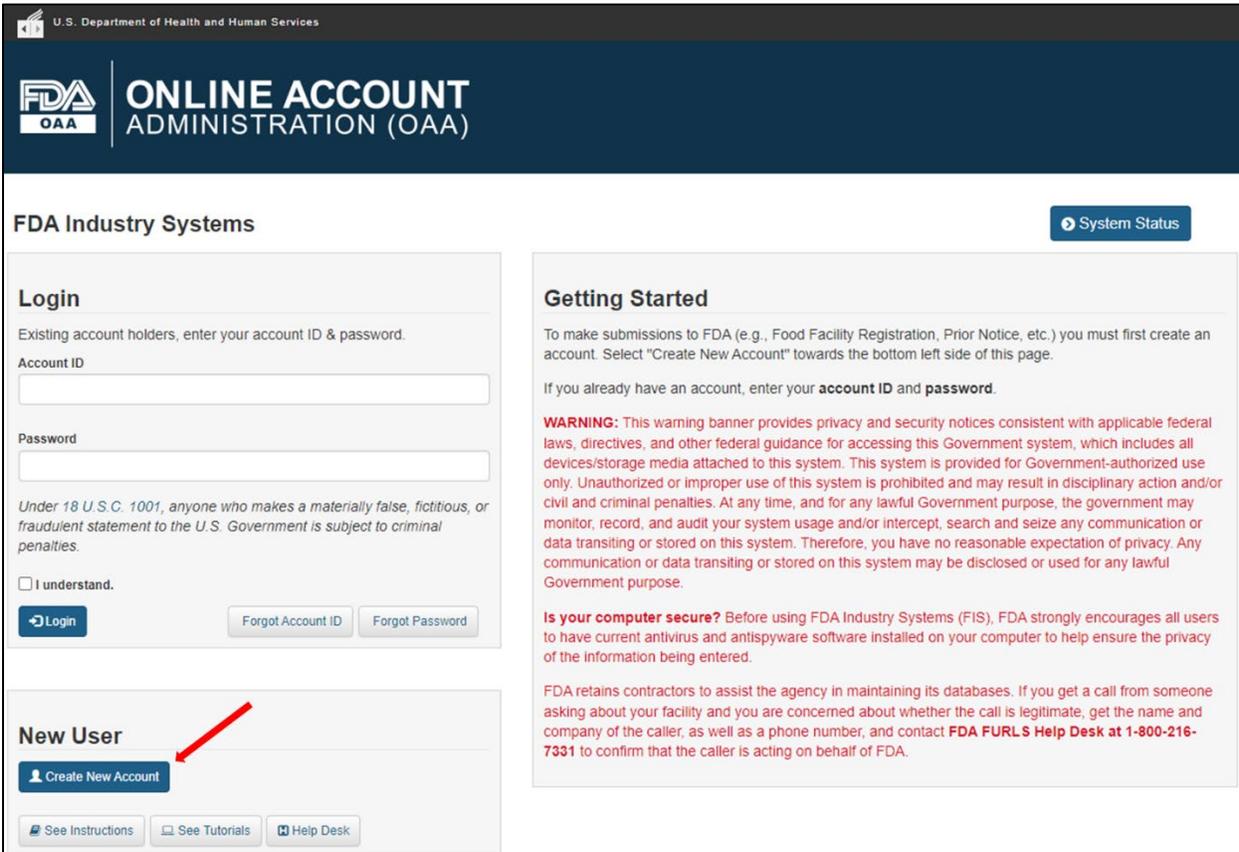
3 Applying for Login Credentials using FIS

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 the FIS Electronic Portal.

To access the FIS electronic portal, navigate to the [FIS Home page](#). Click the **Create New Account** button (Figure 3.1).

Figure 3.1: Create New Account in FDA FIS Electronic Portal



U.S. Department of Health and Human Services

FDA | **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.

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: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government-authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

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.

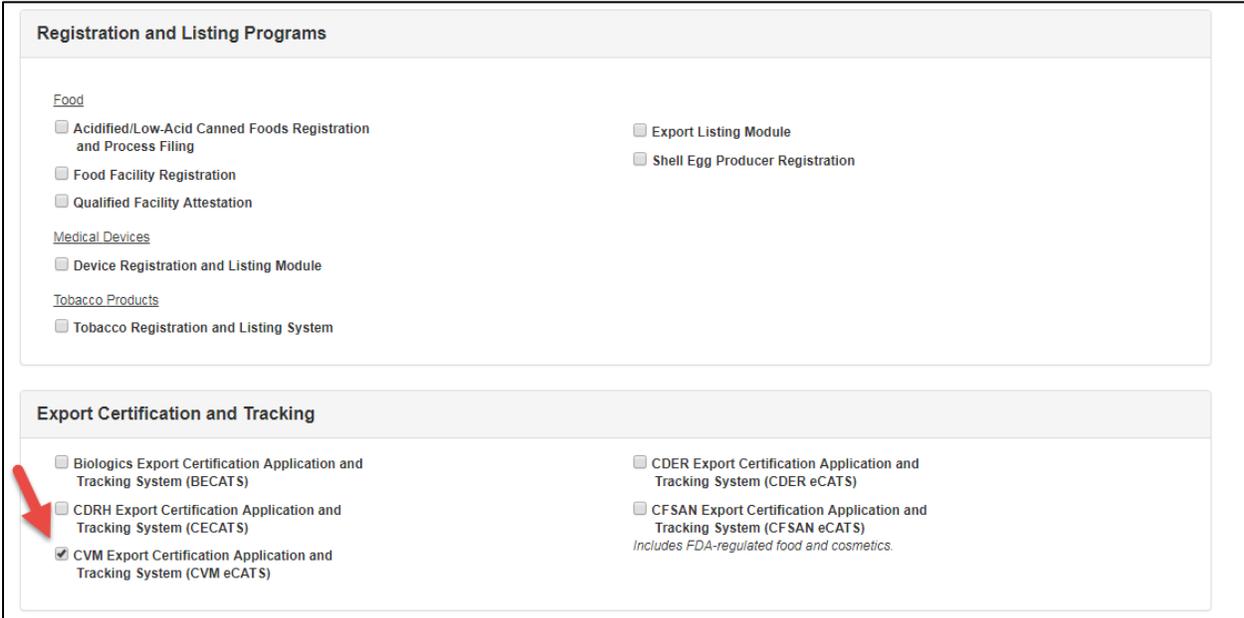
FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact **FDA FURLS Help Desk at 1-800-216-7331**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

New User

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)”. Click the **Continue** button at the bottom of the screen (Figure 3.2).

Figure 3.2: CVM eCATS Checkbox in FIS Electronic Portal



The screenshot displays two main sections of the FIS Electronic Portal:

- Registration and Listing Programs:**
 - Food
 - Acidified/Low-Acid Canned Foods Registration and Process Filing
 - Food Facility Registration
 - Qualified Facility Attestation
 - Medical Devices
 - Device Registration and Listing Module
 - Tobacco Products
 - Tobacco Registration and Listing System
 - Export Listing Module
 - Shell Egg Producer Registration
- Export Certification and Tracking:**
 - Biologics Export Certification Application and Tracking System (BECATS)
 - CDRH Export Certification Application and Tracking System (CECATS)
 - CVM Export Certification Application and Tracking System (CVM eCATS)
 - CDER Export Certification Application and Tracking System (CDER eCATS)
 - CFSAAN Export Certification Application and Tracking System (CFSAAN eCATS)
Includes FDA-regulated food and cosmetics.

A red arrow points to the selected checkbox for CVM eCATS.

Step 3: Fill out your contact information.

Fill out the contact information, including “Name”, “Address”, “Phone number”, and “E-mail address” (Figure 3.3).

Note: FURLS uses the e-mail address for all communication purposes, including notifications regarding your export certification application.

Figure 3.3: Fill out Contact Information in FIS Electronic Portal

? 🖨

Create New Account

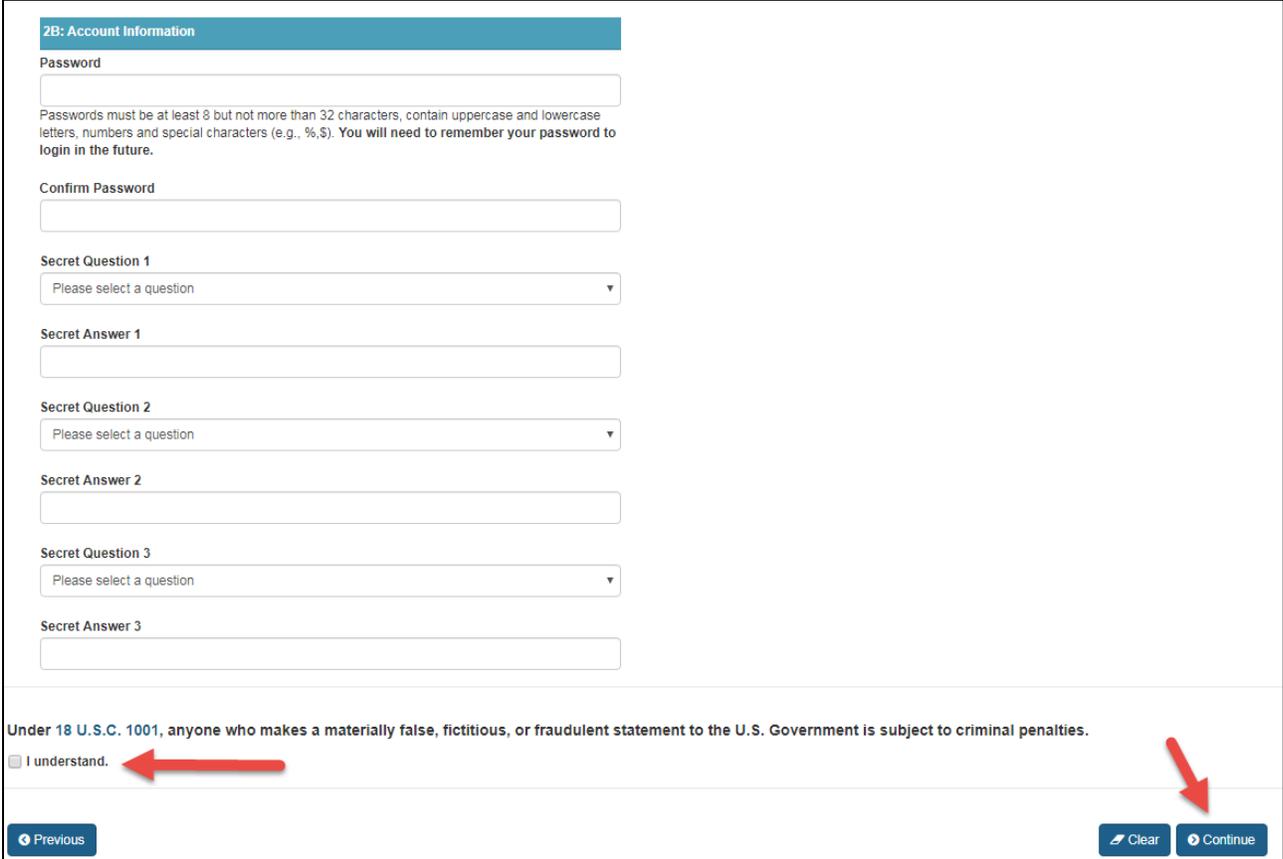
Step 2: Enter Your Account Information

2A: Point of Contact Information	2C: Physical Address (Business) of Account Holder														
<p>First Name <input type="text"/></p> <p>Middle Initial (Optional) <input type="text" value="Optional"/></p> <p>Last Name / Surname <input type="text"/></p> <p>Job Title <input type="text"/></p> <p>Company Name <input type="text"/></p> <p>Web Address (Optional) <input type="text"/> <small>(Example: http://www.name.domain or http://name.domain)</small></p> <p>Phone Number</p> <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid #ccc; padding: 2px;">Country</td> <td style="border: 1px solid #ccc; padding: 2px;">Area</td> <td style="border: 1px solid #ccc; padding: 2px;">Telephone</td> <td style="border: 1px solid #ccc; padding: 2px;">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><small>Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country code is not required for US phone numbers.</small></p> <p>FAX Number (Optional)</p> <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid #ccc; padding: 2px;">Country</td> <td style="border: 1px solid #ccc; padding: 2px;">Area</td> <td style="border: 1px solid #ccc; padding: 2px;">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> <p>E-mail Address <input type="text"/></p> <p>Confirm E-mail Address <input type="text"/></p>	Country	Area	Telephone	Ext	Country	Area	Phone Number	Extension	Country	Area	Fax Number	Country	Area	Fax Number	<p>Country / Area <input type="text" value="Please Select Country"/></p> <p>Address Line 1 <input type="text"/></p> <p>Address Line 2 (Optional) <input type="text" value="Optional"/></p> <p>City <input type="text"/></p> <p>State / Province / Territory <input type="text" value="Please Select"/></p> <p>Zip Code (Postal Code) <input type="text"/></p> <p>Do you have preferred mailing address other than the physical address mentioned above? <input type="radio"/> Yes <input type="radio"/> No </p>
Country	Area	Telephone	Ext												
Country	Area	Phone Number	Extension												
Country	Area	Fax Number													
Country	Area	Fax Number													

Step 4: Enter Security Information and Submit.

Enter a password. Next, select secret questions from the dropdown menu(s) and enter corresponding answers. Click the “I understand” checkbox after reading the statement and click the **Continue** button at the bottom of the screen (Figure 3.4).

Figure 3.4: Complete Contact Information 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 click 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 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](#).

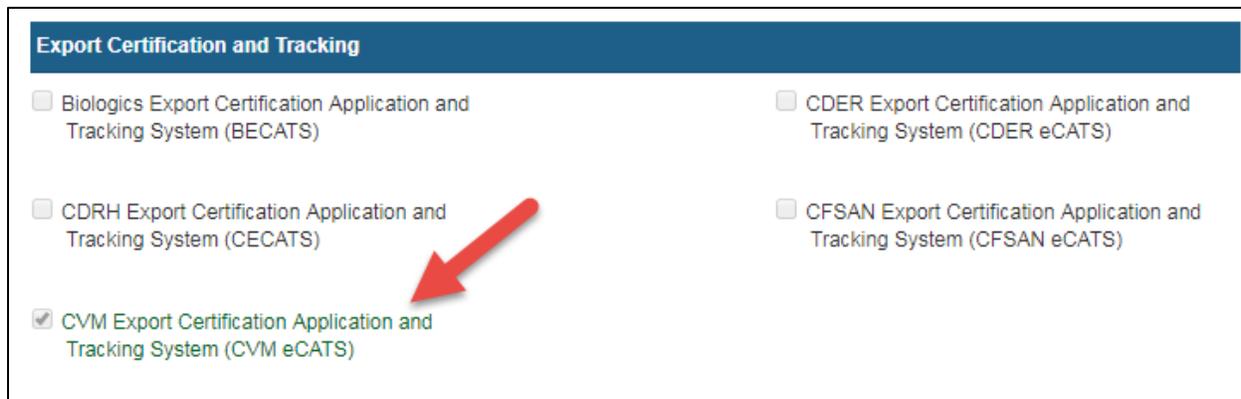
4 Submitting an Application for a Certificate

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

Step 1: Access CVM eCATS.

After you log into FURLS, click the “CVM Export Certification Application and Tracking System (CVM eCATS)” link (Figure 4.1).

Figure 4.1: Click the CVM eCATS Link on FURLS Home Page

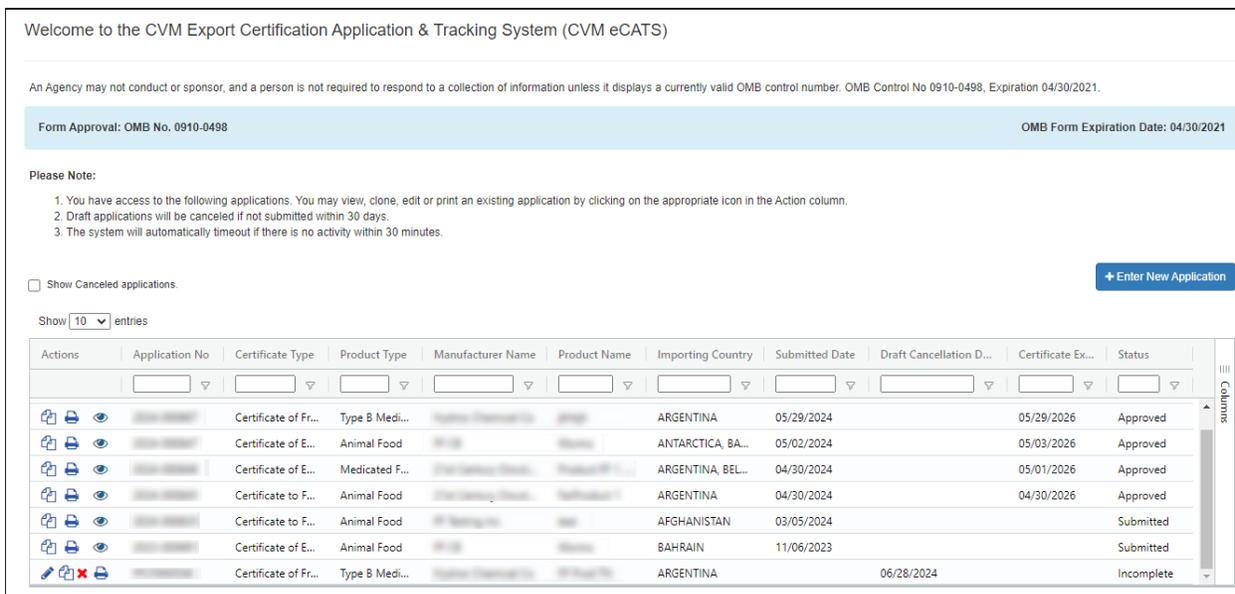


Step 2: Review the Dashboard contents.

FURLS displays the CVM eCATS **Welcome** page, also known as the **Dashboard**, to show your existing application(s) (Figure 4.2). If you have not created or submitted any electronic application(s), the Dashboard will not contain any data. The Dashboard is where you can view, edit, cancel, print, or clone applications. It is also where you can update your application using the **Edit** feature if CVM returned your application for follow-up action(s).

Note: You can monitor the status of your submitted application from the Dashboard. You will also receive notification if the application status changes (Section 11).

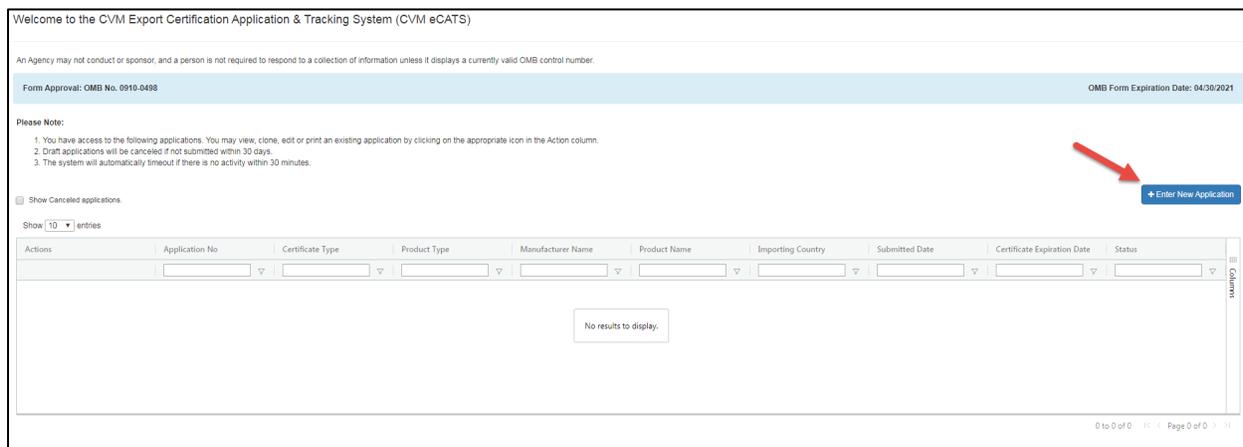
Figure 4.2: Accessing the CVM eCATS User Dashboard



Step 3: Click the Enter New Application button.

To create a new application, click the **Enter New Application** button (Figure 4.3).

Figure 4.3: Enter New Application Button



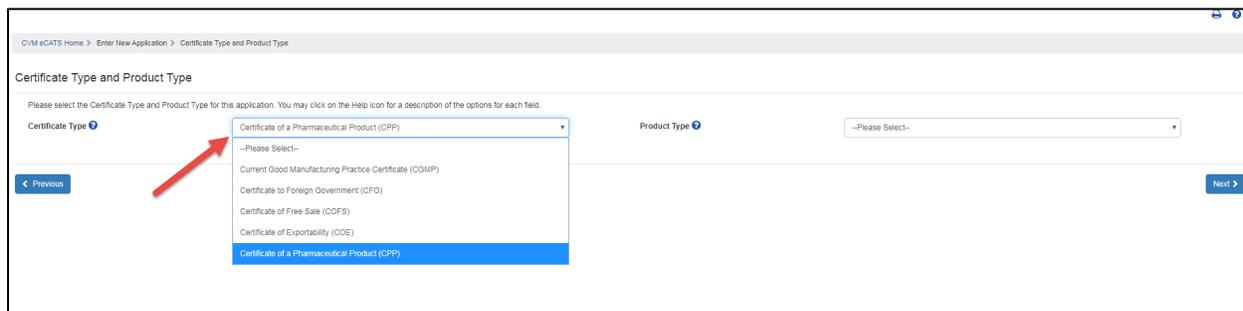
Step 4: Select the Certificate Type.

The system displays the **Certificate Type and Product Type** section (Figure 4.4).

Select the **Certificate Type** for the application you are 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 4.4: Select the Certificate Type



Step 5: Select the Product Type or enter an Associated Certificate Number.

For all certificate types, except CGMP, select the Product Type (Figure 4.5). **Product Type** options vary for each certificate type.

For CGMP certificate type, enter an Associated Certificate Number (Figure 4.6). Only valid and active certificate numbers are allowed.

Click **Next**.

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

Figure 4.5: Select Product Type

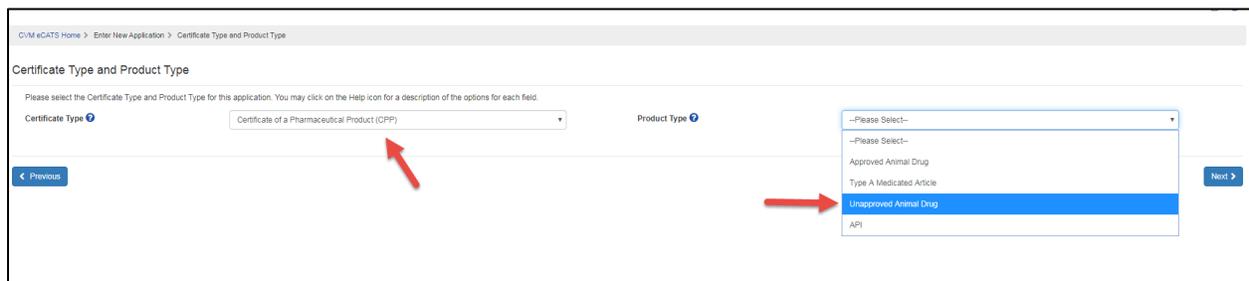
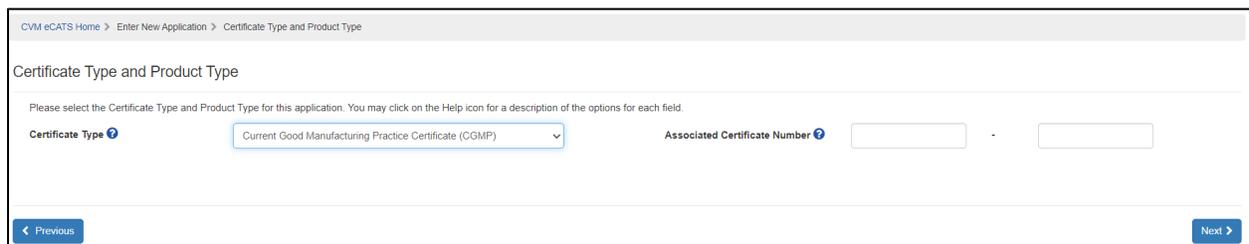


Figure 4.6: Enter Associated Certificate Number



Step 6: Enter Requestor Information.

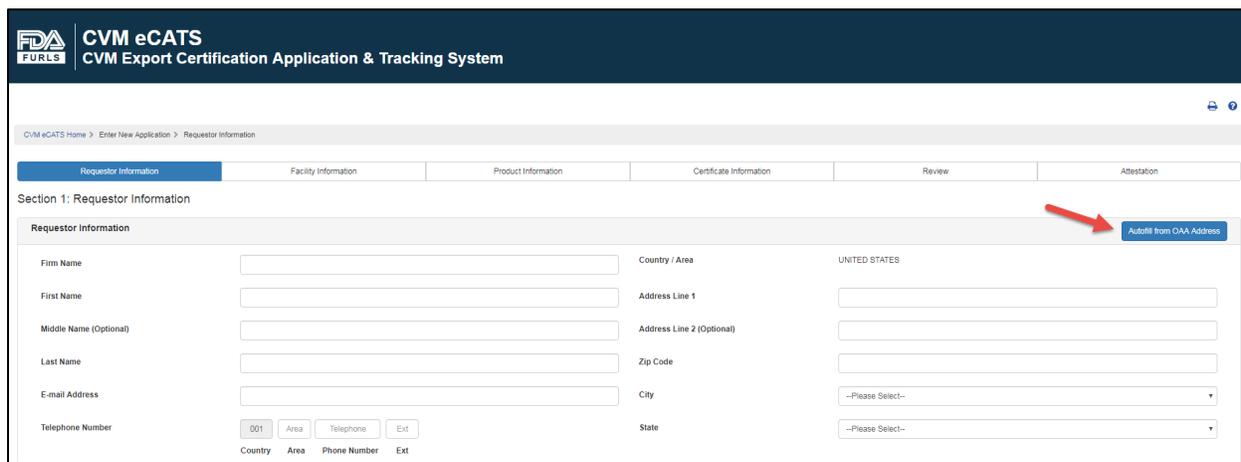
The system displays the **Requestor Information** section. Enter the following:

1. Contact information of the Requestor;
2. Contact information for billing purposes. **Note:** This section does not apply to CGMP certificate type.

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 to auto-populate this information (Figure 4.7).

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

Figure 4.7: Enter Requestor Address Information



Step 7: Enter Billing Information.

Enter the firm name and contact information for the individual(s) responsible for billing. If the billing contact information is the same as that of the Requestor’s contact information, select **Yes** in response to the following question: “Is the Billing Name and Address the same as the Requestor Name and Address?”

Next, enter your Firm Tax ID Code (Figure 4.8).

Note:

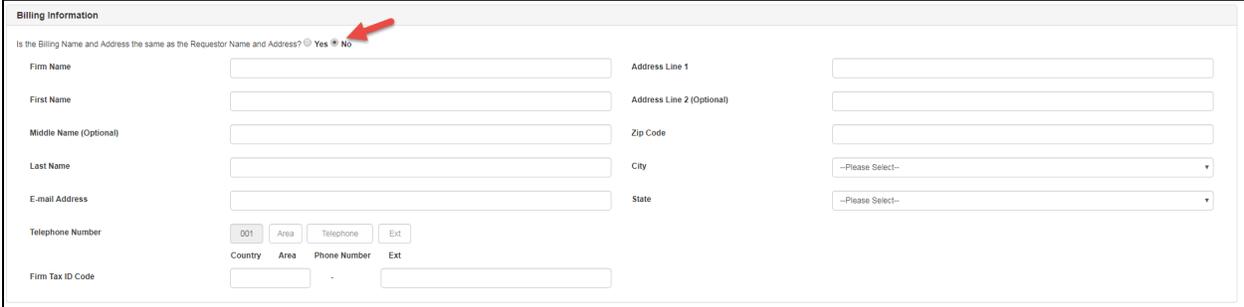
- The billing address must be in the United States;
- The CGMP certificate type does not have a **Billing Information** section. For CGMP, you only need to fill in the Requestor’s information.

Figure 4.8: 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** (Figure 4.9). Enter the Billing Contact address information, and the Firm Tax ID Code.

Figure 4.9: Answer Question - Billing Address is Not the Same as Requestor Address



Billing Information

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

Firm Name Address Line 1

First Name Address Line 2 (Optional)

Middle Name (Optional) Zip Code

Last Name City

E-mail Address State

Telephone Number

Country

Firm Tax ID Code

Step 8: Review the Address Validation.

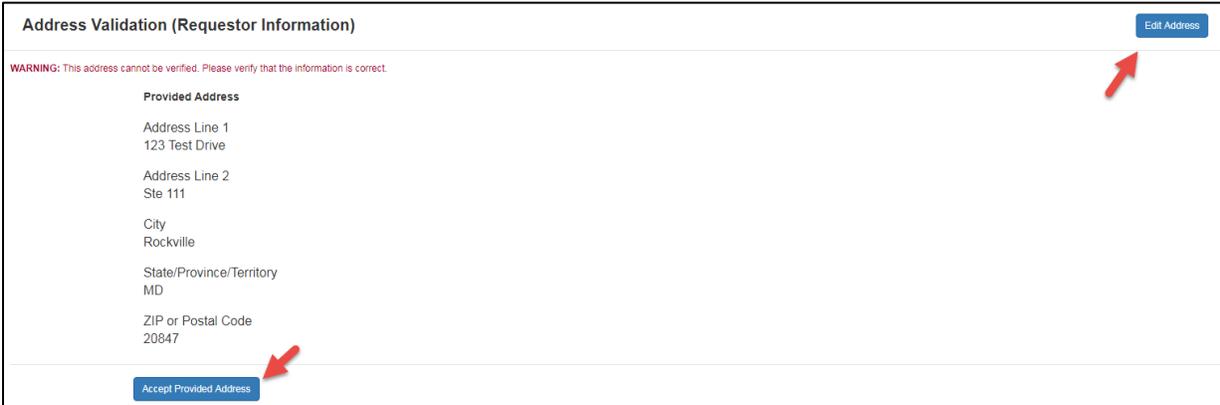
When you have completed the **Requestor and Billing Information** fields, click **Next**. The system validates the addresses you provided against the standard USPS addresses. If the addresses are invalid, the system displays an error message. Otherwise, the system asks you to accept your provided Requestor’s and billing addresses or, accept the system’s validated addresses.

The system’s validated addresses may include minor changes to the provided addresses (e.g., the four-digit extension to the Zip Code). You always have the option of returning to the **Requestor** and **Billing Information** sections to modify your addresses; to do so, click the **Modify** button.

You must click **Accept Provided Address** or **Accept Validated Address** to proceed to next step (Figure 4.10).

Note: Address validation is only applicable to U.S. addresses.

Figure 4.10: Address Validation



Address Validation (Requestor Information) [Edit Address](#)

WARNING: This address cannot be verified. Please verify that the information is correct.

Provided Address

Address Line 1
123 Test Drive

Address Line 2
Ste 111

City
Rockville

State/Province/Territory
MD

ZIP or Postal Code
20847

[Accept Provided Address](#)

For all certificate types, except CGMP, continue to Step 9 in Section 4.1. For CGMP certificate type, continue to Step 9 in Section 4.2.

4.1 All Certificate Types (except CGMP)

Step 9: Access the Facility Information section.

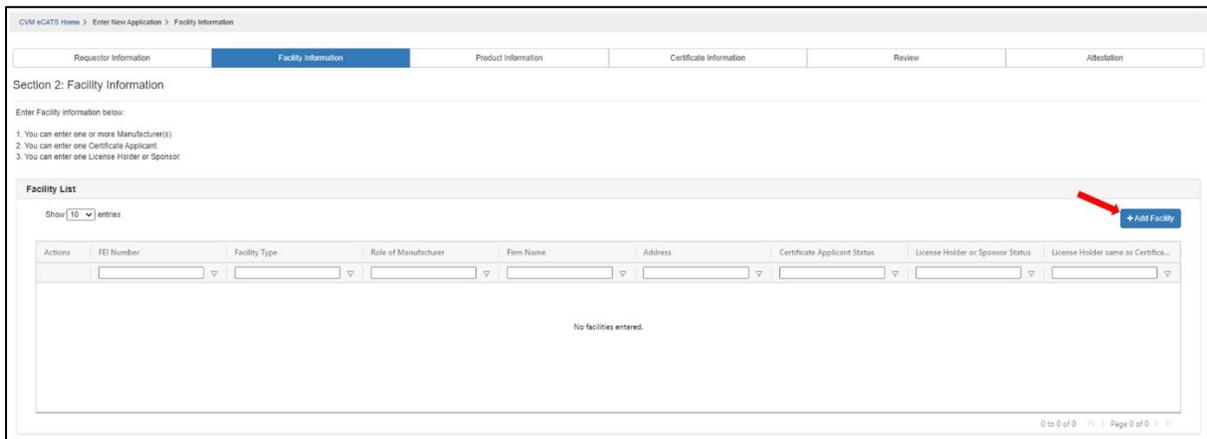
After the address validation is complete, the system displays the **Facility Information** section. Next:

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

Step 10: Enter the Facility Information.

To add a facility, click the **Add Facility** button (Figure 4.11).

Figure 4.11: Add a Facility



Enter the facility information in one of the three ways (Figure 4.12):

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

Please note the following:

- For manufacturers, (and depending on the certificate type), you must either enter the FEI Number and use the **Search** button or enter an address the system can find the FEI number for in FDA’s databases. If you are using the latter approach, the address must be selected from addresses displayed by the system.

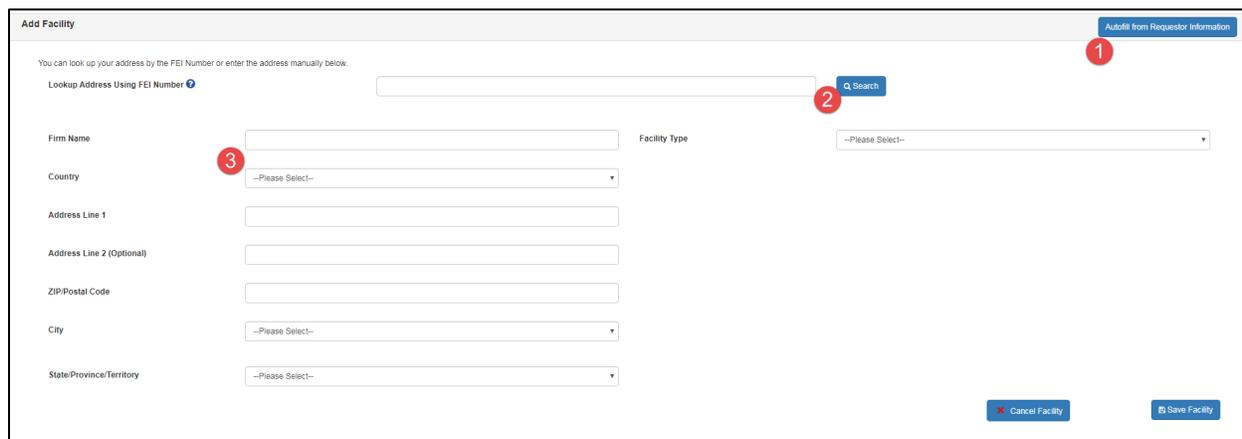
- Distributors do not require an FEI Number association.
- You can also use FDA’s FEI Search Portal [website](#) to locate the FEI number for the address you intend to use.

Note: If a foreign address (of a Distributor) does not have a zip / postal code, enter “00000” before you save the facility.

Table 1 - FEI Number Requirements for Manufacturer

Certificate Type	FEI Number required?
CFG	Yes
COFS	Yes
COE	Yes
CPP	Yes

Figure 4.12: Enter Facility Information.



The screenshot shows the 'Add Facility' form with the following fields and callouts:

- 1:** 'Adapted from Requestor Information' button in the top right corner.
- 2:** 'Search' button next to the 'Lookup Address Using FEI Number' input field.
- 3:** 'Country' dropdown menu.

Other fields include: Firm Name, Facility Type (dropdown), Address Line 1, Address Line 2 (Optional), ZIP/Postal Code, City, and State/Province/Territory. 'Cancel Facility' and 'Save Facility' buttons are at the bottom right.

Step 11: Select a Facility Type.

Select the **Facility Type** (Figure 4.13). The options available will differ, depending on the certificate type.

Figure 4.13: Select Facility Type

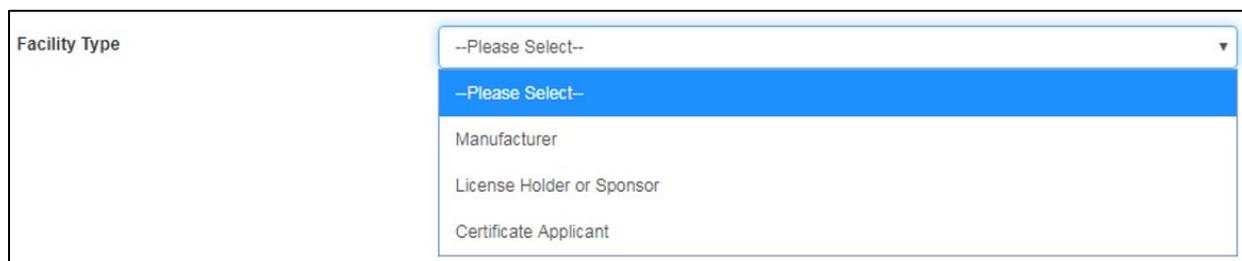


Table 2 – Facility Limitations Number Requirements for Manufacturer

Certificate Type	Facility Type Options	Number allowed	Required/ Optional	Exceptions / Notes
CFG	Manufacturer Distributor	Multiple for drugs; One for food and devices One	Required Optional	Where the “Number allowed” is indicated as “Multiple”, you must enter at least one facility designated as manufacturer
COFS	Manufacturer Distributor	Multiple for drugs; One for food and devices One	Required Optional	
COE	Manufacturer	Multiple for drugs; One for food and devices	Required	
CPP	Manufacturer Certificate Applicant License Holder or Sponsor*	Multiple for drugs; One for food and devices One One	Required Required Required	*License Holder or Sponsor only applicable to Approved Animal Drug and Type A Medicated Article

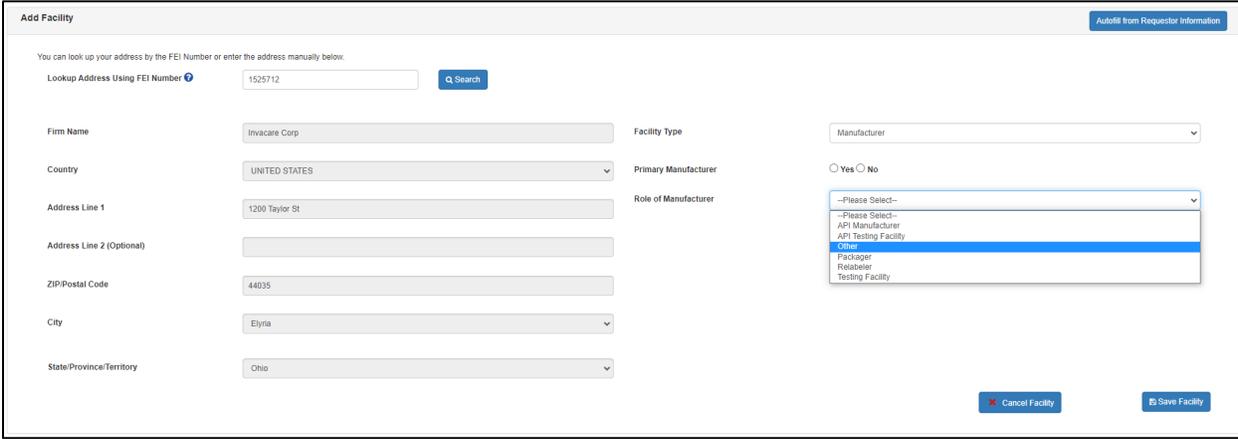
Step 12: CPP-Only – Select the Primary Manufacturer and Role of Manufacturer.

If you are applying for a CPP certificate and you selected “Manufacturer” as the Facility Type, the system requires you to indicate the Primary Manufacturer and the Role of the Manufacturer.

Please note the following:

- If multiple manufacturers are added, only one can be identified as the Primary Manufacturer;
- If “Other” is selected for the Role of Manufacturer, a text box is displayed to provide the information (Figure 4.14).

Figure 4.14: Primary Manufacturer and Role of Manufacturer



The screenshot shows the 'Add Facility' form with the following details:

- Lookup Address Using FEI Number:** 1525712
- Firm Name:** Invacare Corp
- Country:** UNITED STATES
- Address Line 1:** 1200 Taylor St
- Address Line 2 (Optional):** (empty)
- ZIP/Postal Code:** 44035
- City:** Elyria
- State/Province/Territory:** Ohio
- Facility Type:** Manufacturer
- Primary Manufacturer:** Yes No
- Role of Manufacturer:** Open dropdown menu with options: --Please Select--, --Please Select--, API Manufacturer, API Testing Facility, **Other** (highlighted), Fabricator, Relabeler, Testing Facility.

Step 13: CPP-Only – Answer Certificate Applicant address question and select status.

If you are applying for a CPP certificate and you select “Certificate Applicant” as the Facility Type, the system requires you to answer the question: “Is the Certificate Applicant name and address the same as the License Holder or Sponsor name and address?”, displayed at the bottom of the screen (Figure 4.15).

Figure 4.15: Answer Certificate Applicant Question – CPP Only



The screenshot shows a question box with the text: "Is the Certificate Applicant name and address the same as the License Holder or Sponsor name and address?" followed by radio buttons for "Yes" and "No".

If you are applying for a CPP certificate and you selected “Certificate Applicant” or “License Holder or Sponsor” as the Facility Type, the system also requires you to specify the “Certificate Applicant Status” or “License Holder or Sponsor Status” (Figure 4.16).

Figure 4.16: Select Status for License Holder or Sponsor – CPP Only

Step 14: Save a Facility.

Click the **Save Facility** button to add the facility to the application. The system displays all facilities added to the **Facility List** table – from which you can either modify or delete the facility entry, if necessary (Figure 4.17).

Please note the following:

- The Manufacturer designated as the Primary Manufacturer displays “(Primary)” in the **Facility Type** column;
- If “Other” is selected for Role of Manufacturer, this displays as “Other – [entered text]” in the **Role of Manufacturer** column.

Figure 4.17: Save Facility to Facility Table

Actions	FEI Number	Facility Type	Role of Manufacturer	Firm Name	Address	Certificate Applicant Status	License Holder or Sponsor Status	License Holder same as Certifica...
	3000204352	Certificate Applicant		Leona's Foods, Inc	Manzana Center, Hwy 76, Chimay...	Manufacturer		Yes
	3000204352	Manufacturer (Primary)	API Manufacturer	Leona's Foods, Inc	Manzana Center, Hwy 76, Chimay...			

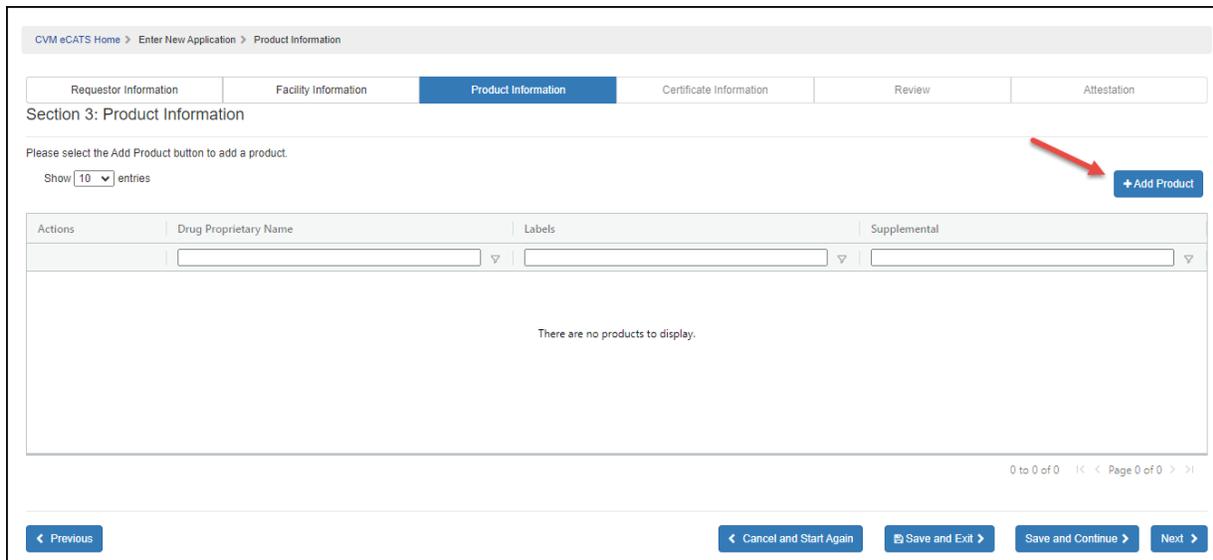
Step 15: Enter Product Information.

When you have completed entering the Facility Information, click **Next**.

The system displays the **Product Information** section (Figure 4.18).

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

Figure 4.18: Access the Product Information Section



Step 16: Add a product.

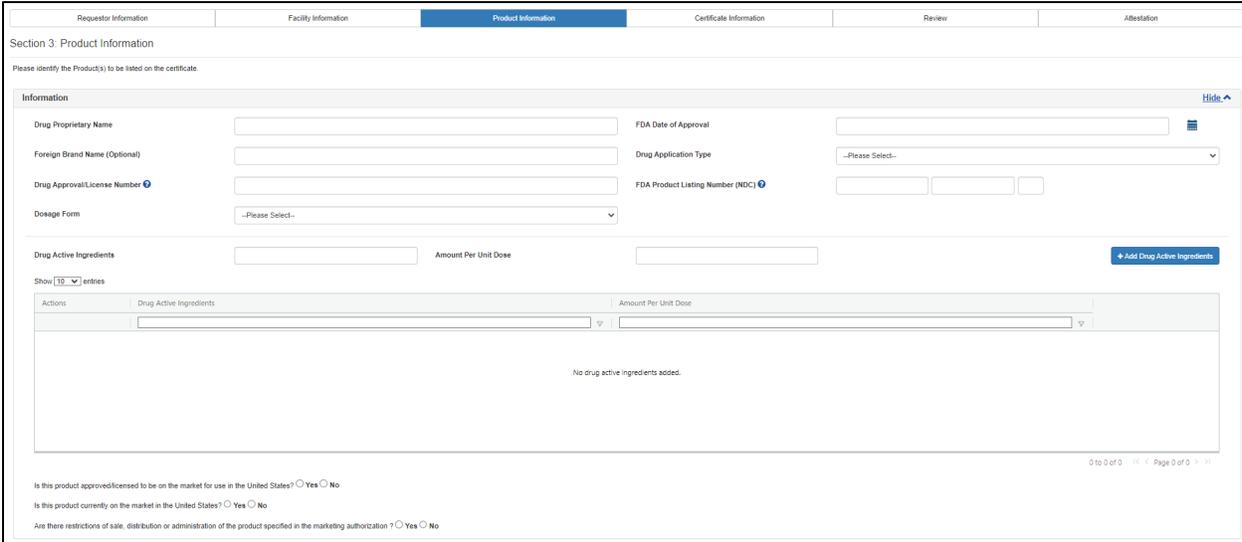
Click the **Add Product** button (Figure 4.18). Please note the product number limitations described in the table below.

Table 3 – Product Number Limitations

Certificate Type	Number of Products Allowed	Exceptions
CFG	Multiple/One*	*Animal Food limited to five products *Animal Device no product limit *Animal Drug limited to one product
COFS	Multiple/One*	*Animal Food limited to five products *Animal Drug Limited to one product
COE	Multiple/One*	*Animal Food limited to five products *Unapproved Animal Drug limited to one product
CPP	One	

Note: In the case of **Animal Devices only**, “See Attached List of Products” may be entered for “Product Trade Name” and “Proper Name” – as well as any details of products provided as label/supplemental attachments.

Figure 4.19: Add a Product



The “Information” fields (Figure 4.19) vary depending on the certificate type and product type. Refer to the table below for the list of data entry fields applicable to each certificate and product type combination (Table 4):

Table 4: Applicable Product Fields

Certificate Type	Fields
COE/Animal Food	Product Name
CFG/Animal Food/Animal Device COFS/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. Attach the details of products as a label/supplemental attachments.
CFG/Approved Animal Drug/ Type A Medicated Article/ Type B Medicated Feed/ 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) (except Type B and Type C Medicated Feed)

Certificate Type	Fields
COFS/Approved Animal Drug/ Type A Medicated Article/ Type B Medicated Feed/ 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) (except Type B and Type C Medicated Feed)
COE/Unapproved Animal Drug/API	Product Name FDA Product Listing Number (NDC)
CPP/Approved Animal Drug/ Type A Medicated Article	Drug Proprietary Name Foreign Brand Name (optional) 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 authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? Question: Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? Question: Are there restrictions of the sale, distribution or administration of the product specified in the marketing authorization?
CFG/API COFS/API	Product Trade Name Product Proper Name FDA Product Listing Number (NDC)

Certificate Type	Fields
CPP/Unapproved Animal Drug/API	Drug Proprietary Name Foreign Brand Name (optional) FDA Product Listing Number (NDC) Dosage Form Drug Active Ingredients Amount per Unit Dose Question: Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? Question: Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? Question: Are there restrictions of the sale, distribution or administration of the product specified in the marketing authorization?
COE/Medicated Feed	Product Name Drug Application Type (Optional) (NADA, ANADA, CNADA) Drug Approval/License Number (Optional) FDA Product Listing Number (NDC) (Optional)

In addition, each field may be required, optional, or not applicable depending on the Certificate and Product Type combinations (Table 5)

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

Table 5 – Required Fields for Products

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

Note: For CPP certificates, you must answer three questions displayed at the bottom of the **Information** section.

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

Please note the following:

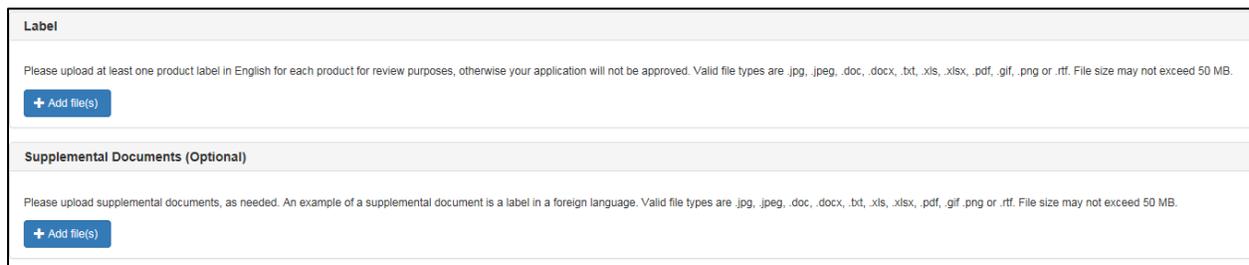
- For “Approved Animal Drug” and “Type A Medicated Product”, the first and the second question (above) requires a **Yes** answer.
- For “Unapproved Animal Drug and API”, the first question (above) requires a **No** answer.
- For “Unapproved Animal Drug”, the second question (above) requires a **No** answer.

Step 17: Add Labels and Supplemental Documents.

Click the **Add file(s)** button to add a product label (Figure 4.20). With the exception of CGMP certificates, you must provide at least one product label in English for FDA review purposes. Navigate to where you stored your label(s), select the label(s), and click the **Start Upload** button to add them to the application.

Although it is optional, you can provide supplemental documents as part of the application (Figure 4.20). You can upload supplemental documents by accessing the **Supplemental Documents** section, clicking on the **Add file(s)** button, selecting the documents, and then clicking on **Start Upload**. When you have finished adding labels and supplemental documents, click the **Save** button.

Figure 4.20: Add Labels and Supplemental Documents



Label

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.

+ Add file(s)

Supplemental Documents (Optional)

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.

+ Add file(s)

Step 18: Enter Certificate Information.

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

The system displays the **Certificate Information** section (Figure 4.21). Next, proceed with the following steps (Figure 4.22):

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

Figure 4.21: Access the Certificate Information Section

Step 19: Add Importing Country and Certificates.

Use the “Country” dropdown menu to select a country.

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 to show them in the table below (Figure 4.22).

You can enter multiple importing countries. You can also add up to 30 certificates per application.

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

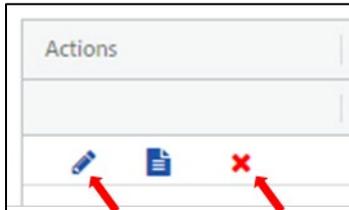
Figure 4.22: Add a Country and Certificates

Actions	Country	Number of Certificates	Append Labels	Append Supplemental Docs
	FRANCE	4	No	No

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. You can delete your entry using the **Delete** icon (Figure 4.23), if necessary.

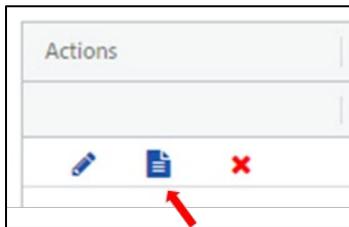
Figure 4.23: Edit and Delete Country and Certificates



Step 21: Associate labels and supplemental documents to certificates.

You can associate the labels and supplemental documents to your certificates by clicking on the **Document** (paper) icon (Figure 4.24).

Figure 4.24: Associate Labels and Documents to Certificates



When you click the **Document** icon, the system displays the **Product Label(s) and Supplemental Document(s)** screen (Figure 4.25). From here, you can indicate each label and supplemental document you want to add to your certificate by clicking the requisite checkboxes. Once you have made the associations, click the **Save** button.

Figure 4.25: 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 the Certificate.

From the **Remarks** (for CPP) or **Additional Information** (non-CPP certificates) sections, you can add remarks or additional information to appear on the certificate (Figure 4.26). The **Remarks** and **Additional Information** are optional fields.

Figure 4.26: 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 30 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 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.

In the **Certificate Fees** section, the system displays the fees for the requested total number of certificates (Figure 4.27).

Figure 4.27: View Certificate Fees

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. OVM 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 finish viewing the Certificate Fees information.

Step 24: Review the application.

The system displays the **Review** section. This section allows you to review your data prior to submitting it to 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 (Figure 4.28).

Figure 4.28: Review Application Prior to Submission

D\VM eCATS Home > Edit Application > Review

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

Form Approval: OMB No. 0910-0498
OMB Form Expiration Date: 04/30/2019

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	Test000147	Submission Date	
Certificate Type	Certificate of a Pharmaceutical Product (CPP)	Product Type	Approved Animal Drug
Application Status	Incomplete		

Section 1: Requestor Information Edit

Firm Name	Test, Inc.	Country / Area	UNITED STATES
First Name	Jane	Address Line 1	123 Test Drive
Middle Name (Optional)	J	Address Line 2	Ste 111
Last Name	Doe	Zip Code	20847
E-mail Address	Jane.Doe123@fda.hhs.gov	City	Rockville
Telephone	001-555-1112222-23232	State	Maryland

Billing Information

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

Firm Name	Test, Inc.	Address Line 1	123 Test Drive
First Name	Jane	Address Line 2	Ste 111
Middle Name (Optional)	J	Zip Code	20847
Last Name	Doe	City	Rockville
E-mail Address	Jane.Doe123@fda.hhs.gov	State	Maryland
Telephone	001-555-1112222-23232		
Firm Tax ID Code	34-3223423		

Delivery Information

Step 25: Attestation

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

The system will display the **Attestation** section. Review the attestation information and warning. Enter your name and title; note that the title is optional.

Click the **I agree** button. Next, click the **Submit** button to submit your application (Figure 4.29).

Figure 4.29: Fill out Attestation Section

D\VM eCATS Home > Edit Application > Attestation

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

Section 6: Attestation

Firm Name: Test, Inc.

As the 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(ies) and the products identified on the application 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:

- All facilities that appear on the application 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;
- Each product(s) identified for export is legally marketed within the United States and is the subject of a Biologics License, NADA, or ANADA;
- Each product(s) identified is not subject of an open recall or the subject of any current enforcement action initiated by FDA;
- All manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process have been identified on the application;
- 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
- Each product(s) identified for export is being exported from the United States.

Name Title (Optional)

I agree

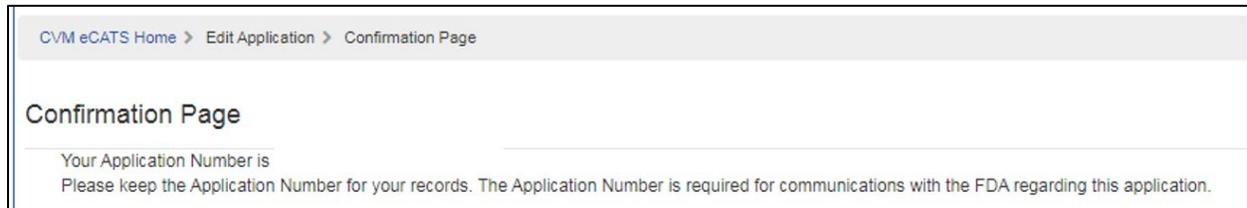
I hereby make this certification of compliance statement for FDA with full knowledge that the making or submission of false statements represent violations of the United States Code Title 18, Chapter 47, Section 1001. Penalties include up to \$250,000 in fines and up to five years imprisonment.

[Previous](#) [Cancel and Start Again](#) [Submit](#)

Step 26: Submission Confirmation

After you submit the application, the system displays a confirmation message with your application number, which is required for any communications with FDA regarding the application (Figure 4.30).

Figure 4.30: 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 e-mail notification to inform you that FDA received your submission.

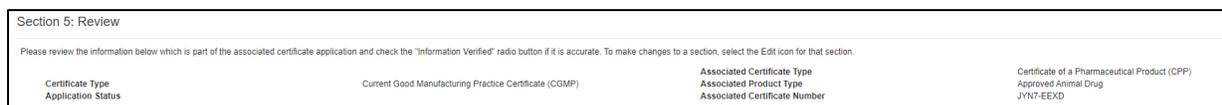
4.2 CGMP Certificate Type

Step 9: Review the CGMP application.

After address validation, the system displays the **Review** page. Review the information in each section:

- Summary Information – Displays the following (Figure 4.31):
 - a. Certificate Type
 - b. Application Status: Status is displayed once the application is saved and/or submitted
 - c. Associated Certificate Type
 - d. Associated Product Type
 - e. Associated Certificate Number

Figure 4.31: CGMP Summary Information



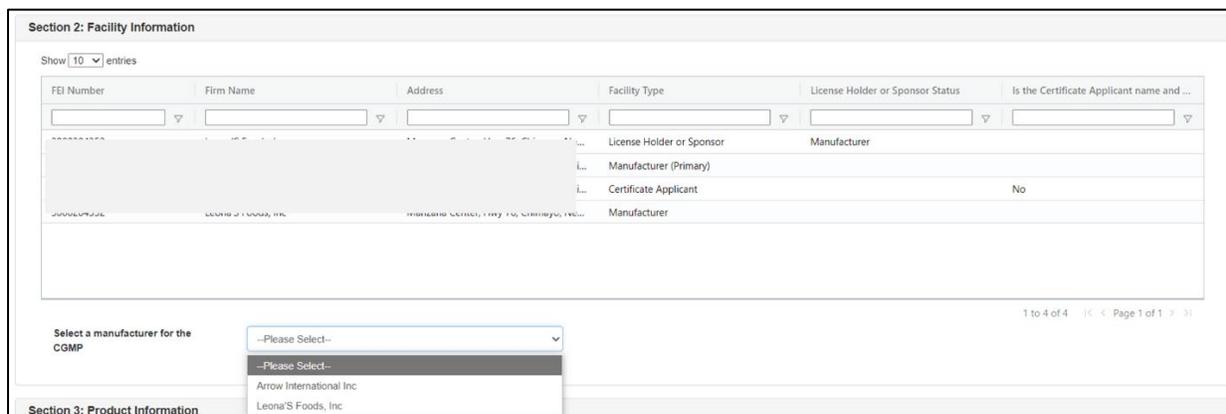
- Section 1 – Displays the Requestor Information entered (Figure 4.32)

Figure 4.32: CGMP Requestor Information



- Section 2 – Displays the Facility Information from the associated certificate. You must select a value for the “Select the manufacturer for the CGMP” field (Figure 4.33). Note: The manufacturers listed only includes manufacturer facility types.

Figure 4.33: Select a Facility for the CGMP



Section 2: Facility Information

Show 10 entries

FEI Number	Firm Name	Address	Facility Type	License Holder or Sponsor Status	Is the Certificate Applicant name and ...
			License Holder or Sponsor	Manufacturer	
			Manufacturer (Primary)		
			Certificate Applicant		No
			Manufacturer		

Select a manufacturer for the CGMP

--Please Select--

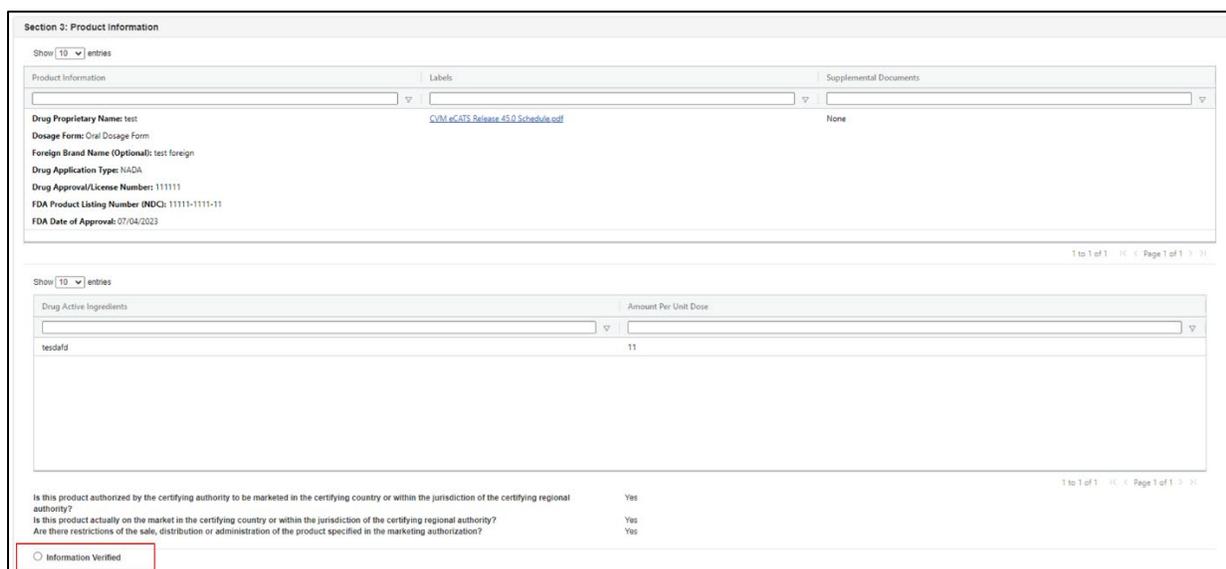
Arrow International Inc

Leona'S Foods, Inc

Section 3: Product Information

- Section 3 – Displays the Product Information from the associated certificate. You must select the radio button “Information Verified” (Figure 4.34).

Figure 4.34: Confirm Product Information is Valid



Section 3: Product Information

Show 10 entries

Product Information

Drug Proprietary Name: test

Dosage Form: Oral Dosage Form

Foreign Brand Name (Optional): test foreign

Drug Application Type: NADA

Drug Approval/License Number: 111111

FDA Product Listing Number (NDC): 11111-1111-11

FDA Date of Approval: 07/04/2023

Labels

Supplemental Documents

None

Drug Active Ingredients

Amount Per Unit Dose

tesdafa 11

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

Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? Yes

Are there restrictions of the sale, distribution or administration of the product specified in the marketing authorization? Yes

Information Verified

- Section 4 – Displays the Certificate Information (Figure 4.35). This displays the Country from the associated certificate. You must enter the number of certificates requested. The maximum number that can be requested is 30 certificates.

Figure 4.35: Enter Number of CGMP Certificates

Section 4: Certificate Information	
Please enter the requested number of certificates which may be up to 30.	
Importing Country	AUSTRIA
Number of Certificates	<input type="text"/>
Total Fees \$0	

Step 10: Preview the CGMP Certificate

Click **Preview Certificate** when you have reviewed your data for accuracy to preview the certificate (Figure 4.36).

Figure 4.36: Preview CGMP Certificate – Animal Food Example

 CURRENT GOOD MANUFACTURING PRACTICE CERTIFICATE (CGMP) FOR ANIMAL FOOD			
CERTIFICATE NUMBER XXXXX-XXXX1	ASSOCIATED CERTIFICATE NUMBER 8XCE-RU23	IMPORTING COUNTRY Kingman Reef	EXPIRY DATE December 23, 2026
PRODUCT NAME			
Trade Name: Product Trade Name entry ; Proper Name: Product Proper Name entry			
Trade Name: Product Trade Name entry Also ; Proper Name: Product Proper Name entry Also			
Trade Name: Product Trade Name entry Too ; Proper Name: Product Proper Name entry Too			
ATTESTATION			
<p>I declare as follows: The United States Food and Drug Administration (FDA) certifies that the above manufacturing facility is subject to the jurisdiction of the FDA, and subject to periodic inspections. The last inspection showed that the facility, at the time the inspection occurred, was in substantial compliance with the Current Good Manufacturing Practice requirement(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations for the animal food identified above and referenced in the associated electronic certificate whose number is listed above. Based on this inspection and all other available information, FDA certifies the product(s) listed above is made in compliance with all applicable CGMP requirements of the FD&C Act, including FDA's implementing regulations.</p> <p>This document is not a substitute for a Certificate to Foreign Government that attests to the legality and exportability of a specific animal food. In issuing this document, FDA did not review whether the animal food above meets the FD&C Act's labeling requirements or the requirements applicable to food additives.</p>			
FACILITY INFORMATION			
FEI Number 3014892542	Manufacturer Name Testing Domestic One	Address One Here, Washington, District of Columbia 20001 United States	
NAME, TITLE Isaac K. Carney, Director, Division of Food Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, United States Food and Drug Administration Signature: 		DATE ISSUED December 23, 2024	
<small>This certificate expires 24 months from the date the associated certificate was issued (December 23, 2026). To verify the authenticity of the information on this certificate, you may scan the QR code or visit https://access.gsa.gov/facv/searchCvmCertificate to view a copy of the certificate as issued by the FDA.</small>			

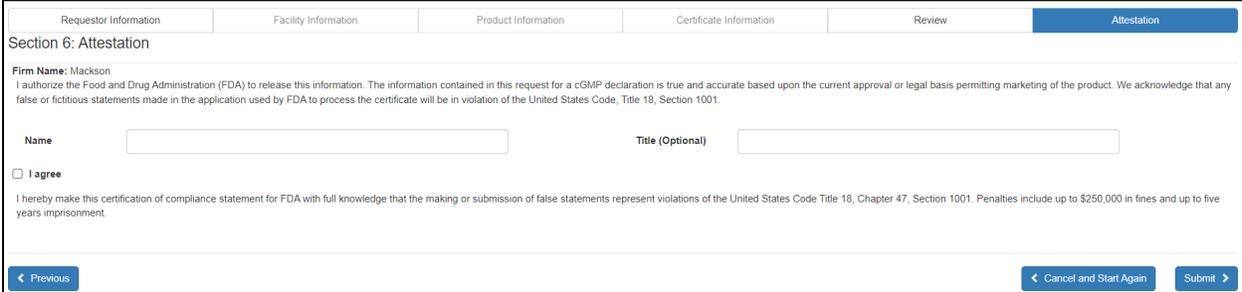
Step 11: CGMP Attestation

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

The system will display the **Attestation** section. Review the attestation information and warning. Enter your name and title; note that the title is optional.

Click the **I agree** button. Next, click the **Submit** button to submit your application (Figure 4.37).

Figure 4.37: Fill out CGMP Attestation Section



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

Section 6: Attestation

Firm Name: Mackson

I authorize the Food and Drug Administration (FDA) to release this information. The information contained in this request for a cGMP declaration is true and accurate based upon the current approval or legal basis permitting marketing of the product. We acknowledge that any false or fictitious statements made in the application used by FDA to process the certificate will be in violation of the United States Code, Title 18, Section 1001.

Name Title (Optional)

I agree

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.

[← Previous](#) [Cancel and Start Again](#) [Submit →](#)

Step 12: Submission Confirmation

After you submit the application, the system displays a confirmation message with your application number, which is required for any communications with FDA regarding the application (Figure 4.38). **Note:** The application number for CGMP applications have a different numbering convention (e.g., CGMP-YYYY-XXXXXX).

Figure 4.38: View Confirmation and Application Number



Confirmation Page

Your Application Number is CGMP-2024-000969

Please keep the Application Number for your records. The Application Number is required for communications with the FDA regarding this application.

[Exit →](#)

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

As part of the confirmation, the system will also send you an e-mail notification to inform you that FDA received your submission.

5 Saving and Editing an Application

You may save your application prior to submission when the application is in “Incomplete” status. 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 submit the application.

Step 1: Click the Save button.

On each page of the workflow, except for the **Attestation** page, you can save your application by clicking on the **Save and Exit** or **Save and Continue** buttons (Figure 5.1).

- **Save and Exit** – When you click on the **Save and Exit** button the first time, the system will save the information entered as “Incomplete”, and a draft application ID will be assigned. The system will exit the application process and an application ID will be displayed on the **Confirmation** page. When you log back into the CVM eCATS system, all applications in an “Incomplete” status will be displayed on the **Dashboard**.
- **Save & Continue** – When you click on the **Save and Continue** button the first time, the system will save the information entered as “Incomplete”, and a draft application ID will be assigned. The application ID will be displayed on the top of the next screen. You may continue with the application process without exiting, until you complete and submit the application.

You may also use the following navigation buttons at the bottom of each page (Figure 5.1):

- **Previous** – Navigates to the previous screen;
- **Cancel and Start Again** – The system will erase any entered information and allows you to start again from the **Requestor Information** screen;
- **Next** – Navigates to the next screen to continue entering application information.

Figure 5.1: Saving an Application



Step 2: Click the Edit Application button.

If you saved your application prior to submission, the system saves the application as “Incomplete”. You can view the incomplete application on the **Dashboard**. “Incomplete” means the application has not been submitted.

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

To edit your application, locate it on the **Dashboard**, and click the **Edit Application** (pencil) icon (Figure 5.2). You can then update and submit your application to FDA or save your application again for later edits.

Figure 5.2: 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

6 Viewing and Printing an Application

You can view and print your application from the **Dashboard** at any time.

To view your application from the **Dashboard**, you can click the **View Application** (“eye”) icon (Figure 6.1). The system displays the application in View (Read Only) mode.

Note: You cannot modify your application when you are in View mode.

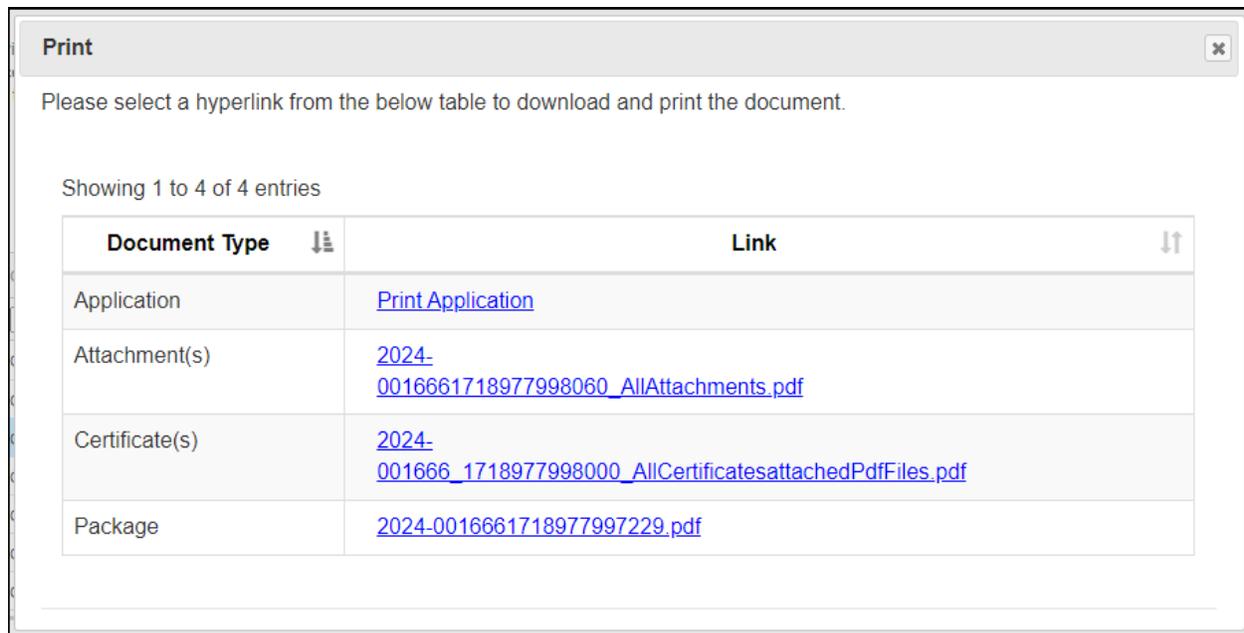
Figure 6.1: View an Application and Print

Actions	Application No	Certificate Type	Product Type
	<input type="text"/>	<input type="text"/>	<input type="text"/>
  	2024-001668	Certificate of Free Sale (CO...	Animal Food
  	2024-001667	Certificate of Free Sale (CO...	Animal Food
  	2024-001666	Certificate of Free Sale (CO...	Animal Food

To print your application from the **Dashboard**, you can click the **Print** (“printer”) icon (Figure 6.1). The system displays a “Print” pop-up window that allows you to download the following options in PDF format, and view and/or print through a secure network / locally attached printer – **Application**, **Certificates**, **Attachments**, and **Packages** (if available) (Figure 6.2).

Note: Only approved applications will display “Certificates”, “Attachments”, and “Package” options. Additional information regarding the print feature can be found in Section 10.

Figure 6.2: Print Pop-up



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.

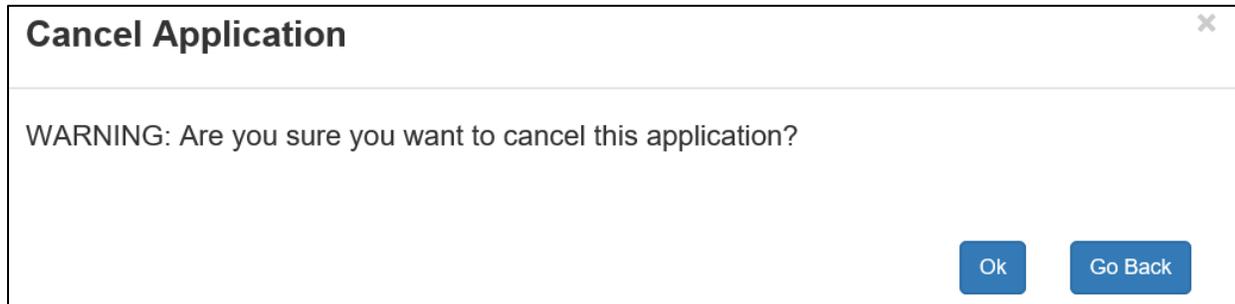
Locate the application you want to cancel from the Dashboard and click the red **Cancel Application** (“X”) icon (Figure 7.1).

Figure 7.1: Cancel an Application

Actions	Application No	Certificate Type	Product Type
   	TEST000145	Certificate of Free Sale (COF...	Approved Animal Drug
   	TEST000144	Certificate to Foreign Gover...	Type A Medicated Article

The system displays a “Cancel Application” confirmation message, prompting you to proceed. Click **OK** if you want to continue with the cancellation or, click **Go Back** if you do not wish to proceed (Figure 7.2).

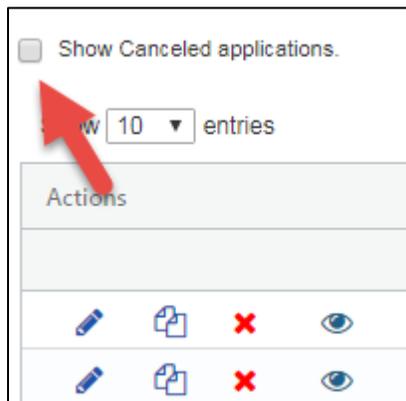
Figure 7.2: Acknowledge Cancel Warning



Step 2: View Canceled Applications.

By default, the system does not show your canceled applications. If you want to view the canceled applications on your **Dashboard**, click the “Show Canceled applications” checkbox (Figure 7.3).

Figure 7.3: 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.

Note: CGMP applications cannot be cloned. Please create a new application.

Step 1: Click the Clone button.

You can clone your application from the **Dashboard** by clicking the **Clone Application** (“copy document”) icon (Figure 8.1). All data from the existing application will be copied into the new application, except for the **Attestation** section. You can then edit the new application, fill in the attestation data, and submit it as a new application.

Note: In clone mode, you cannot change the “Certificate Type” or “Product Type” information.

Figure 8.1: Clone an Application

Actions	Application No	Certificate Type	Product Type
   	TEST000145	Certificate of Free Sale (COF...	Approved Animal Drug
   	TEST000144	Certificate to Foreign Gover...	Type A Medicated Article

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 scans on the uploaded documents.

Step 2: View Clone Source in View Application.

After you submit a cloned application, you can see the source application from which this application was cloned (Figure 8.2). The system displays this information when you open the application in View mode, with values in the “Cloned From” and “Clone Date”.

Figure 8.2: 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	04/08/2020	Cloned From	Test000145
Cloned Date			

9 Responding to Return for Action

The FDA Reviewer may return the application to you for modification. **Note:** This is not applicable for CGMP applications.

Step 1: Review the e-mail notification.

If your application is incomplete, the system sends you an e-mail 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 the application that has the status of “Returned for Action” on the **Dashboard**. Click the **Modify Application** (“pencil”) icon (Figure 9.1).

Figure 9.1: Modify Application

Actions	Application No	Certificate Type	Product Type	Manufacturer Name
  	2021-000417	Certificate to Foreign Governmen...	Animal Food	Meridian Chemical And Equip
   	MACK000285	Certificate of a Pharmaceutical Pr...	Approved Animal Drug	Arrow International Inc, Invacare Corp

Step 3: Make the requested change and submit.

Make the required change(s) described in your e-mail 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” 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.

If your application was “Approved”, “Return for Action”, or “Rejected”, an FDA Reviewer can re-review your application and change the status accordingly.

10 Printing or Obtaining the Certificate

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

1. Log into FURLS and access the CVM eCATS module.
2. On the **Dashboard**, locate the approved application. You can sort the listing of the **Dashboard** in ascending order on the “Status” column. It can display applications with an “Approved” status to be on top of the listing.
3. Click on the **Print** icon next to the application you want to print the certificate for (Figure 10.1).

Figure 10.1: Print Certificate

Actions	Application No	Certificate Type	Product Type	Manufacturer Name
  	2021-000417	Certificate to Foreign Governmen...	Animal Food	Meridian Chemical And Equip
   	MACK000285	Certificate of a Pharmaceutical Pr...	Approved Animal Drug	Arrow International Inc, Invacare Corp

4. The “Print” pop-up window is displayed with hyperlinks for the generated certificate, application, attachment(s), and package PDF(s).

- The attachment PDF includes all label and supplemental attachments that have been selected to be displayed with the certificate.
 - The package PDF includes certificates and attachments.
5. Select the hyperlink to open/download the PDF to print. You can print it on your secure network or locally attached printer.
 6. Click the “Return to Dashboard” button to close the window and return to the Home dashboard.

You can print your application from the **Dashboard** at any time. Whereas you can print certificates, attachments, and/or package only when an application is “Approved”.

If your application is re-reviewed and the status of the application is changed from “Approved” to “Rejected” or “Return for Action”, you will no longer have access to the certificates.

11 Obtaining and Responding to Notifications

The system provides automated notifications to your e-mail address whenever:

- You save an application to draft prior to submittal;
- You submit your application;
- You cancel your application;
- You modify and resubmit your application based on a Return for Action request from FDA;
- Your application is approved by FDA;
- Your application is canceled by FDA;
- Your application is rejected by FDA;
- Your application is canceled because it has been in “Incomplete” status for more than 30 days;
- Your application is canceled because it has been in “Return for Action” status for more than three business days.

12 Validating the Authenticity of CVM-Issued Export Certificate

Certificates and export permit letters may be validated by foreign governments and others using the FDA’s FURLS Export Certificate Validator (FECV) database for the period they are in effect. The FECV can be accessed using the URL address or QR code displayed at the bottom of each certificate issued.

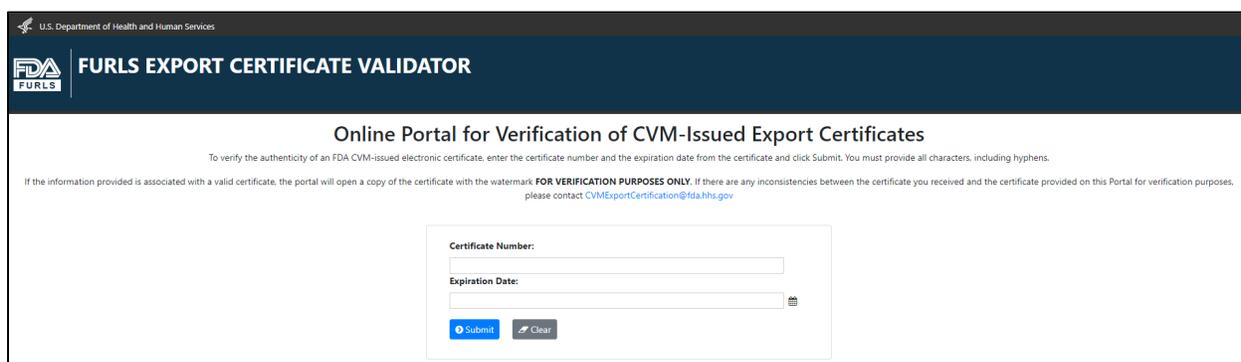
There are two ways to access this online portal:

- Visit [FDA’s Online Portal for Verification of CVM-Issued Export Certificates](#). The URL address is also included in the footer of each electronic certificate issued.
- Scan the QR code included at the bottom of each electronic certificate issued. Each document has a unique QR code based on the document number.

Online Portal

If accessing the online portal, the foreign governments and others must have the Certificate Number and Expiration Date of the certificate for verification. Enter the information and click the **Submit** button (Figure 12.1).

Figure 12.1: Online Portal for Verification of CVM-Issued Export Certificates using URL



U.S. Department of Health and Human Services

FURLS EXPORT CERTIFICATE VALIDATOR

Online Portal for Verification of CVM-Issued Export Certificates

To verify the authenticity of an FDA CVM-issued electronic certificate, enter the certificate number and the expiration date from the certificate and click Submit. You must provide all characters, including hyphens.

If the information provided is associated with a valid certificate, the portal will open a copy of the certificate with the watermark **FOR VERIFICATION PURPOSES ONLY**. If there are any inconsistencies between the certificate you received and the certificate provided on this Portal for verification purposes, please contact CVMExportCertification@fda.hhs.gov

Certificate Number:

Expiration Date:

QR Code

Use a QR Reader to scan the QR Code displayed on FDA’s issued electronic certificates. The QR Codes are displayed at the bottom of the certificates (Figure 12.2 and Figure 12.3).

Figure 12.2: QR Code on CGMP, CFG, COFS, or COE Electronic Certificates

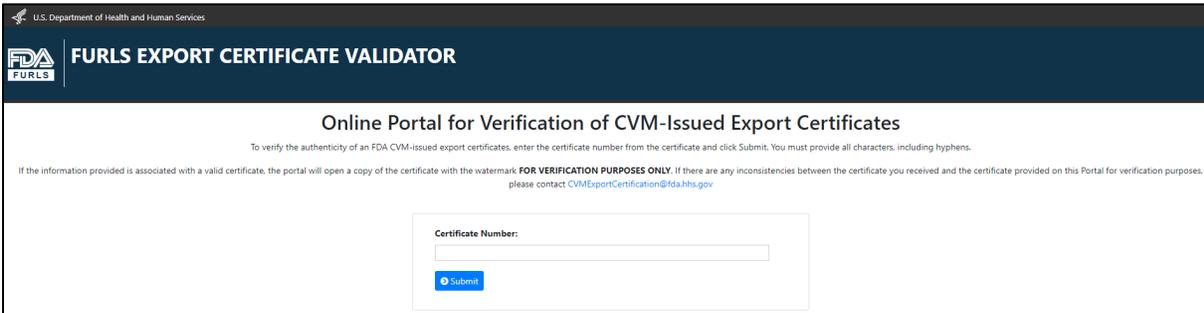
<p>NAME, TITLE Neal Bataller, ME, DVM, Director, Division of Drug Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine</p>	<p>DATE ISSUED October 19, 2023</p>		
<p>Signature: </p>			

Figure 12.3: QR Code on CPP Electronic Certificate



The FGO will enter the Certificate Number and click the **Submit** button (Figure 12.4)

Figure 12.4: Online Portal for Verification of CVM-Issued Export Certificates using QR Code



If a certificate is not found (i.e., the certificate expired or is no longer valid), an error message will be displayed: “No certificates found matching the search criteria. This could be due to an error in the entered criteria, the certificate has expired, or the status of the application was changed.”

Note: If your application was initially “Approved”, an FDA Reviewer can re-review your application and change the status to “Return for Action” or “Rejected” – which may revoke your access to the certificate.

If the provided information is correct, a PDF will be generated (Figure 12.5, Figure 12.6, or Figure 12.7). The certificate will display a “For Verification Purposes Only” watermark.

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

Figure 12.5: Certificate Authentication for CFG, COFS, or COE Electronic Certificates

CERTIFICATE TO FOREIGN GOVERNMENT (CFG) FOR ANIMAL FOOD

CERTIFICATE NUMBER	EXPORTING COUNTRY United States of America	IMPORTING COUNTRY Azerbaijan	EXPIRATION DATE January 17, 2026
<p>In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the animal food to be exported listed below:</p>			
FACILITY INFORMATION			
Manufacturer Name/Address		FEI Number	
PRODUCT INFORMATION			
Product Trade Name	Product Proper Name	NADA/ANADA/CNADA	
		ANADA:	
ADDITIONAL INFORMATION			
ATTESTATION			
<p>FDA certifies that the above product may be marketed in, and legally exported from, the United States at this time. The product described above and the facility which produces it are subject to the jurisdiction of the FDA. The manufacturing facility which produces the product is subject to periodic inspections. The last inspection showed that the facility, at that time, appeared to be in substantial compliance with the Current Good Manufacturing Practice requirements for the product listed above.</p>			
NAME, TITLE Isaac K. Carney, Director, Division of Food Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, United States Food and Drug Administration Signature:		DATE ISSUED January 17, 2024	

This certificate expires 24 months from the date issued. To verify the authenticity of the information on this certificate, you may scan the QR code or visit <https://access-aws.test.fda.gov/fevw/searchCvmCertificate> to view a copy of the certificate as issued by the FDA.

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Figure 12.6: Certificate Authentication for CPP Certificates

U.S. Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, USA			
CERTIFICATE OF A PHARMACEUTICAL PRODUCT (CPP): Approved Animal Drug			
CERTIFICATE NUMBER	EXPORTING COUNTRY	IMPORTING COUNTRY	EXPIRATION DATE
	United States of America	Aruba	January 22, 2026
1.1 Drug trade name, international or national non-proprietary name (as applicable) & dosage form:			
1.2 Active ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): 1			
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 the sale, distribution or administration of the product specified in the marketing authorization? No			
1.4 Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? Yes			
2.A.1 Number of marketing authorization & date of issuance:			
2.A.2 Marketing authorization holder (name and address):			
2.A.3 Status of marketing authorization holder: Manufacturer			
2.A.4 Is a summary basis for approval appended? Yes		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):			
2.A.7 Web-link to the product marketing authorization information (if available): Green Book			
Remarks: This is going to be under 500 characters! OK?			
3.1 Manufacturer name & Address & FEI number: Bimbo Bakeries, FEI Number:			
3.2 Does the certifying authority arrange for periodic inspections of the manufacturing plant in which the dosage form is produced? Yes			
3.3 Periodicity of routine inspections (years): Inspection frequency is risk-based. Inspections of FDA-registered animal drug manufacturers generally occur every 2-3 years, and FDA seeks to inspect all registered animal drug manufacturers: once every 5 years.			
3.4 Has the manufacturer of this type dosage form been inspected? Yes			
3.5 Do the facilities and operations conform to GMPs as recommended by the World Health Organization? Yes, at time of the most recent inspection, the site was in substantial compliance with FDA CGMP requirements.			
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? Yes			
NAME, TITLE	Neal Batalar, ME, DVM, Director, Division of Drug Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine		DATE ISSUED
			January 22, 2024
 			
<small>This certificate expires 24 months from the date issued. To verify the authenticity of the information on this certificate, you may scan the QR code or visit https://access-ews.test.fda.gov/ewsearch/CvmCertificate to view a copy of the certificate as issued by the FDA. This certificate conforms to the format recommended by the World Health Organization format revised March 25, 2021. Website: www.who.int</small>			

Figure 12.7: Certificate Authentication for CGMP Electronic Certificates

CURRENT GOOD MANUFACTURING PRACTICE CERTIFICATE (CGMP) FOR ANIMAL FOOD

CERTIFICATE NUMBER	ASSOCIATED CERTIFICATE NUMBER	IMPORTING COUNTRY	EXPIRY DATE
H7TB-G8RY	SXCE-RU23	Kingman Reef	December 23, 2026
PRODUCT NAME			
Trade Name: Product Trade Name entry ; Proper Name: Product Proper Name entry			
Trade Name: Product Trade Name entry Also ; Proper Name: Product Proper Name entry Also			
Trade Name: Product Trade Name entry Too ; Proper Name: Product Proper Name entry Too			
ATTESTATION			
<p>I declare as follows: The United States Food and Drug Administration (FDA) certifies that the above manufacturing facility is subject to the jurisdiction of the FDA, and subject to periodic inspections. The last inspection showed that the facility, at the time the inspection occurred, was in substantial compliance with the Current Good Manufacturing Practice requirement(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations for the animal food identified above and referenced in the associated electronic certificate whose number is listed above. Based on this inspection and all other available information, FDA certifies the product(s) listed above is made in compliance with all applicable CGMP requirements of the FD&C Act, including FDA's implementing regulations.</p> <p>This document is not a substitute for a Certificate to Foreign Government that attests to the legality and exportability of a specific animal food. In issuing this document, FDA did not review whether the animal food above meets the FD&C Act's labeling requirements or the requirements applicable to food additives.</p>			
FACILITY INFORMATION			
FEI Number	Manufacturer Name	Address	
3014892542	Testing Domestic One	One Here, Washington, District of Columbia 20001 United States	
NAME, TITLE	DATE ISSUED		
Isaac K. Carney, Director, Division of Food Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, United States Food and Drug Administration	December 23, 2024		
Signature: 			

This certificate expires 24 months from the date the associated certificate was issued [December 23, 2026]. To verify the authenticity of the information on this certificate, you may scan the QR code or visit <https://access-aws-test.fda.gov/efcv/search/CvmCertificate> to view a copy of the certificate as issued by the FDA.

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