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

Table of Contents

Table of Figures

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.

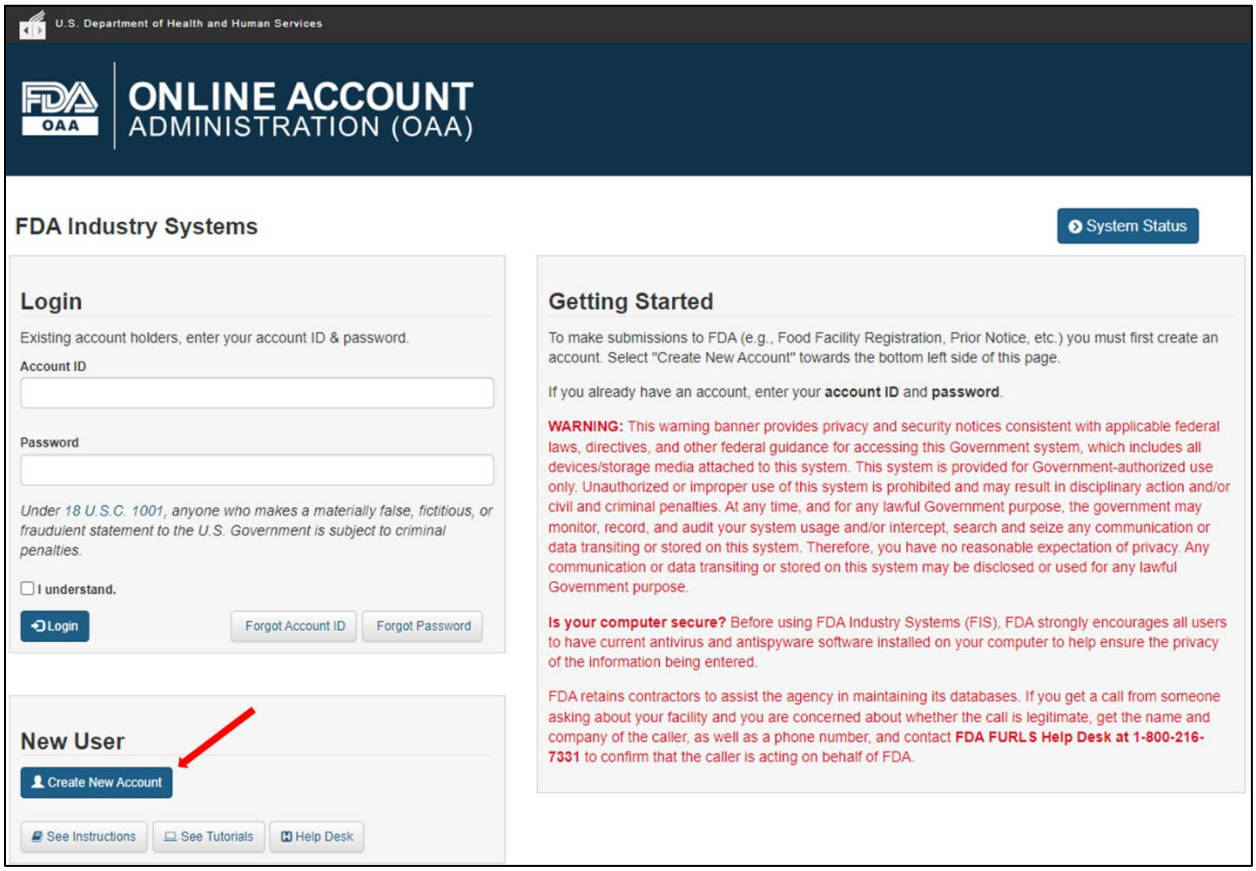
3 Applying for Login Credentials using FIS

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).

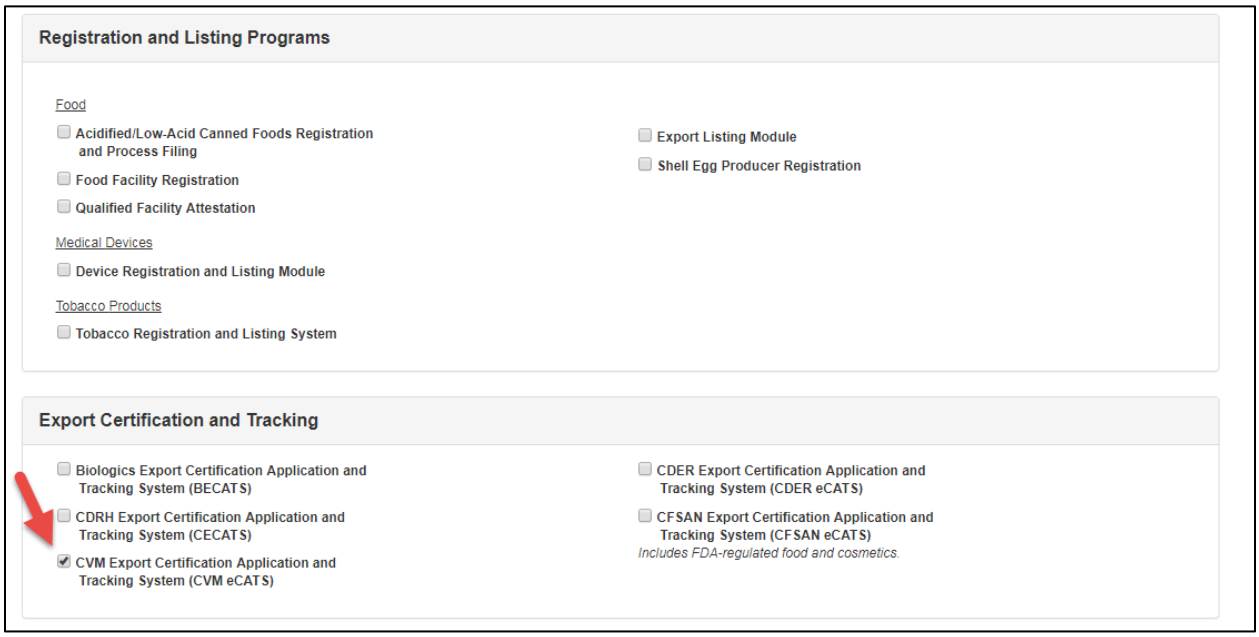
Figure 3.1: Create New Account in FDA FIS Electronic Portal



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

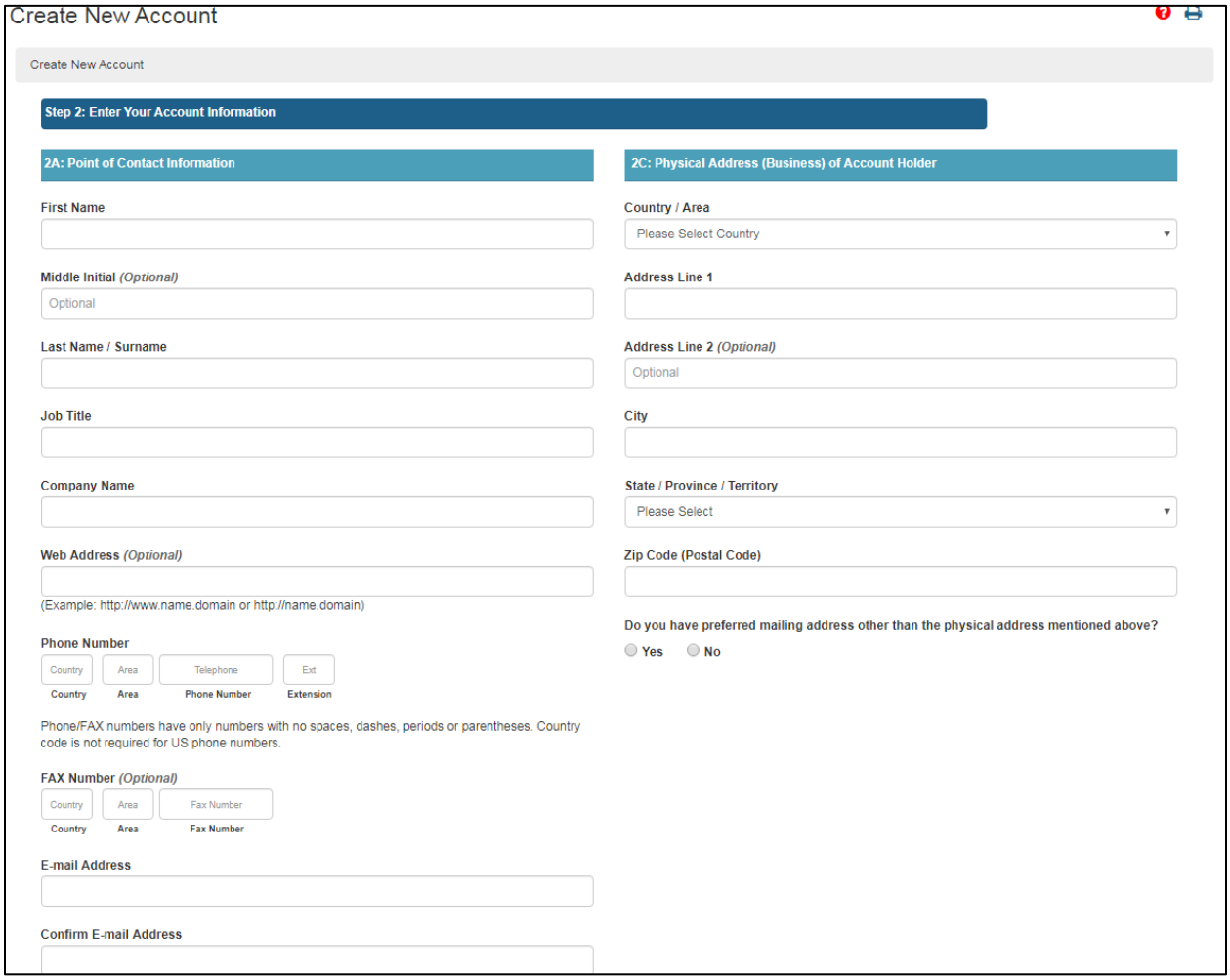


Step 3: Fill out your contact information.

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.

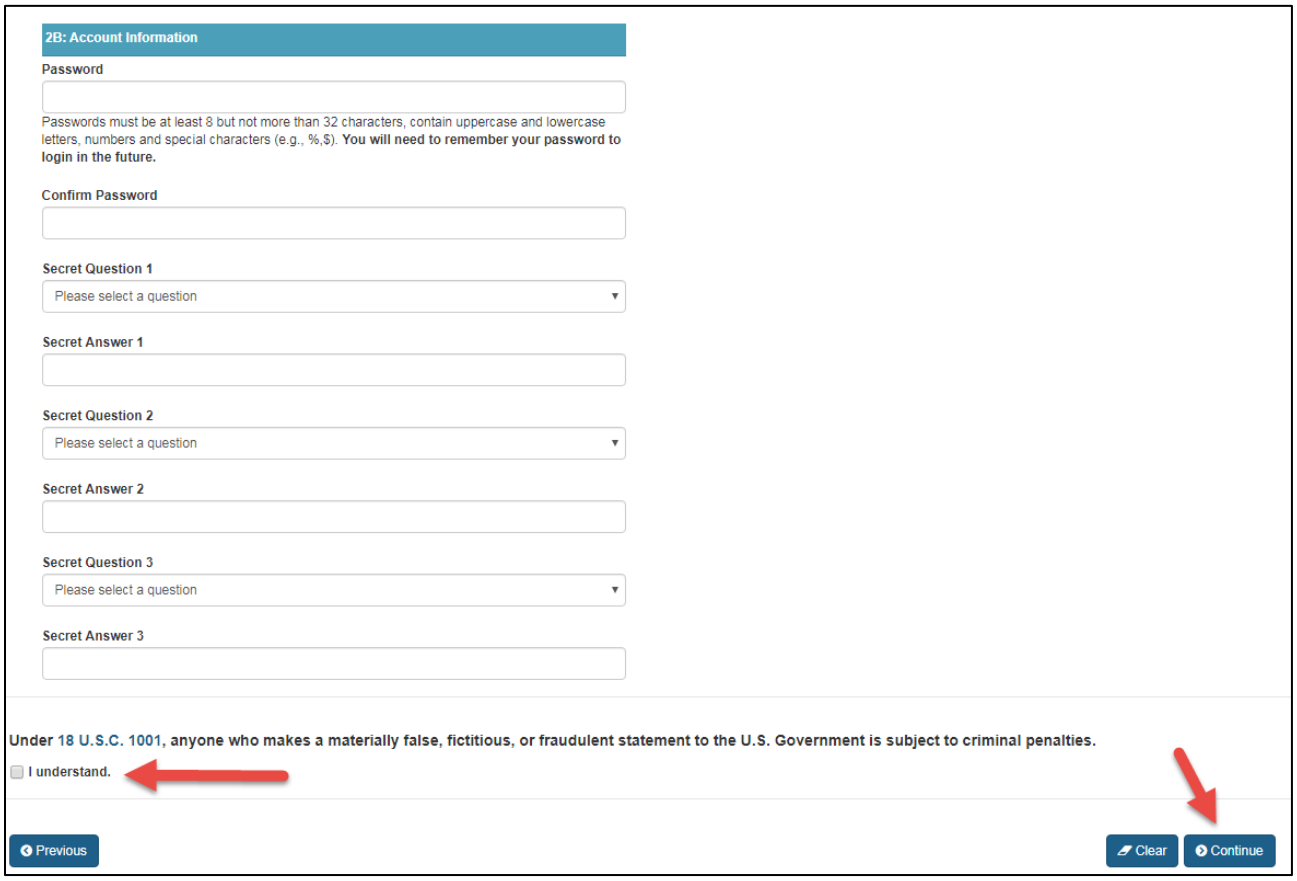
Figure 3.3: Fill out Contact Information in FIS Electronic Portal



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



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.

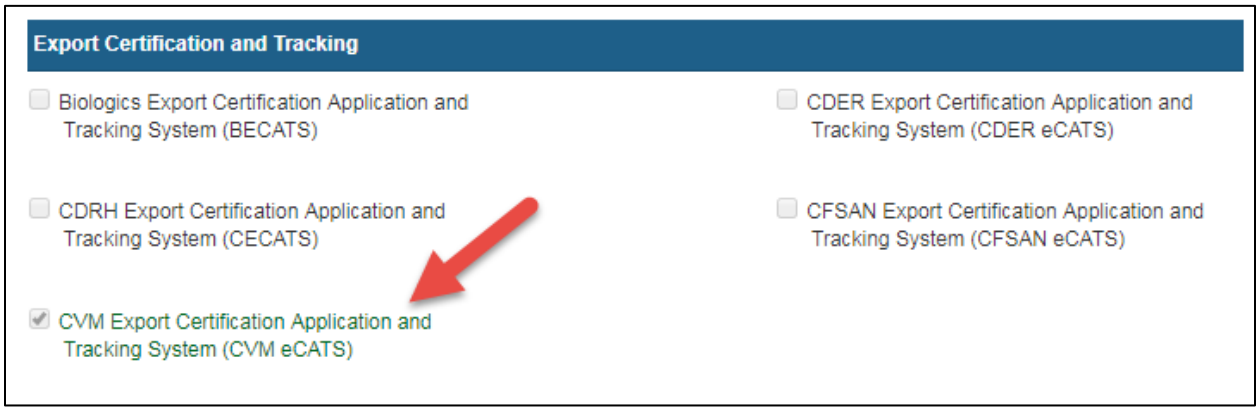
4 Submitting an Application for a Certificate

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

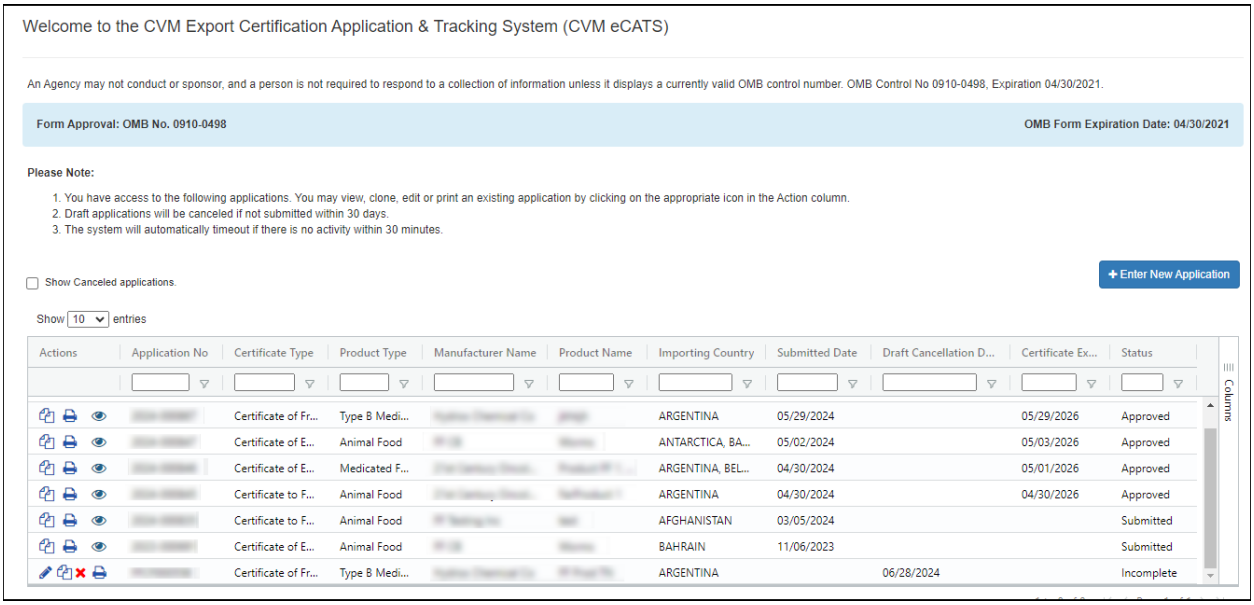


Step 2: Review the Dashboard contents.

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).

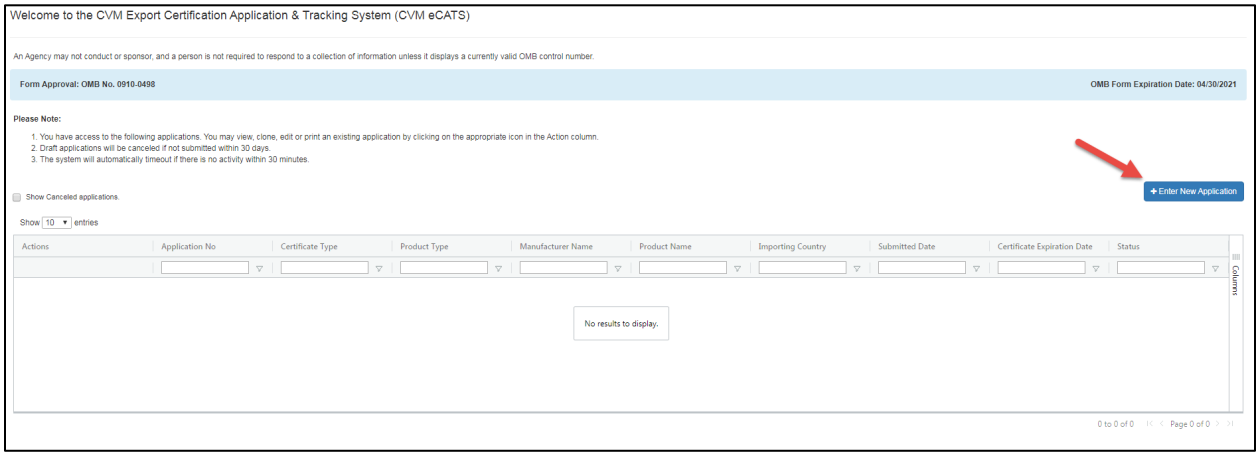
Figure 4.2: Accessing the CVM eCATS User Dashboard



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



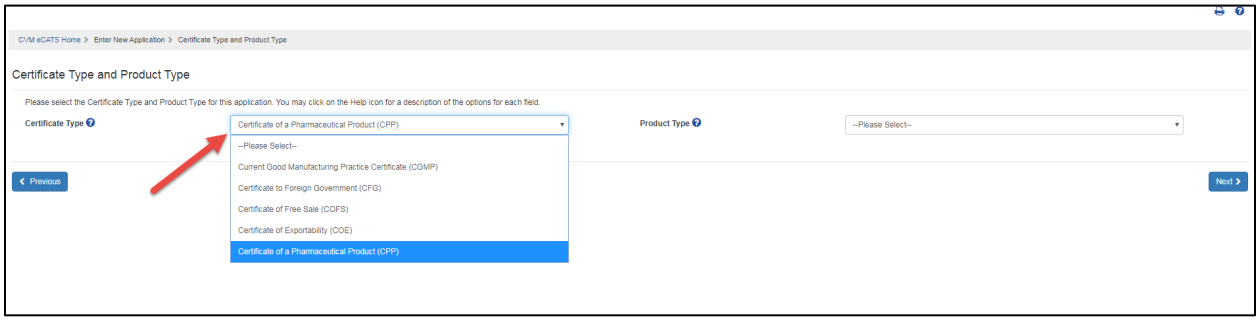
Step 4: Select the Certificate Type.

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

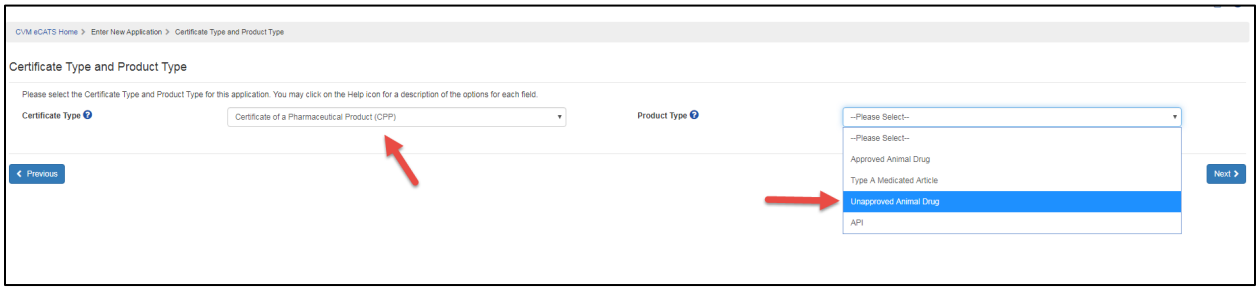
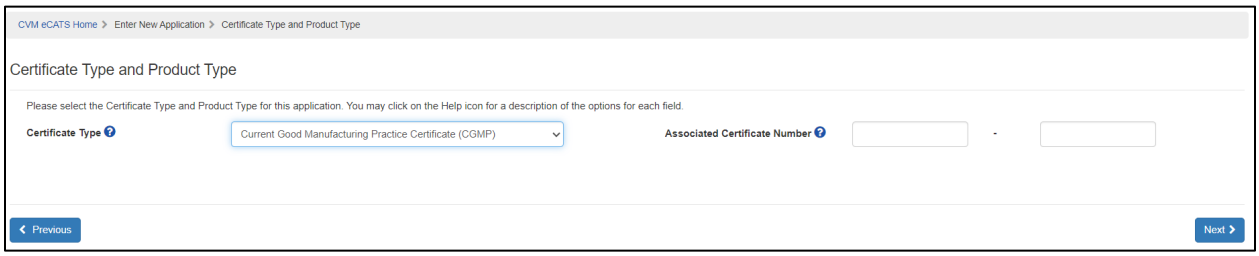


Figure 4.6: Enter Associated Certificate Number



Step 6: Enter Requestor Information.

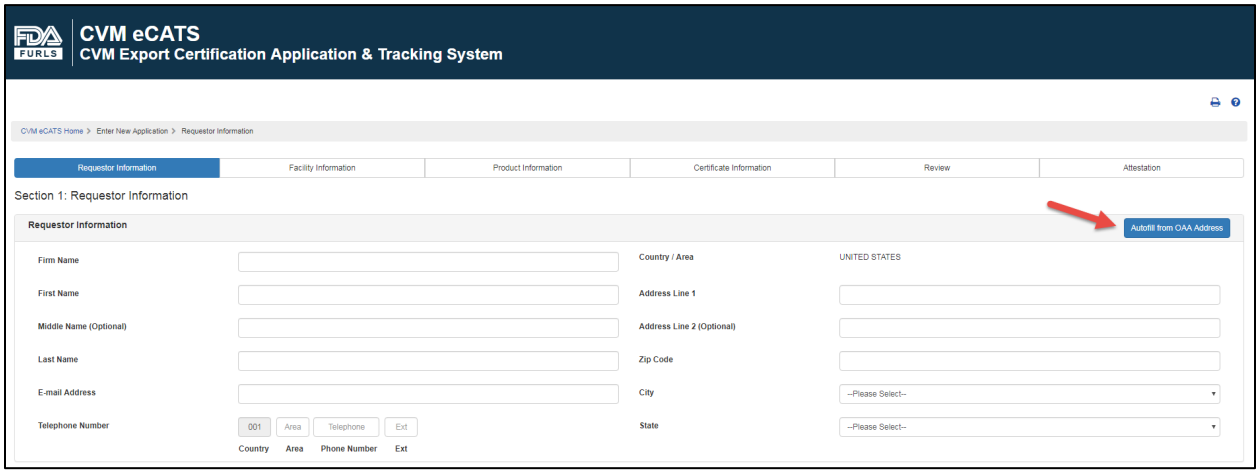
The system displays the ***Requestor Information*** section. Enter the following:

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).

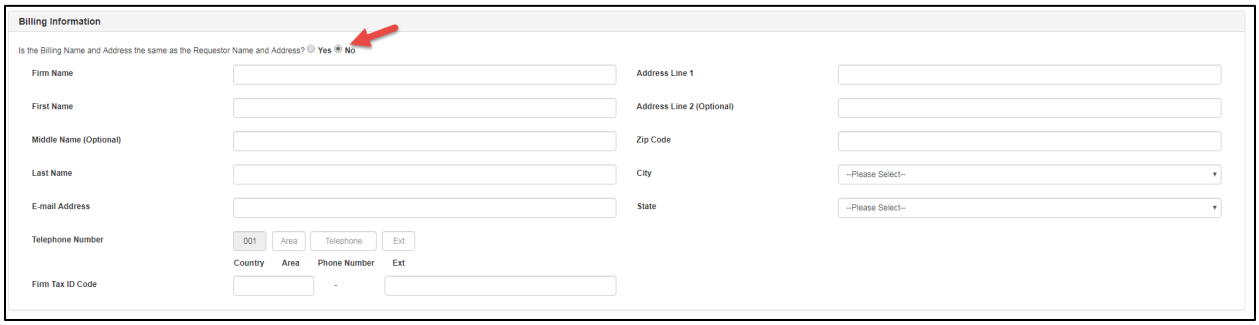
Note:

- 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



Step 8: Review the Address Validation.

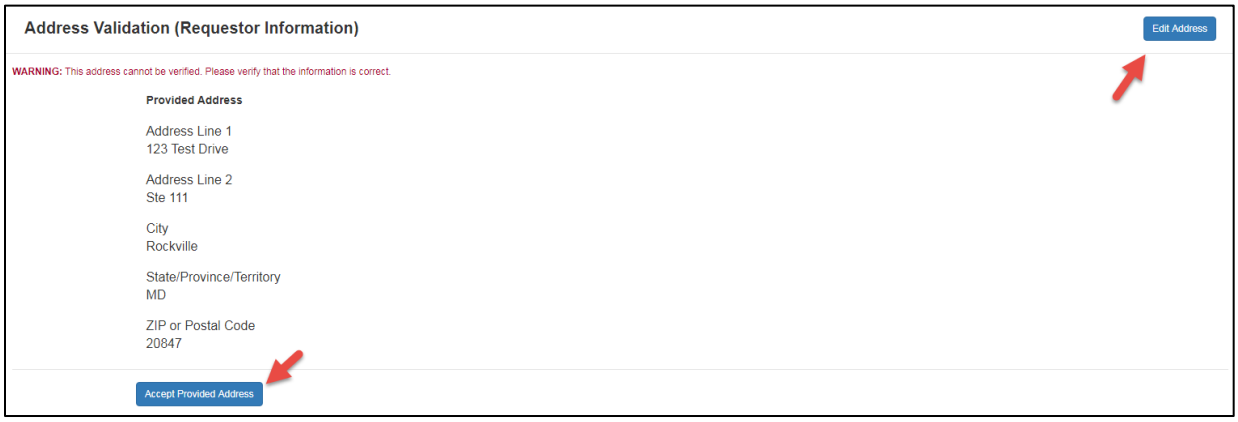
When you have completed the **Requestor and Billing Information** fields, click **Next**. The system validates the addresses you provided against the standard USPS addresses. If the addresses are invalid, the system displays an error message. Otherwise, the system asks you to accept your provided Requestor's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



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.

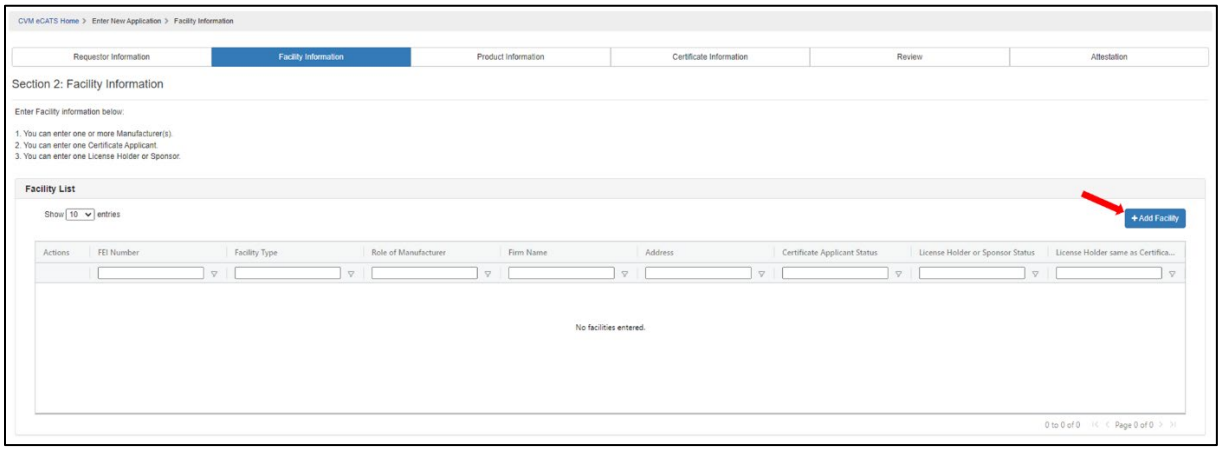
After the address validation is complete, the system displays the ***Facility Information*** section. Next:

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.

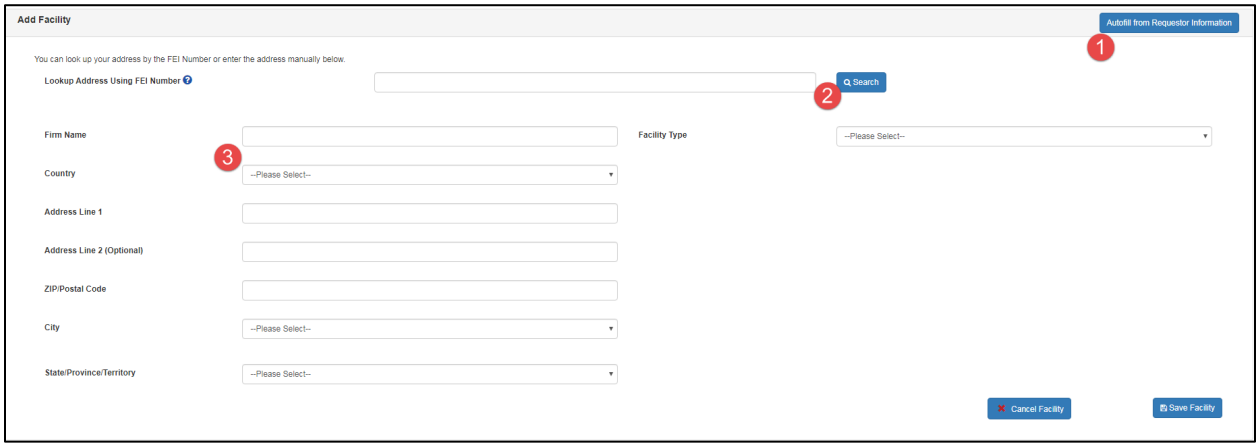
- Distributors do not require an FEI Number association.
- You can also use FDA's FEI Search Portal website to locate the FEI number for the address you intend to use.

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.



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

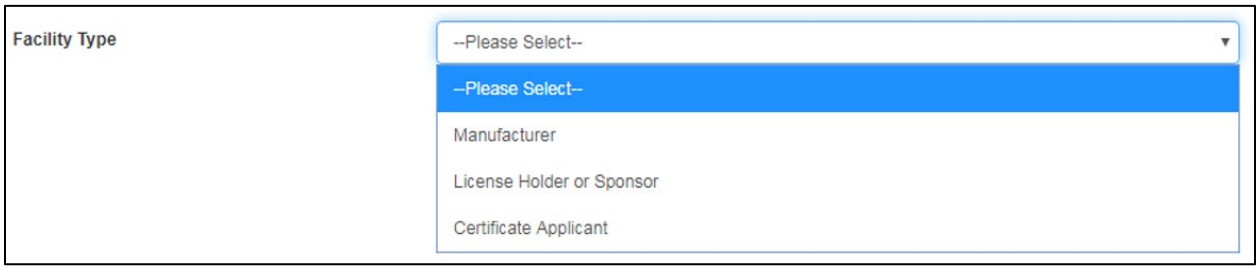


Table 2 – Facility Limitations Number Requirements for Manufacturer

Certificate Type	Facility Type Options	Number allowed	Required/ Optional	Exceptions / Notes
CFG	Manufacturer Distributer	**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 Distributer	**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

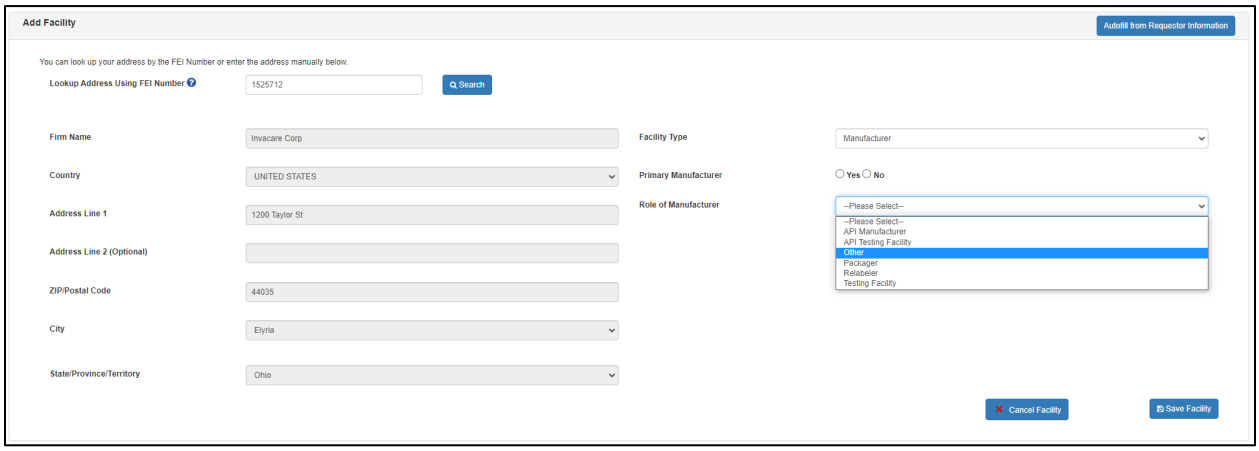
Step 12: CPP-Only – Select the Primary Manufacturer and Role of Manufacturer.

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



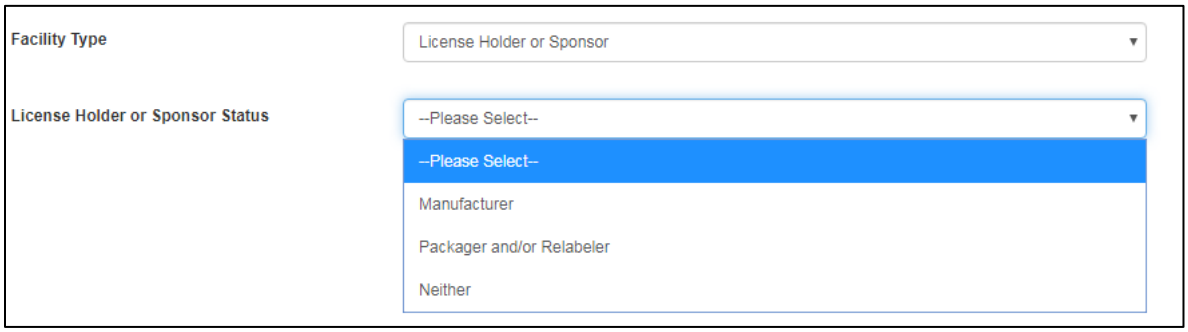
Step 13: CPP-Only – Answer Certificate Applicant address question and select status.

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

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



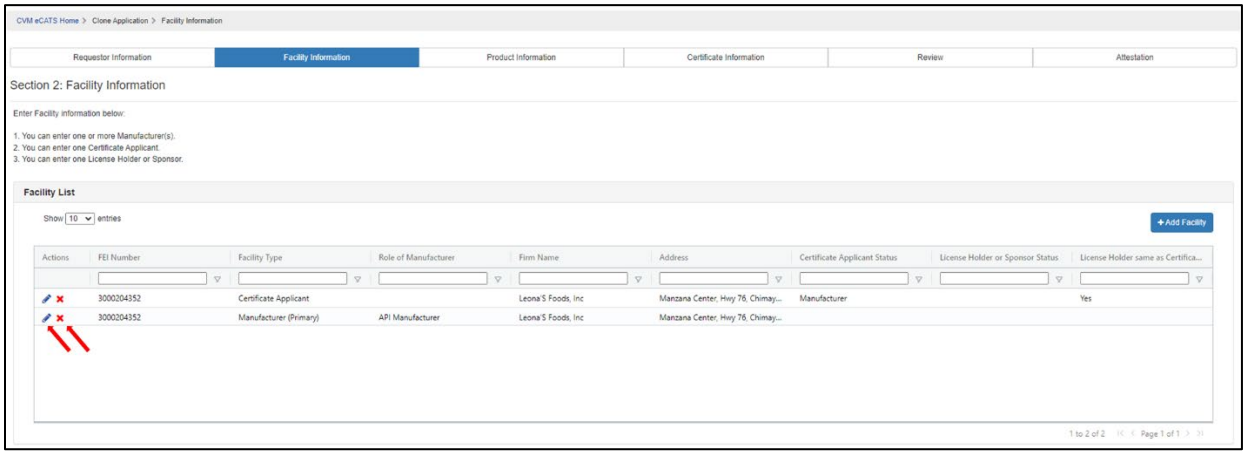
Step 14: Save a Facility.

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



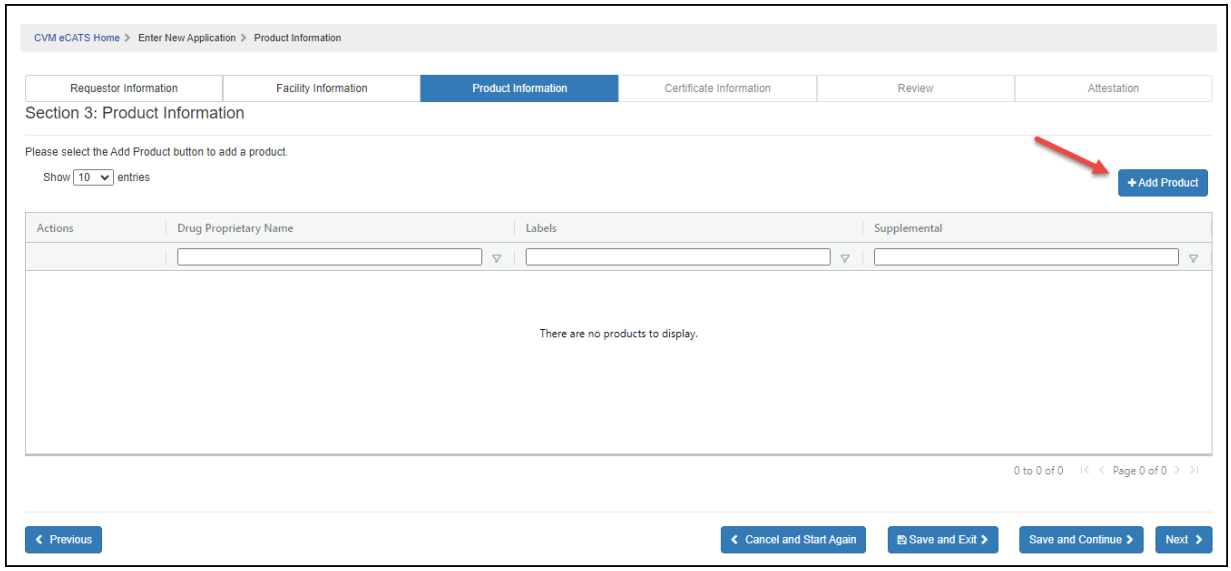
Step 15: Enter Product Information.

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.

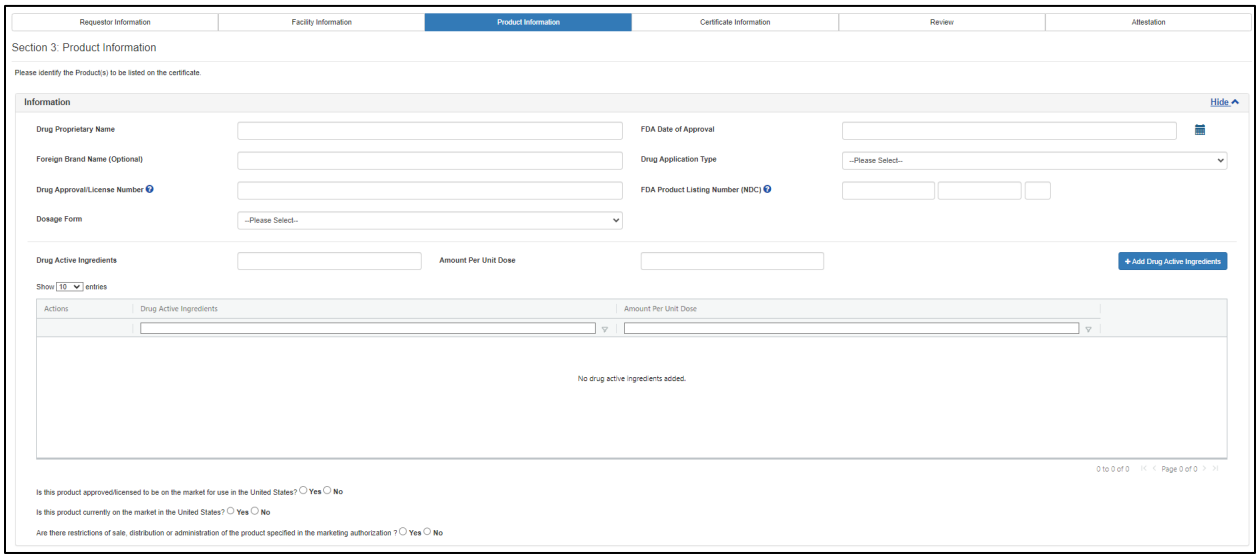
Click the **Add Product** button (Figure 4.18). Please note the product number limitations described in the table below.

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:

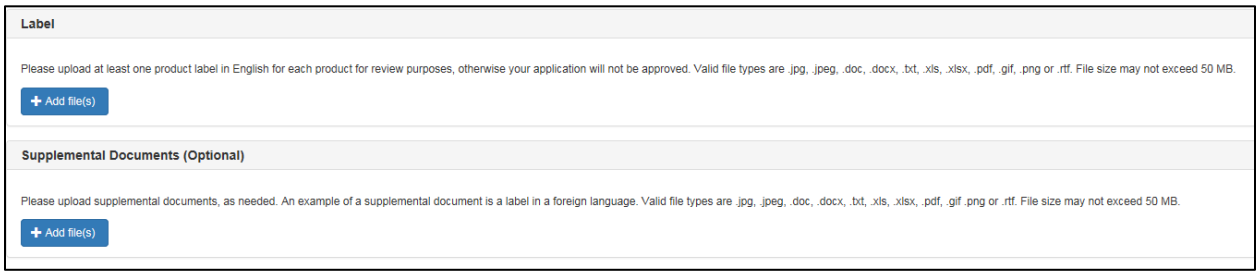
- For “Approved Animal Drug” and “Type A Medicated Product”, the first and the second question (above) requires a **Yes** answer.
- For “Unapproved Animal Drug and API”, the first question (above) requires a **No** answer.
- For “Unapproved Animal Drug”, the second question (above) requires a **No**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



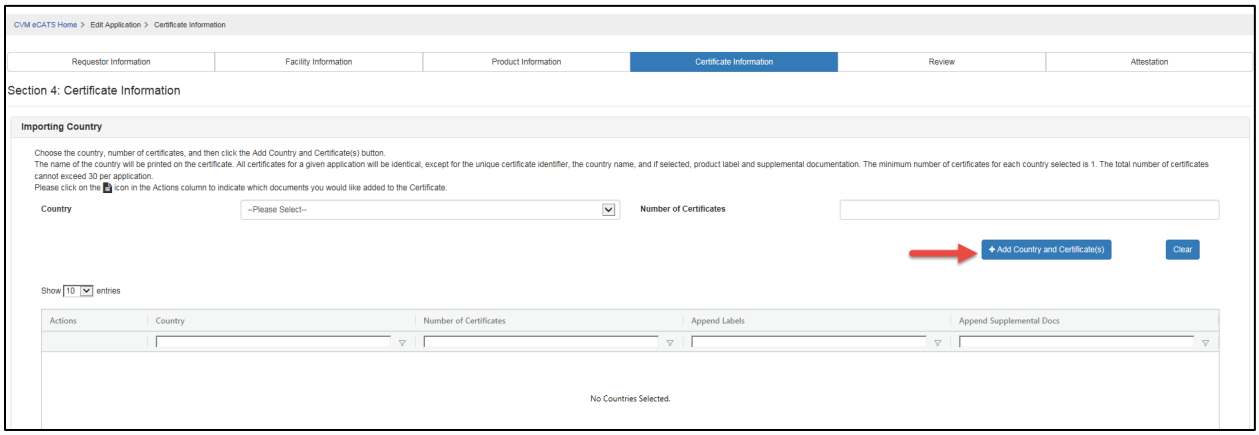
Step 18: Enter Certificate Information.

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.

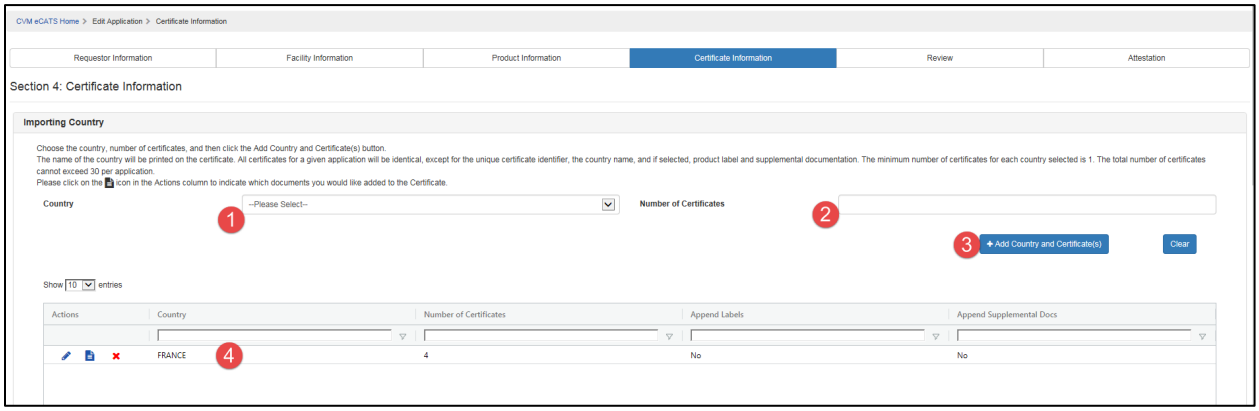
Enter the number of certificates in the “Number of Certificates” field.

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.

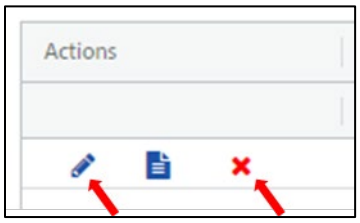
Figure 4.22: Add a Country and Certificates



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.

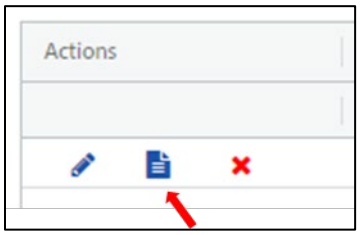
Figure 4.23: Edit and Delete Country and Certificates



Step 21: Associate labels and supplemental documents to certificates.

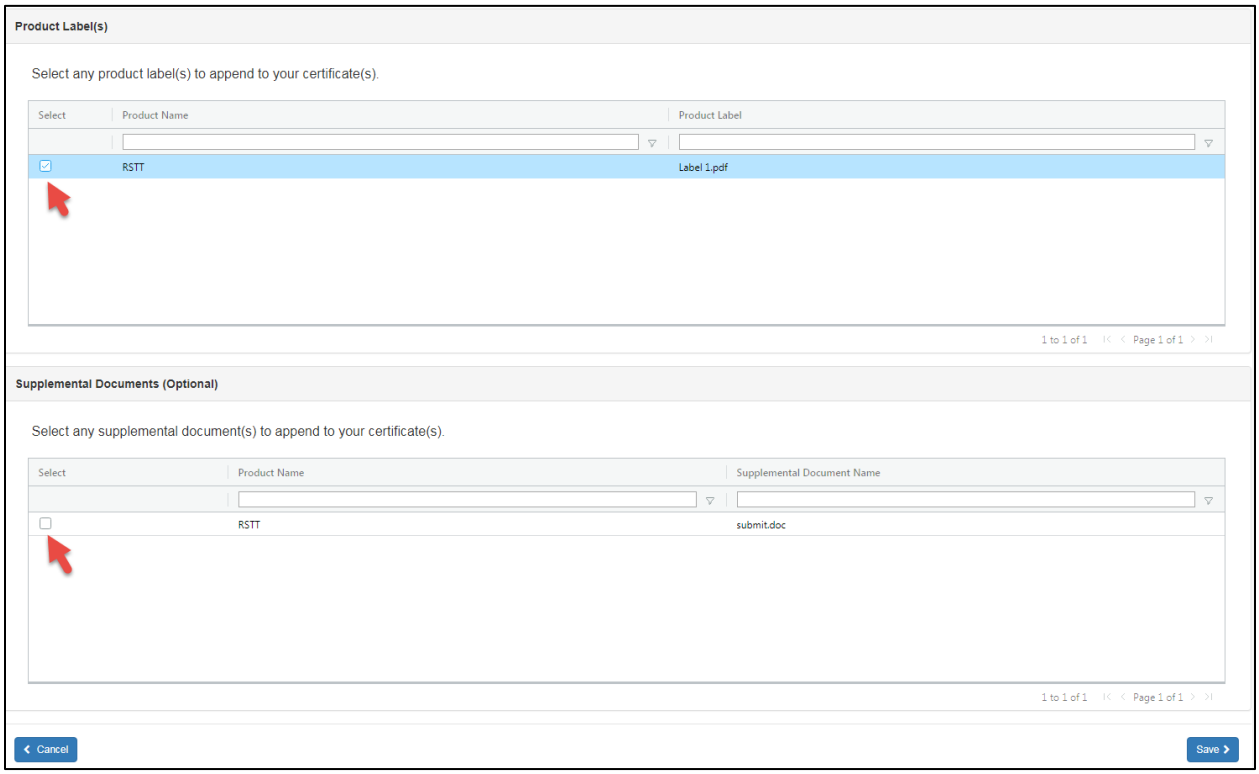
You can associate the labels and supplemental documents to your certificates by clicking on the **Document** (paper) icon (Figure 4.24).

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.

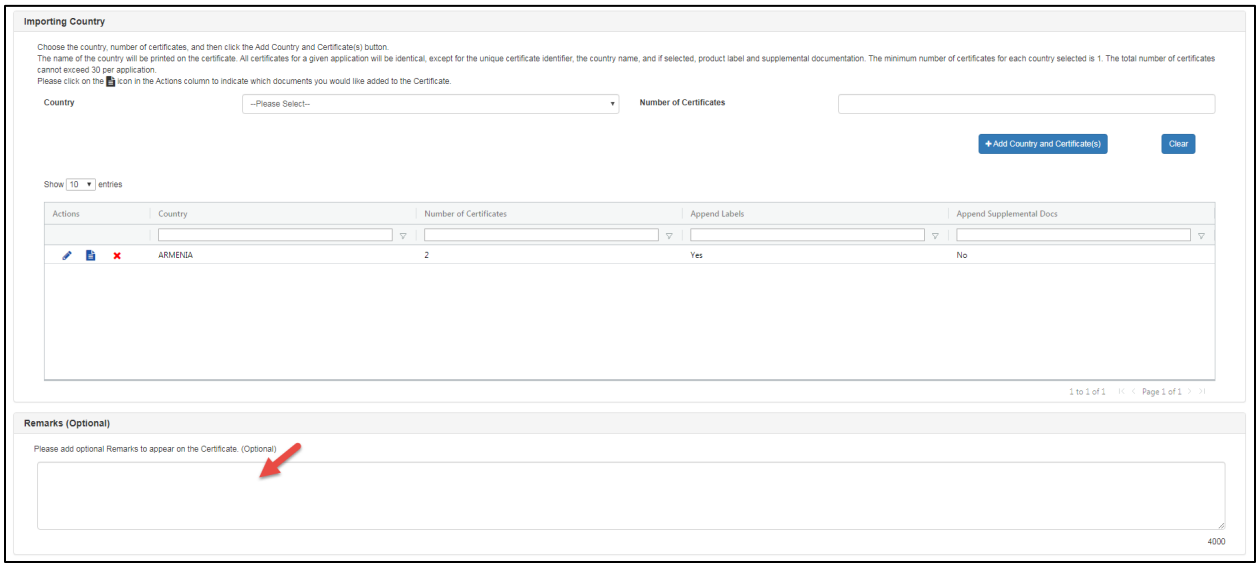
Figure 4.25: Associate Labels and Documents to Certificates



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.

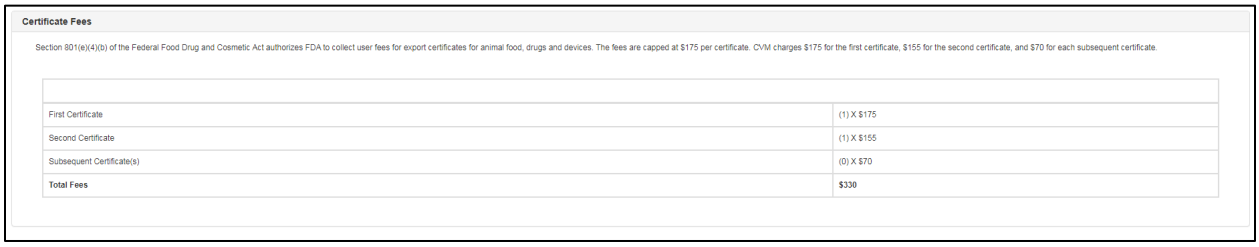
Figure 4.26: Add Optional Remarks to Certificate



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

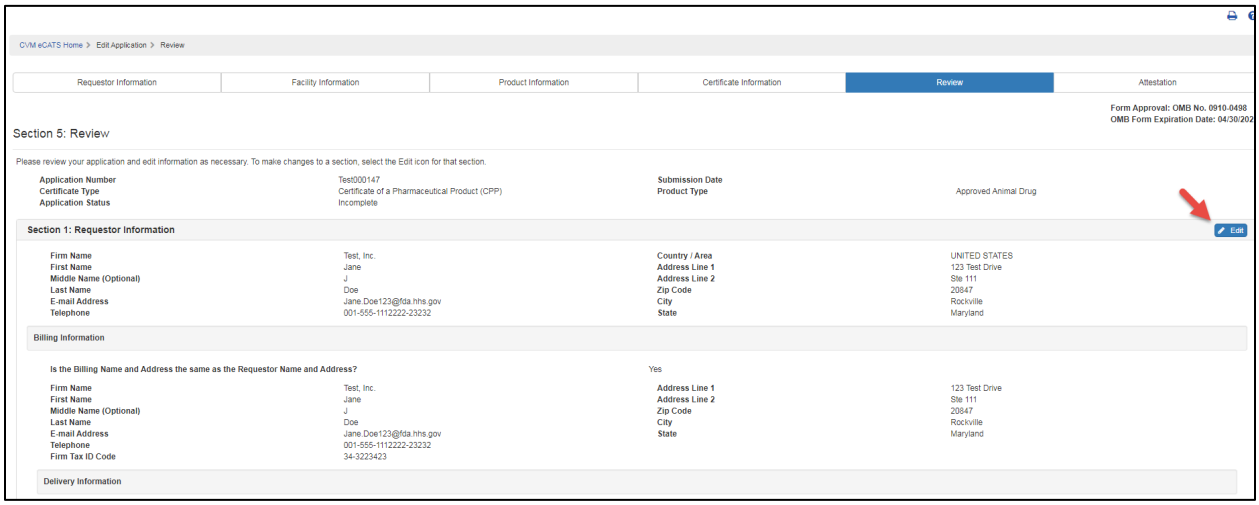


Click **Next** when you finish viewing the Certificate Fees information.

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



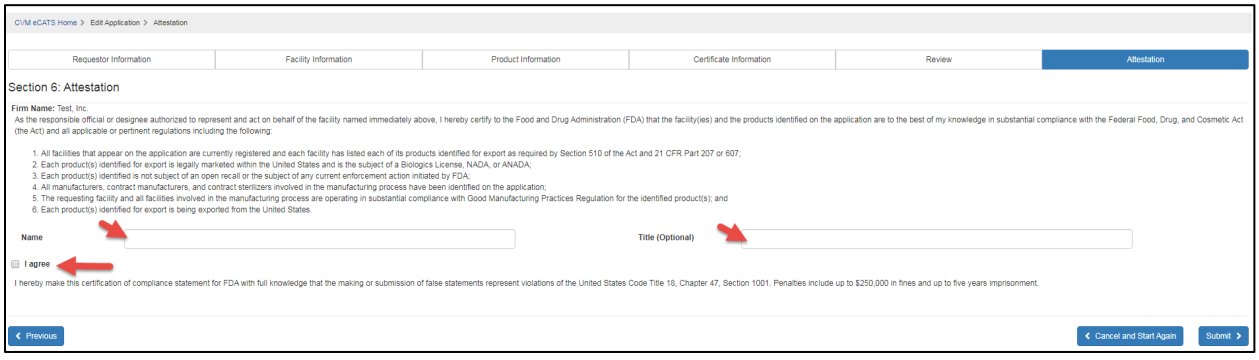
Step 25: Attestation

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).

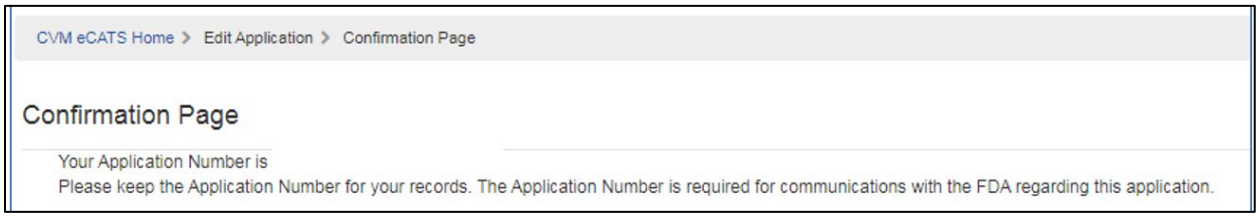
Figure 4.29: Fill out Attestation Section



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.

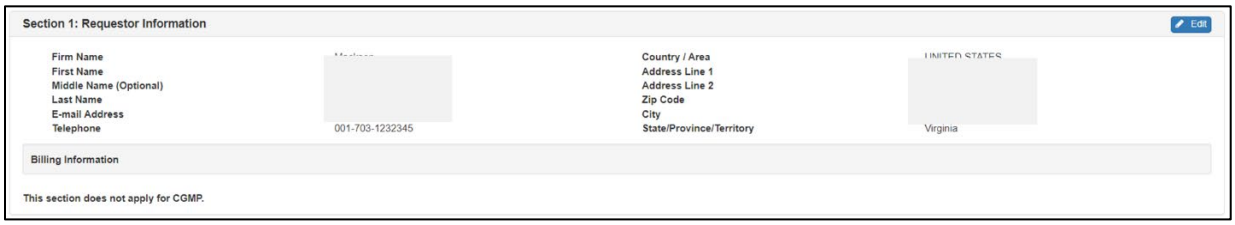
After address validation, the system displays the ***Review*** page. Review the information in each section:

- 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

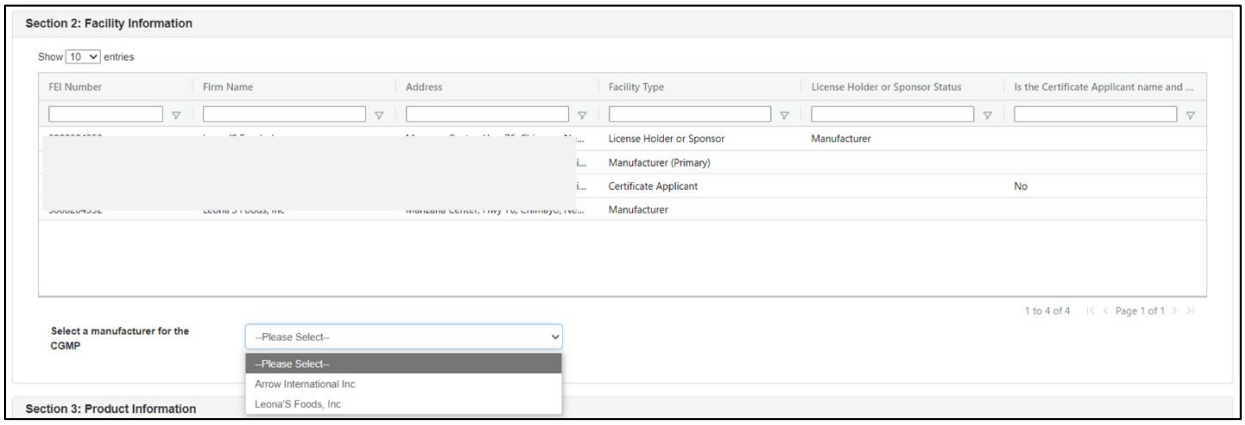
- Section 1 – Displays the Requestor Information entered (Figure 4.32)

Figure 4.32: CGMP Requestor Information



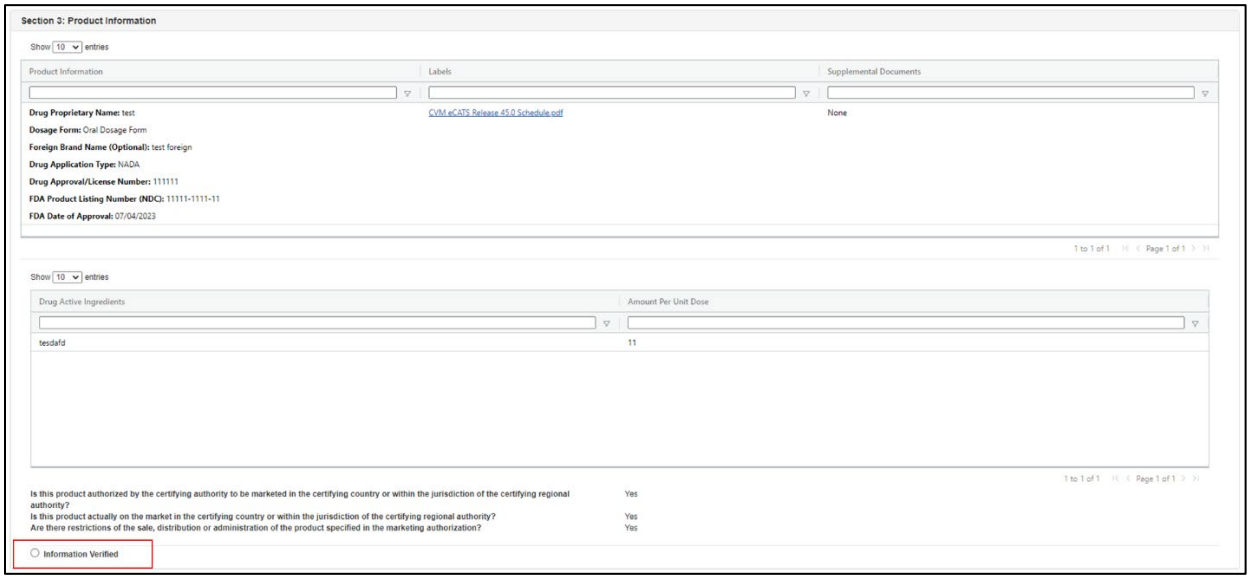
- Section 2 – Displays the Facility Information from the associated certificate. You must select a value for the “Select the manufacturer for the CGMP” field (Figure 4.33). Note: The manufacturers listed only includes manufacturer facility types.

Figure 4.33: Select a Facility for the CGMP



- Section 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



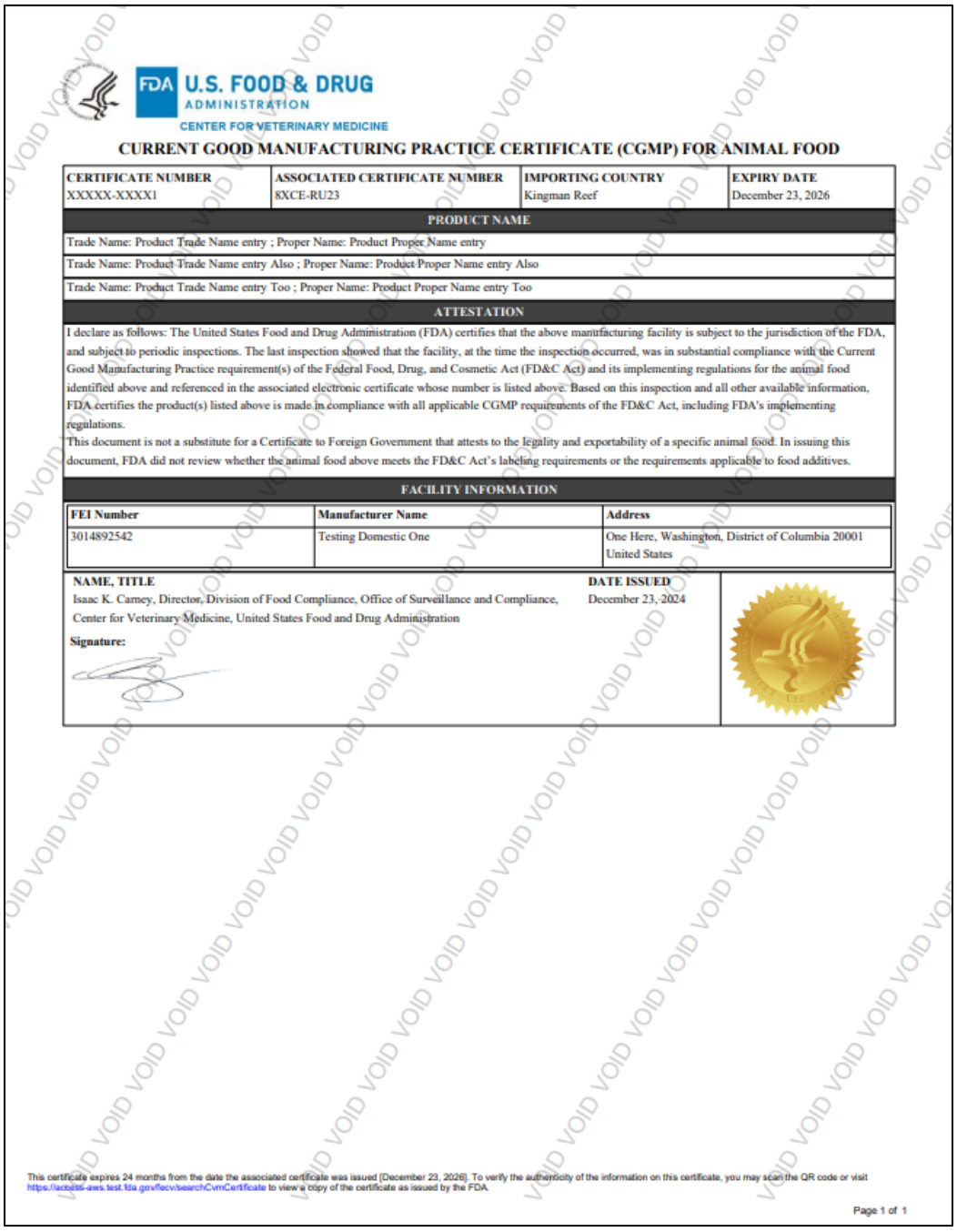
- Section 4 – Displays the Certificate Information (Figure 4.35). This displays the Country from the associated certificate. You must enter the number of certificates requested. The maximum number that can be requested is 30 certificates.

Figure 4.35: Enter Number of CGMP Certificates

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



FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

CURRENT GOOD MANUFACTURING PRACTICE CERTIFICATE (CGMP) FOR ANIMAL FOOD

CERTIFICATE NUMBER	ASSOCIATED CERTIFICATE NUMBER	IMPORTING COUNTRY	EXPIRY DATE
XXXXX-XXXX1	8XCE-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

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.

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.

FACILITY INFORMATION

FEI Number	Manufacturer Name	Address
3014892542	Testing Domestic One	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

DATE ISSUED
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://acbstst-aws.test.fda.gov/fecv/searchCvmCertificate to view a copy of the certificate as issued by the FDA.

Page 1 of 1

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

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

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

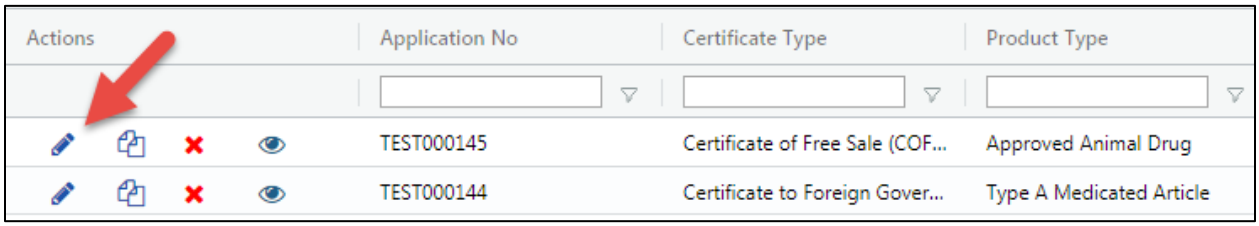
Step 2: Click the Edit Application button.

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



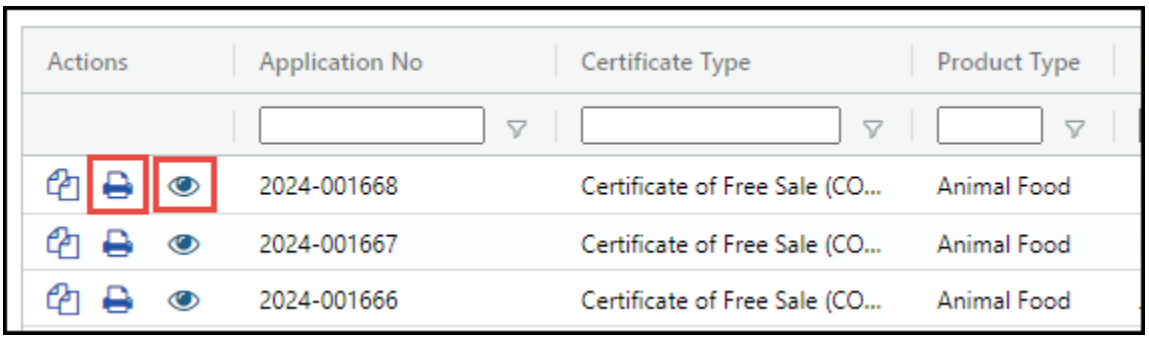
6 Viewing and Printing an Application

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.

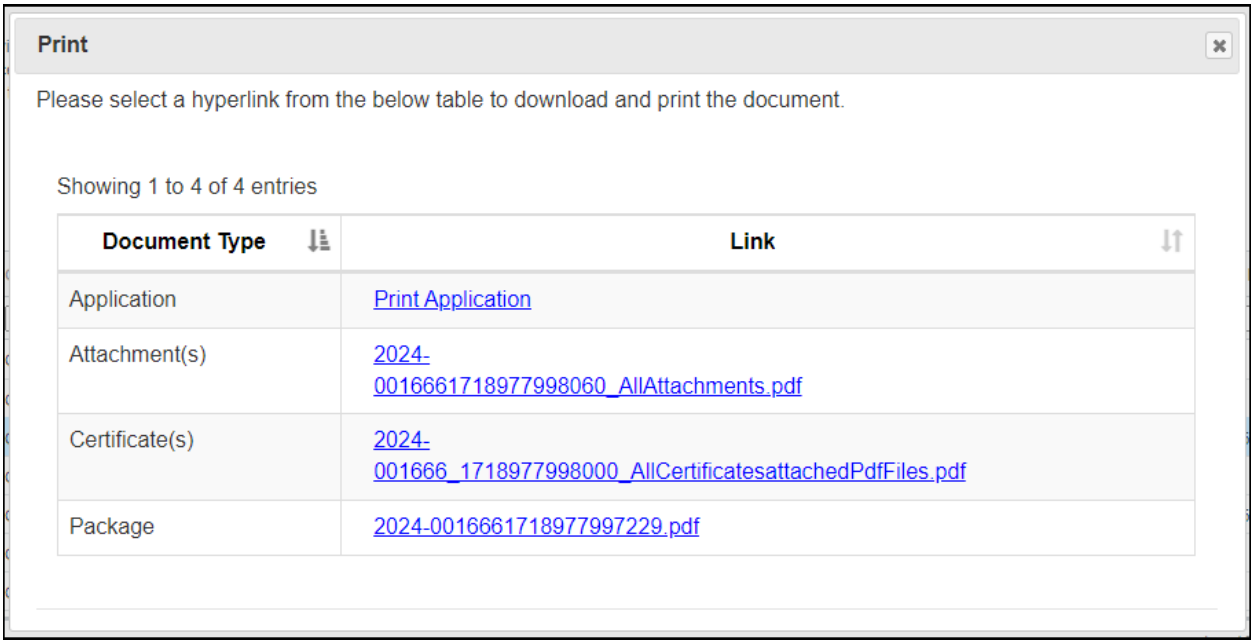
Figure 6.1: View an Application and Print



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



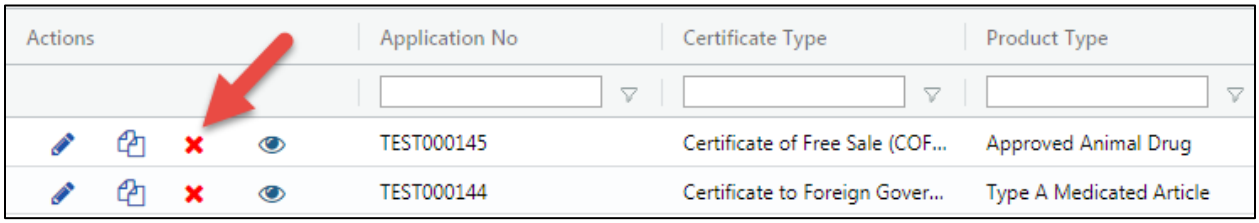
7 Canceling an Application

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

Step 1: Click the Cancel button.

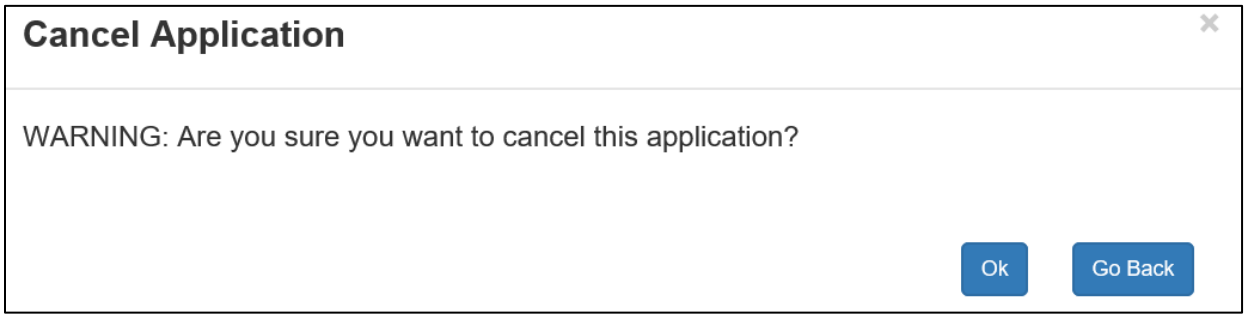
Locate the application you want to cancel from the Dashboard and click the red **Cancel Application** (“**X**”) icon (Figure 7.1).

Figure 7.1: Cancel an Application



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).

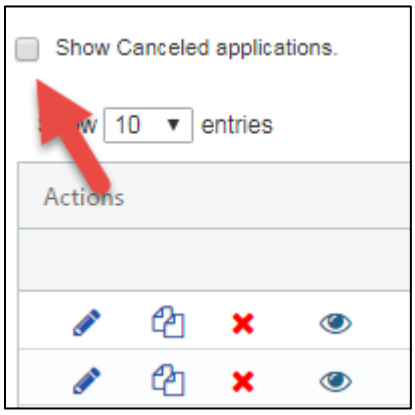
Figure 7.2: Acknowledge Cancel Warning



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.

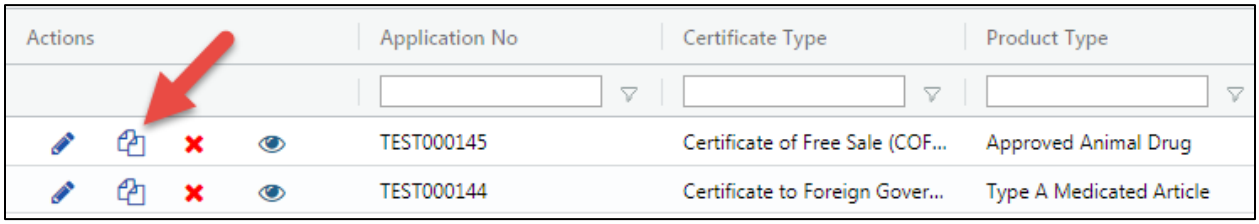
Note: CGMP applications cannot be cloned. Please create a new application.

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



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

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.

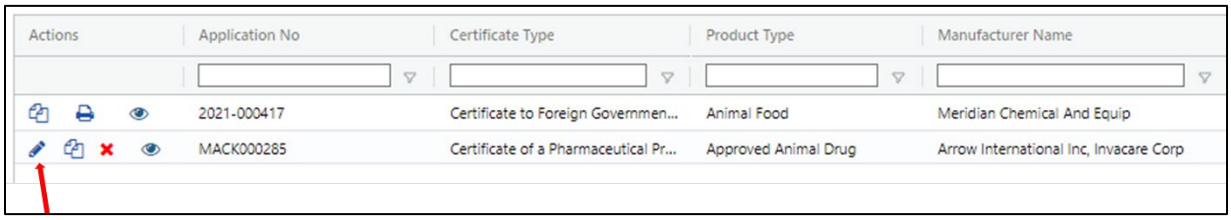
Step 1: Review the e-mail notification.

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



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.

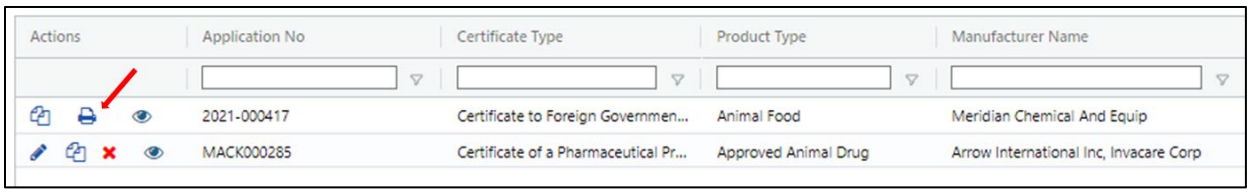
If your application was "Approved", "Return for Action", or Rejected", an FDA Reviewer can re-review your application and change the status accordingly.

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



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.

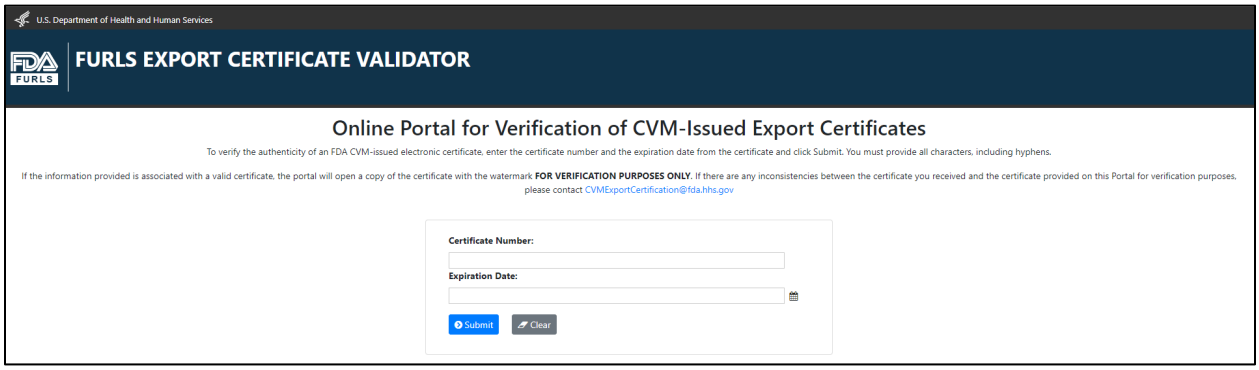
There are two ways to access this online portal:

- 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



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

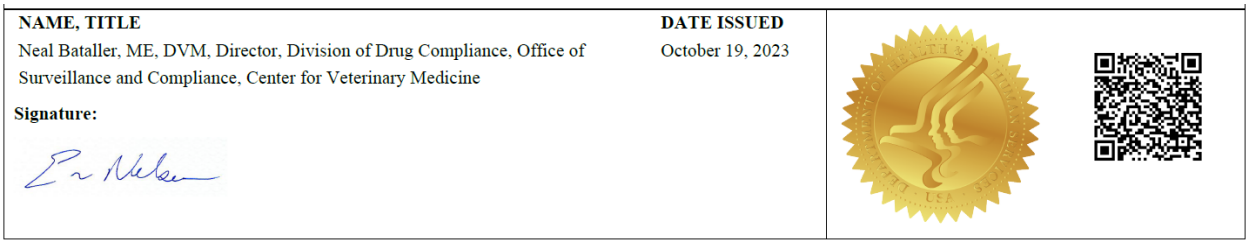
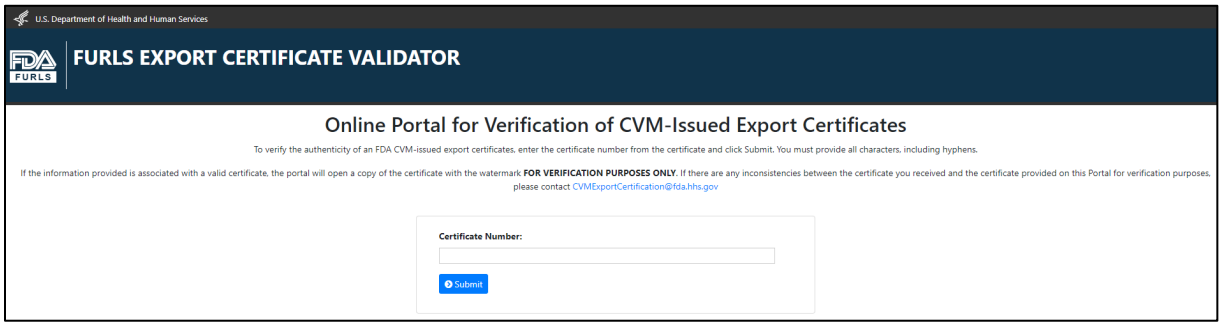


Figure 12.3: QR Code on CPP Electronic Certificate

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

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

CERTIFICATE TO FOREIGN GOVERNMENT (CFG) FOR ANIMAL FOOD

CERTIFICATE NUMBER	EXPORTING COUNTRY	IMPORTING COUNTRY	EXPIRATION DATE
[redacted]	United States of America	Azerbaijan	January 17, 2026

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:

FACILITY INFORMATION

Manufacturer Name/Address	FEI Number
[redacted]	[redacted]

PRODUCT INFORMATION

Product Trade Name	Product Proper Name	NADA/ANADA/CNADA
[redacted]	[redacted]	ANADA: [redacted]

ADDITIONAL INFORMATION

[redacted]

ATTESTATION

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.

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

DATE ISSUED
January 17, 2024

Signature:

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/fecv/searchCvmCertificate to view a copy of the certificate as issued by the FDA.

Page 1 of 1

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
[redacted]	United States of America	Aruba	January 22, 2026

1.1 Drug trade name, international or national non-proprietary name (as applicable) & dosage form: [redacted]

1.2 Active ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): [redacted]

1.3 Is this product authorised 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: [redacted]

2.A.2 Marketing authorization holder (name and address): [redacted]

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,** [redacted]; **FEI Number:** [redacted]

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 Bataller, ME, DVM, Director, Division of Drug Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine **DATE ISSUED** January 22, 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/fecvi/searchCvmCertificate 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

Page 1 of 1

Figure 12.7: Certificate Authentication for CGMP Electronic Certificates

U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR VETERINARY MEDICINE

CURRENT GOOD MANUFACTURING PRACTICE CERTIFICATE (CGMP) FOR ANIMAL FOOD

CERTIFICATE NUMBER	ASSOCIATED CERTIFICATE NUMBER	IMPORTING COUNTRY	EXPIRY DATE
H7TB-G8RY	8XCF-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

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.

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.

FACILITY INFORMATION

FEI Number	Manufacturer Name	Address
3014892542	Testing Domestic One	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

DATE ISSUED

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/fecw/searchCvmCertificate to view a copy of the certificate as issued by the FDA.

Page 1 of 1