

FAQs for CVM Export Certification Application

General Information

What are FDA export certificates?

Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply a "certificate" for products regulated by the U.S. Food and Drug Administration (FDA). The FDA Center for Veterinary Medicine issues multiple forms of [export certificates](#).

Why do foreign governments want FDA export certificates?

In many cases, foreign governments seek official assurance that products exported to their countries can be lawfully marketed in the United States or meet specific U.S. regulations, such as Quality System Regulation (also known as Good Manufacturing Practice requirements). An export certificate issued by FDA Center for Veterinary Medicine may be required by the destination country as part of the process to import a product into the country.

How do I learn other countries' requirements?

If you are an exporter, it is your responsibility to ensure that your products comply with regulations in the destination country. Significant differences may exist across countries. FDA does not provide information on regulations in other countries. Embassies may be of assistance, or you may contact regulatory agencies in the destination countries directly for information.

Can I request a CVM export certificate if I am not the manufacturer of the product?

Yes. However, the requestor will need to identify the manufacturer of the product or products for export to successfully complete an application for an export certificate.

Does CVM issue certificates for Current Good Manufacturing Practices (CGMPs)?

Yes. CVM provides Current Good Manufacturing Practice (CGMP) Certificates which attest to the fact that a specific manufacturing facility may manufacture, market and legally export products from the United States and that the last FDA inspection showed that the manufacturing facility is in compliance with Current Good Manufacturing Practice regulations as required by the Federal Food, Drug, and Cosmetic Act.

Can CVM issue a Certificate of Free Sale or Certificate of Exportability if the facility for the food or drug product has not yet been inspected by FDA?

Yes. Both certificates can be issued if the facility has not yet been inspected by FDA. However, neither certificate can be issued if the facility was inspected and failed the inspection.

Can CVM issue a Certificate to Foreign Government or a Certificate of a Pharmaceutical Product if the facility has not yet been inspected by FDA?

No. Both certificates can only be issued if the facility was inspected by FDA.

Do I need a certificate for export of products to the European Union or Canada?

No. You do not need an export certificate for the export of products to the European Union or Canada.

Application Process

Which type of certificate or export document do I need for my product?

Each certificate is described on [our website](#) and also under the help option in the CVM eCATS application itself.

How do I access CVM eCATS and who do I contact if I have a problem accessing the system?

You can access CVM eCATS through the [FDA Industry Systems web page](#). Enter your FURLS Account ID and password, click the **“I understand”** radio-button, and then **Login**. If you have any questions, you may click on the “Help Desk” link on the same web page.

How can I apply for a CVM-issued export certificate?

Applications for all CVM export certificates may be submitted through the [FDA Industry Systems web page](#)

If you are unable to use CVM eCATS, you may contact FDA for assistance at CVMExportCertification@fda.hhs.gov.

How long does the application review process take?

CVM has 20 business days to issue an export certificate. If the export certificate is not issued by the 20 day deadline, CVM does not charge a fee for the certificate. Requests for export certificates are usually processed within a few days, but the processing time may vary based on factors such as the following:

- The number of products on the application.
- Whether the application is complete or if additional information is required from the requestor to complete the application review.
- FDA's regulatory workload when we receive your request.

Is there an option for expedited review/processing of applications?

No. We process requests in the order that they are received.

What is meant by an application status of “Return for Action”?

An application status of “Return for Action” indicates that the application needs additional information from the requestor, or there is a discrepancy between information provided by the applicant that needs to be corrected before processing of the application can be completed.

If the applicant does not respond in three business days to a “Return for Action” notification, the application will be automatically cancelled.

I already submitted an application and now wish to withdraw it and not be billed for the certificate. Is this possible?

You may click the "Cancel Application" icon on the main screen only if the application status has not already changed to "Under Review," "Approved," or "Rejected," in which case, you will not be billed for the certificate. If your application status is "Under Review," you may reach out to the reviewer to have the application withdrawn on your behalf by emailing: CVMexportcertification@fda.hhs.gov. However, in the latter case, please note that your message might not be processed prior to certificate issuance. Once a certificate is issued, you will be billed for the certificate even if you do not wish to use it.

Does the "Clone" feature allow me to create a new application based on information in a similar application?

Yes. If the information on a new application that you would like to submit is similar to that of one you have submitted in the past, the clone feature is very helpful as it will allow you to copy all the information from the cloned application into a new application. You have the ability to clone any application that you have submitted in the past.

Can certificate language be modified or language added to certificates?

Certificate language cannot be modified; however, the application has a section for the applicant to enter "additional language" and in the case of the CPP "Remarks" that will appear on the certificate. CVM reserves the right to edit or refuse a request for this additional language.

Is it possible to have more than one product listed on a certificate?

We allow more than one food product or device to be listed on a single certificate; however, only a single drug product may be listed on a single certificate.

In the case of devices, can I enter "See Attached List of Products" instead of the specific device name in the Product Trade Name and Product Proper Name fields of the Certificate to Foreign Government application and provide a list of products as an attachment to the certificate?

Yes, in the case of devices only, you may enter "See Attached List of Products" instead of the specific device name in the Product Trade Name and Product Proper Name fields of the Certificate to Foreign Government application and provide a list of products as an attachment to the certificate.

If I would like a product to be exported to more than one country, do I need a new application for each country?

No. You only need to complete one application and list all countries on this application. Each country will have its own certificate.

Is there a cap on the number of certificates that can be requested in one application?

Yes. We limit the number of certificates that can be requested in one application to 30.

When will I be billed for my certificate?

FDA generates the billing file every quarter. For example, should you receive a certificate during the first quarter of the year, you will be billed on March 31st.

What is the cost of each copy of a certificate?

With the exception of CGMP certificates which are issued at no charge, CVM charges \$175 for the first certificate, \$155 for the second copy and \$70 for each subsequent copy.

The 20 day deadline for certificate issuance passed and I have not yet received my certificate. What should I do?

Please email the Program Administrators at: CVMexportcertification@fda.hhs.gov. The system keeps track of missed deadlines and you will not be billed for certificates issued after the 20 day deadline.

Information needed to complete application

Is there a public site where I can look up my FEI number?

The [FDA FEI Search Portal](#) can be used to look up your FEI number. Please note that in rare cases, an FEI number cannot be found using this method.

What is the process for animal drug registration and listing?

For registration and listing of animal drugs, you can follow instructions found on the [Structured Product Labeling Resources web page](#)

How do I find my FDA Product Listing Number/National Drug Code (NDC)?

For identifying your NDC, you may use either of the following directories:

- [FDA Electronic Animal Drug Product Listing Directory](#)
- [US National Library of Medicine](#)

How will my labels be reviewed?

Food and Drug labels are reviewed based on Title 21 of the Code of Federal Regulations (CFR) Part 500. The Association of American Feed Control Officials (AAFCO) manual is used as a more comprehensive resource to determine whether an ingredient in animal food is safe by FDA standards.

For Foreign Government Officials (FGO)

How can I verify that an export certificate was issued by FDA?

FDA provides the Export Certificate Validation public web site for the FGO to search and validate export certificates submitted electronically via CVM eCATS (CVM Export Certification Application and Tracking System) and issued by Center for Veterinary Medicine. The web site requires entry of at least two certificate identifying information of: Certificate Number, Facility Name, Dates of Certificate Expiration, and Product Name. The results displayed include the facility name and address, certificate type, expiration date, certificate number, and expiration date, product name, and importing country.