U.S. FOOD & DRUG ADMINISTRATION

Center for Veterinary Medicine

FAQs for FDA Center for Veterinary Medicine (CVM) Export Certification Application

[Updated December 2024]

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 (CVM) 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 comply with other requirements, such as Current Good Manufacturing Practice (CGMP) 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 the laws of 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.

When should I request an export certificate be issued by FDA CVM, as opposed to other FDA centers?

Within FDA, CVM regulates products intended for use in animals including animal food, animal drugs, and medical devices for animals. If you are exporting FDA-regulated products for animal use and need an export certificate, you should contact CVM.

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

Yes. However, you will need to identify the manufacturer of the product for export to successfully complete an application for an export certificate. You must provide the actual manufacturing

facility's name and address (not merely a distributor and/or corporate headquarters address).

Which certificates can FDA CVM issue if the manufacturing facility has not been inspected?

If the manufacturing facility has not been inspected, FDA CVM can issue the following certificates:

- For animal food or drugs: Certificate of Free Sale (COF), or Certificate of Exportability (COE)
- For animal devices: Certificate to Foreign Government (CFG)

Does FDA CVM issue certificates for compliance with Current Good Manufacturing Practice (CGMP) requirements?

Yes. FDA CVM issues several different certificates that contain a CGMP certification. For example, FDA CVM can issue a Certificate to Foreign Government (CFG) for animal drugs or food that identifies a specific product and makes certain certifications, including a CGMP certification. FDA CVM can also issue a separate Current Good Manufacturing Practice (CGMP) certificate. However, the CGMP certificate is only issued after CVM has issued one of the other certificate types (CFG, COFS, CPP, or COE) referred to as the "associated certificate" that identifies a specific product and facility. The CGMP certificate may be thought of as an update to the associated certificate and certifies that the facility is still in compliance with the Current Good Manufacturing Practice requirements of the Food, Drug, and Cosmetic Act (FD&C Act) for the product listed on the associated certificate. The associated certificate number is referenced on the CGMP certificate, and the CGMP certificate has the same expiration date as the associated certificate. The CGMP certificate does not attest to the legality and exportability of a specific animal food or drug. The CGMP certificate may only reference the product listed on the associated certificate and is issued at no charge.

Does FDA CVM issue certificates for compliance with Current Good Manufacturing Practice (CGMP) requirements for animal devices (i.e. medical devices for animal use)?

No. In the United States, there are no CGMP or Quality System Regulation (QSR) requirements for animal devices. Therefore, FDA inspections do not assess animal device manufacturers for CGMP compliance, and FDA cannot certify CGMP compliance for animal devices.

If an inspection of a manufacturing facility found significant noncompliance with applicable requirements (e.g., CGMP requirements), could this result in FDA CVM not issuing an export certificate?

Yes. FDA may not issue the Certificate to Foreign Government (CFG), Certificate of Free Sale (COFS), CGMP certificate, or Certificate of a Pharmaceutical Product (CPP) in those circumstances.

A Certificate of Exportability may be issued to a facility if noncompliance with CGMP requirements are found during an inspection. If the applicant is requesting a Certificate of Exportability (used to export products that are not legal to sell in the U.S.), the applicant should submit information demonstrating how, despite noncompliance with the applicable U.S. requirements, the product meets the conditions of FD&C Act section 801(e) [21 U.S.C. § 381(e)]. In particular, the

information should demonstrate how the non-compliant product accords to the specifications of the foreign purchaser and is not in conflict with the laws of the country to which it is intended for export.

Can FDA CVM issue a Certificate to Foreign Government (CFG) or a Certificate of a Pharmaceutical Product (CPP) if the facility has not yet been inspected for compliance with applicable manufacturing requirements?

No. FDA CVM may not issue these certificates for animal food or drugs without an inspection because we do not have the information needed to make the applicable certifications. A Certificate to Foreign Government for animal food or drugs, or a Certificate of a Pharmaceutical Product for animal drugs may be issued after the facility is inspected for compliance with the applicable CGMP requirements for that type of product. (Note: FDA will issue the Certificate to Foreign Government for animal devices without a CGMP inspection because there are no CGMP requirements for animal devices.)

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

As of this time, to our knowledge, you do not need an export certificate for the export of FDA-regulated animal products to the European Union or Canada. As noted above, exporters are responsible for determining the requirements of the countries to which they are exporting, including staying informed of any changes.

When does my certificate expire?

All certificates except for the CGMP certificate expire 24 months from the date the certificate is issued. The CGMP certificate expires 24 months from the issuance date of the associated certificate.

Where can I get more general information on Export Certificates?

For more information, please see:

- FDA Export Certification Guidance for Industry (August 2021)
  - https://www.fda.gov/media/151701/download
- Guidance for Industry: Exports Under the FDA Export Reform and Enhancement Act of 1996
  - https://www.fda.gov/media/138075/download

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 Export Certification Application and Tracking System (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 FDA's

Unified Registration and Listing System (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 twenty (20) business days to issue an export certificate. If the export certificate is not issued by this time, 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 complexity of the application / review process.
- 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 regarding 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 (3) 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.

How many products can be listed of each commodity type?

A single application may list up to five animal products (a single product being defined as an identical set of ingredients, which may be labeled for sale under multiple brand names and package sizes). There is no limit on the number device products which can be listed on a single certificate. One animal drug may be listed on a single certificate, where a product is defined as an NDC with a unique product and labeler code (identical first and second segments) with no limitation on the number of packaging code variations (third segment).

For device applications, how should I complete the “Product Trade Name” and “Product Proper Name” fields of the Certificate to Foreign Government application when the length of the names presents a problem?

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, but you will need multiple certificates because each certificate lists a single country. You only need to complete one application and can list multiple countries on this application. We will issue separate certificates for each country based on a single application. FDA will charge a fee for each of the certificates that it issues. For example, if you request certificates for twenty (20) countries, you will be billed for twenty (20) certificates.

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 thirty (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 (January through March), you will be billed on or around March 31st.

What is the cost of each copy of a certificate?

You may use a single application to apply for up to thirty (30) certificates. You may apply for the same certificate for up to thirty (30) countries, or for up to thirty (30) copies of the same certificate for a single country, or for any combination of multiple certificate copies and multiple countries to

add to a total of 30 certificates. With the exception of CGMP certificates which are issued at no charge, CVM charges $175 for the first certificate, $155 for the second certificate, and $70 for each subsequent certificate. Therefore, you may obtain up to 28 certificates for $70 using a single application.

The twenty (20) business 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 twenty (20) business day deadline.

Information needed to complete application, common questions / issues

Where can I look up my FDA Establishment Identifier (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. If that is the case, please contact a Program Administrator at CVMExportCertification@fda.hhs.gov.

What is the process for animal food facility registration?

For animal food facility registration, you can follow instructions found on the Food Facility Registration webpage.

How does CVM verify information pertaining to animal drugs?

Among other steps, CVM verifies the manufacturing facility is registered with FDA as an animal drug manufacturer and the drug is listed with FDA. During the animal drug listing review process, among other things, drugs are assigned unique National Drug Code (NDC) numbers and their labeling is submitted to FDA. Listing information must be updated periodically. See Title 21, Code of Federal Regulations, Part 207 (21 CFR Part 207) for additional information on the registration and listing requirements.

CVM may not issue an export certificate if the animal drug manufacturer is not registered, the drug is not listed, or the drug's listing information is out-of-date (i.e., CVM cannot verify the product in the export certification application is the listed product because the product's listing with FDA was not updated to provide the current labeling).

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)?

The labeling for your animal drug may contain its NDC. You may obtain this information from the manufacturer or distributor's regulatory affairs personnel. For additional resources for identifying your NDC, you may use either of the following directories:

- FDA Electronic Animal Drug Product Listing Directory
- US National Library of Medicine

If you are attempting to identify an NDC using these online tools, please remember that seemingly similar drugs have different NDCs (e.g., different strengths of the same drug, approved versions vs. unapproved export-only versions, etc.). The NDC provided in the application needs to match the product you are seeking to export.

Can I use the NDC of an FDA-approved drug in the export certificate application for an "export-only" version of the drug (i.e., a drug sold under the same proprietary name or made with the same active ingredient, but with different labeling that was not part of the approved application / drug listing?)

No. The "export-only version" is a separate, unapproved animal drug that should be listed independently (i.e., have its own NDC and submit its labeling to FDA as part of its listing process). Due to the labeling mismatch between the approved drug and the export-only drug, FDA may be unable to verify the information on the export certificate application unless the applicant provides the export-only (unapproved) drug's NDC. See FDA's drug listing SPL resources page for more information on marketing categories (including "Export only"): https://www.fda.gov/industry/structured-product-labeling-resources/marketing-category.

How will my labels be reviewed?

Animal food labels are reviewed based on the requirements in the FD&C Act as well as FDA's regulations. Title 21 CFR Part 501 contains many of these requirements for non-medicated animal food. Title 21 CFR Part 558 contains the primary set of additional requirements related to Type B and Type C medicated feed. Chapter six of the 2024 The Association of American Feed Control Officials (AAFCO) Official Publication is used as an animal food ingredient resource.

Animal drug labels are reviewed based on FD&C Act section 502, 21 CFR Part 201, and any other applicable requirements to that specific drug. Additionally, FDA CVM compares the labels of the drug to be exported with the labeling submitted to FDA as part of drug listing.

For Foreign Government Officials (FGO)

In what form does FDA CVM issue export certificates?

FDA CVM only issues export certificates electronically. FDA CVM does not issue hard copies of certificates.

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

FDA provides the Export Certificate Validation public website for FGOs to search and validate

export certificates issued by FDA CVM. To access the website, the FGO should click on the link at the bottom of the issued certificate. The web site requires entry of the following information: Certificate Number and Certificate Expiration Date. The system will display a copy of the issued certificate.

The FGO may also validate the certificate by using a mobile device to scan the QR code found in the bottom right-hand corner of the issued certificate. This will take the FGO to a portal which requires entry of only the Certificate Number to display a copy of the issued certificate.

If an export certificate contains an expiration date, what does that mean?

FDA CVM recommends foreign governments not rely on a certificate after its expiration date because, by that time, the information FDA used to issue the certificate is likely to be outdated (e.g., new inspections are likely to have occurred). However, the foreign government, not FDA, determines how recent of a certification it will accept. A foreign government may choose not to accept an export certificate issued by FDA CVM earlier than its stated expiration date (i.e., the foreign government may request the person obtain a more recent export certificate from FDA). FDA CVM accepts new export certificate applications for any product at any time, and FDA will use the most recent information available at the time of the application to determine whether it will issue the new certificate.