General Information for Consideration Prior to Applying for Certificates Using Center for Veterinary Medicine (CVM) Export Certification Application and Tracking System (CVM eCATS)

I. Certificate to Foreign Government (CFG), Certificate of Free Sale (COFS) and Certificate of Exportability (COE)

A. General Information

- Before preparing your application, please consult with the importing country to determine exactly what type of certificate is needed.
- The FDA will not issue a certificate for products that do not meet the applicable requirements of the Federal Food, Drug and Cosmetic Act.
- There are limitations on the number of products that can be included on a single certificate, which varies by FDA regulated commodity. Five food products (a product being defined by unique ingredients, which may be labeled with different brand names or sold in different package sizes), may be listed on an application for animal food. There is no limit on the number of device products that can be listed on an application. One drug (including Type A medicated articles) can be listed on each application (where a single drug is considered an NDC with identical first and second segments) with no limitation on the number of packaging code variations (third segment).
- In the case of devices only requesting a Certificate to Foreign Government, 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.
- Only one manufacturer should be listed on an animal food or animal device certificate. An animal drug certificate may list multiple manufacturers, each of whom perform part of the manufacturing of the drug listed on the certificate.
- Up to thirty (30) countries can be listed on a single application. A separate certificate is issued for each country and each certificate will be assessed a fee.
- The FDA intends to issue certificates within twenty (20) working days of receipt of an application; applicants will not be charged for certificates issued after the twenty (20) day timeframe.
- The FDA is authorized to charge a fee for certificates issued within twenty (20) days of receipt of an application. The fees are as follows: First certificate: $175.00; second certificate: $155.00; third and subsequent certificates: $70.00.
- The FDA may request (via email) additional information or noting potential problems with the application for which correction may be required before a certificate can be issued. If information is not provided or the application is not amended within three business days, the application will be canceled.
- Errors made by FDA during the preparation of the certificate will be corrected at no cost to the applicant if requested within forty-five (45) days after certificate issuance.

- Errors made in the application by the requestor cannot be corrected once the application is submitted. In this case, a new application must be submitted.

B. Information to have available prior to applying for CFG, COFS and COE

- Firm Tax ID Code.
- You will have a choice to provide one of the following two pieces of information to identify your manufacturing facility(ies): 1) Address of product manufacturer or 2) Firm Establishment Identifier (FEI) number.
- Product trade name(s) and product proper name(s) in the case of CFG and COFS; Product name(s) only in the case of a COE.
- National Drug Code (NDC) for all drugs (approved drugs, unapproved drugs and Type A medicated articles).
- The NADA, ANADA, or CNADA number for an approved drug, Type A medicated article and Type B or Type C medicated feed, or Minor Species Index File (MIF) number for an indexed product.
- Legible label(s) for each product. The labels must be the same version of the label to be used on the exported product. If the labels contain any information in a foreign language, include translations or copies in English. Drug labels should match labels submitted to FDA as part of drug listing. If you have changed your labels but have not updated your listing information with FDA to reflect your new labels, we recommend updating the listing immediately.
- If an application lists more than one product, each product must have a label.
- Any supplemental document(s) you wish to be attached to the certificate such as a label(s) in the language of the importing country.
- There is a section for entry of additional information. Please note that FDA reserves the right to remove and/or update any additional information.

II. Certificate of a Pharmaceutical Product (CPP)

A. General Information

- Before preparing your application, please consult with the importing country to determine exactly what type of certificate is needed.
- FDA will not issue a Certificate of a Pharmaceutical Product for products that do not meet the applicable requirements of the Federal Food, Drug and Cosmetic Act.
- Only one drug may be listed on the application.
- All product manufacturers must be listed on the application.
- Up to thirty (30) countries may be listed on an application; a separate certificate is issued for each country. Each certificate will be assessed a fee.
- The requestor is the firm or person filling out the application.
- The applicant is the firm or person requesting the CPP. A firm (applicant) may use another firm (requestor) to fill out an application on its behalf.
- CPPs have images of ribbons of different colors depending on the type of product:
  - red designates approved drug and Type A medicated article
  - blue designates unapproved drug

    - orange designates active pharmaceutical ingredient (API)
- The FDA intends to issue certificates within twenty (20) working days of receipt of an application; applicants will not be charged for certificates issued after the twenty (20) day timeframe.
- The FDA is authorized to charge a fee for certificates issued within twenty (20) days of receipt of an application. The fees are as follows: First certificate: $175.00; second certificate: $155.00; third and subsequent certificates: $70.00.
- The FDA may notify the applicant (via email) of corrections to the application required before a certificate can be issued. If the corrected application is not submitted within three business days, the application will be canceled.
- Errors made by FDA during the preparation of the certificate will be corrected at no cost to the applicant if requested within forty-five (45) days after certificate issuance.
- Errors made in the application by the requestor cannot be corrected once the application is submitted. In this case, a new application must be submitted.

B. Information to have available prior to applying for the CPP

- Firm Tax ID Code.
- You will have a choice to provide one of the following two pieces of information to identify your manufacturing facility(ies) 1) Address of manufacturer or 2) FEI number.
- Role of manufacturer i.e., API manufacturer, API Testing Facility, Packager, Relabeler, Testing Facility, Other.
- Address of applicant.
- Address of the marketing authorization holder for an approved drug or Type A medicated article.
- Drug trade name.
- Active ingredient(s) and amount(s) per unit dose
- The National Drug Code (NDC)
- The NADA, ANADA, or CNADA number and approval date for an approved drug and Type A medicated article or Minor Species Index File (MIF) number for an indexed product.
- Remarks section allows for any special information, for example, if you wish to include shelf-life of the product on the CPP. Please note that FDA reserves the right to remove and or update this information.
- Legible label(s) in English language.
- Any supplemental document(s) you wish to attach to the certificate such as a label(s) in the language of the importing country.

III. Current Good Manufacturing Practice (CGMP) Certificates

A. General Information

- The CGMP certificate may only be issued after the issuance of one of the certificate types above (CFG, COFS, COE, or CPP) referred to as the “associated certificate.” The CGMP certificate must reference a specific product or products (and can only reference the product or products listed on the associated certificate). The CGMP certificate references the associated certificate number and expiration date.

- Upon verification by the applicant, the manufacturer and name of product(s) from the associated certificate will auto-populate the CGMP certificate. Should more than one manufacturer be listed on the associated certificate, the applicant must select only one manufacturer to appear on the CGMP Certificate and request another CGMP Certificate for the other manufacturing site(s).
- FDA intends to issue CGMP certificates within twenty (20) working days of receipt of an application.
- Applicants are not charged a fee for this certificate type.

B. Information to have available prior to applying for CGMP certificate

- The number on the associated certificate, i.e., CFG, COFS, COE or CPP.
- Address or FEI number of the product manufacturer for verification purposes.
- Product Label for verification purposes.
- NDC number for verification purposes in the case of a drug product.

For inquiries about certificates, please e-mail CVMExportCertification@fda.hhs.gov.