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

I. Current Good Manfacturing Practice (CGMP) Certificates

A. General Information

1. Before preparing your application, please consult with the importing country to determine exactly what type of information is required for the certificate.
2. U.S. Food and Drug Administration (FDA) will not issue a certificate for products that do not meet the applicable requirements of the Federal Food, Drug and Cosmetic Act.
3. Only one manufacturer can be listed on an application.
4. Multiple countries can be listed on an application; however, a separate certificate is issued for each country.
5. FDA may issue CGMP certificates within 20 working days of receipt of an application.
6. Applicants are not charged a fee for this certificate type.
7. The FDA may email a notification detailing corrections to the application required before a certificate can be issued. If the corrected application is not submitted within three business days, your application will be canceled.
8. Errors made by FDA during the preparation of the certificate will be corrected at no cost to the applicant if requested within 45 days after certificate issuance.
9. 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 CGMP certificates

1. You will have a choice to provide one of the following two pieces of information to identify your manufacturing facility: 1) Address of product manufacturer or 2) FEI number.
2. Product(s) may be listed on the certificate.
3. The importing country may be listed on the certificate.
4. There is a section for entry of additional information. Please note that FDA has the right to remove and or update any additional information.

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

A. General Information

1. Before preparing your application, please consult with the importing country to determine exactly what type of information is required for the certificate.
2. The FDA will not issue a certificate for products that do not meet the applicable requirements of the Federal Food, Drug and Cosmetic Act.
3. Multiple food or device products may be listed on the application; only one drug, Type A medicated article, or Type B or Type C medicated feed product can be listed on one application.
4. 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.
5. All product manufacturers must be listed on the application.
6. Multiple countries can be listed on an application; however, a separate certificate is issued for each country.
7. The FDA may issue certificates within 20 working days of receipt of an application.
8. The FDA is authorized to charge a fee for certificates issued within 20 days of receipt of an application. The fees are as follows: First certificate: $175.00, Second copy of certificate: $155.00, Third and subsequent copies of certificates: $70.00.
9. The FDA may email a notification detailing corrections to the application required before a certificate can be issued. If the corrected application is not submitted within three business days, your application will be canceled.
10. Errors made by FDA during the preparation of the certificate will be corrected at no cost to the applicant if requested within 45 days after certificate issuance.
11. 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

1. Firm Tax ID Code.
2. 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) FEI number.
3. 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.
4. National Drug Code (NDC) for an approved and unapproved drug and Type A medicated article.
5. The NADA/ANADA/CNADA number for an approved drug, Type A medicated article and Type B and Type C medicated feed.
6. Legible label(s) in English language.

7. If a certificate is required for more than one product, each product must have a label.
8. Any supplemental document(s) you wish to be attached to the certificate such as a label(s) in the language of the importing country.
9. There is a section for entry of additional information. Please note that FDA reserves the right to remove and or update any additional information.

III. Certificate of a Pharmaceutical Product (CPP)

A. General Information

1. Before preparing your application, please consult with the importing country to determine exactly what type of information is required for the certificate.
2. FDA will not issue a certificate for products that do not meet the applicable requirements of the Federal Food, Drug and Cosmetic Act.
3. Only one drug may be listed on the application.
4. All product manufacturers must be listed on the application.
5. Multiple countries can be listed on an application; however, a separate certificate is issued for each country.
6. The requestor is the firm or person filling out the application.
7. 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.
8. CPPs have ribbons of different colors depending on the type of product.
9. Red designates approved drug and Type A medicated article
10. Blue designates unapproved drug
11. Orange designates active pharmaceutical ingredient (API)
12. FDA is authorized to charge a fee for certificates issued within 20 working days of receipt of an application. The fees are as follows: First certificate: $175.00, Second copy of certificate: $155.00, Third and subsequent copies of certificate: $70.00.
13. The FDA may email a notification detailing corrections to the application required before a certificate can be issued. If the corrected application is not submitted within three business days, your application will be canceled.
14. Errors made by FDA during the preparation of the certificate will be corrected at no cost to the applicant if requested within 45 days after certificate issuance.
15. 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

1. Firm Tax Code.
2. 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.
3. Address of applicant.
4. Address of the license holder for an approved drug or Type A medicated article.
5. The National Drug Code (NDC) for an approved and unapproved drug and Type A medicated article.

6. The NADA/ANADA/CNADA number and approval date for an approved drug and Type A medicated article.
7. 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.
8. Legible label(s) in English language.
9. Any supplemental document(s) you wish to attach to the certificate such as a label(s) in the language of the importing country.

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