

Department of Health and Human Services
Food and Drug Administration

SUPPLEMENTARY INFORMATION CERTIFICATE OF A PHARMACEUTICAL PRODUCT

Send the Export Certificate Requests and supporting documents to the appropriate Center within FDA that would have control over your product:

CBER: CBER regulates biological products, including blood and blood products, vaccines, allergenics, tissues, and cellular and gene therapies. CBER also regulates the medical devices involved in the collection, processing, testing, manufacture and administration of licensed blood, blood components and cellular products and all HIV test kits used both to screen donor blood, blood components, and cellular products and to diagnose, treat, and monitor persons with HIV and AIDS. Please apply for your application using <https://www.access.fda.gov/oa>. Please see page 5 for CBER instructions on how to apply for this certificate.

CVM: Feed/food, drugs and devices used in pets, farm animals, and other animals are regulated by the Food and Drug Administration, Center for Veterinary Medicine, Division of Compliance (HFV-235), 7519 Standish Place Rockville, MD 20855. Please call 240-276-9227 or email CVMExportCertification@fda.hhs.gov. Please see page 6 for CVM instructions for applying and filling out this form.

1. Requestor Information

Name		Address		
Firm				
Telephone number	FAX number	Firm Tax ID code	Email address	

2. Section 1.0

Proprietary name
Dosage form

3. Section 1.1

Active ingredient	
Amount per unit dose	Is the product currently marketed in the United States? <input type="checkbox"/> Yes <input type="checkbox"/> No

Note: The information for this section may be provided in the approved product labeling and may be attached to the certificate. For certificate requests for more than one country, provide a copy of the attachments for each country. Provide one copy of the attachments for FDA. **Attachments are limited to a total of 10 pages for CBER and CVM.**

4. Billing and Shipping Account Information

Is the Billing Contact and Address the same as the applicant? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If no, please provide Billing Contact and Address below.</i>	
Billing contact name	Address
Mail carrier name	Account number and/or Shipping Label

CBER instructions are on page 5.

CVM instructions are on page 6.

5. Section 2A.1 - 2A.6: Approved Pharmaceutical Product

FDA product approval (BLA/STN, NADA, ANADA, NDA) <i>(Enter either FDA Approval, Submission, License or New Drug Application Number, as applicable)</i>	Date of issue (mm/dd/yyyy)
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Also, provide a copy of the approval letter as verification of the product license or NDA or NADA number and approval date

Product-license holder	Address
Status of product license holder <i>(mark appropriate item(s))</i>	
<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Packager and/or Relabeler
<input type="checkbox"/> Neither	

6. Section 2B.1 - 2B.3: Other Pharmaceutical Product

Applicant name	Address
Status of applicant <i>(mark appropriate item(s))</i>	
<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Packager and/or Relabeler
<input type="checkbox"/> Neither	
For unapproved biological drugs, mark the category that indicates why authorization is lacking <i>(mark appropriate item(s))</i>	
<input type="checkbox"/> Not required	<input type="checkbox"/> Not requested
<input type="checkbox"/> Under consideration	
<input type="checkbox"/> Refused	

7. Facilities Involved in the Manufacturing of the Exported Product *(A maximum of four facilities may be listed for CBER and CVM.)*

Facility name (1)	Address
License number <i>(if applicable)</i>	
Firm FDA Registration Number	Date of most recent inspection
Facility name (2)	Address
License number <i>(if applicable)</i>	
Firm FDA Registration Number	Date of most recent inspection
Facility name (3)	Address
License number <i>(if applicable)</i>	
Firm FDA Registration Number	Date of most recent inspection
Facility name (4)	Address
License number <i>(if applicable)</i>	
Firm FDA Registration Number	Date of most recent inspection
Do you want the manufacturing location(s) listed on the certificate?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	

8. Importing Countries *(list in columns)*

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9. Number of certificates requested: _____

EXPORTER'S CERTIFICATION STATEMENT
"CERTIFICATE OF A PHARMACEUTICAL PRODUCT"
for CBER and CVM

FIRM NAME

As the responsible official or designee of the company named above, I hereby certify to the United States Food and Drug Administration that:

- the company, the manufacturing plant, and the product being exported, as identified in the Supplementary Information, continue to be, to the best of my knowledge, in compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act;
- the product being exported has been manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements;
- the product labeling provided with the Supplementary Information is a true and accurate representation of the product labeling approved by the FDA; and
- the product will be exported from the United States.

SIGNATURE

DATE

NAME AND TITLE

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to \$250,000 in fines and up to 5 years imprisonment.

Department of Health and Human Services
Food and Drug Administration

EXPORT CERTIFICATION

***Submission Requirements for Requesting Certificates for
Exporting Products to Foreign Countries (for CBER)***

Background

Firms exporting products from the U.S. are often asked by foreign customers or foreign governments to supply a certification relating to products subject to the Federal Food, Drug, and Cosmetic Act and other acts the Food and Drug Administration (FDA) administers. Under the FDA Export Reform and Enhancement Act of 1996 (the Act), FDA is authorized to issue certificates for drugs, animal drugs, and devices within 20 days of receipt of a request for such a certificate. A fee of up to \$175 may be charged for each certificate issued. In addition to issuing export certificates for approved or licensed products, the FDA will also issue export certificates for unapproved products that meet the requirements of Sections 801(e) or 802 of the Act.

General Instructions:

- The “**Certificate of a Pharmaceutical Product**” conforms to the format established by the World Health Organization (WHO) and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending or reviewing a license. WHO Certificate requests should include the information listed in **Supplementary Information – Certificate of a Pharmaceutical Product Requests (PDF, Text)**. Please ensure that the Exporter’s Certification Statement is signed by a responsible official of the exporting firm and is enclosed with the certificate request. Enclose labels for each product.
- Please type certificate requests or print clearly.
- In most cases, one product will be listed per certificate. However, products that were approved under the same BLA/STN or NDA application may be listed on the same certificate based on the available space for a one page certificate. Certificate requests for listing multiple products will be evaluated on a case-by-case basis.
- If information is omitted in the application by the requester or if clarification is needed on the supplied information, the requester will be contacted via telephone, FAX, or email. If the requester does not provide the necessary information within 48 hours, the request for certificates will be returned and will need to be resubmitted for FDA review.

- Questions may be directed to the Import/Export Team at 240-402-9155 or by email at CBERBECATS@fda.hhs.gov.

- Request an Export Certificate using one of the following methods. To facilitate your certificate request, please apply for your application using <https://www.access.fda.gov/oa>. Create a new account and select the Biologics Export Certificate Application and Tracking System (BECATS). If you have any problems, then please contact us at HYPERLINK “mailto:CBERBECATS@fda.hhs.gov” (CBERBECATS@fda.hhs.gov). You may also send the request and supporting documents to:

Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Case Management
10903 New Hampshire Ave.
Building 71, Room G112
Silver Spring, MD 20993-0002

- On October 1, 1996, CBER was given the authority to charge \$175 for the first two certificates and \$85 for any subsequent certificates issued for the same product(s) in response to the same certificate request. Please do not submit a check with your request, as FDA will bill you quarterly for issued certificates.
- Errors made by FDA during the preparation of export certificates will be corrected, at no cost to the applicant, within 45 days after issuance.
 - Errors made in the application, by the submitter, cannot be corrected. A new application must be submitted.
- You may enclose a completed air billing number and mailing supplies to expedite the return of Certificates.

Issuance of a “Certificate to Foreign Government”, “Certificate of Exportability” or “Certificate of a Pharmaceutical Product” will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.

A “Certificate to Foreign Government”, “Certificate of Exportability” or “Certificate of a Pharmaceutical Product” is issued by FDA solely for export purposes and may not be used for domestic advertising.

Department of Health and Human Services
Food and Drug Administration

**INSTRUCTIONS FOR COMPLETION OF
APPLICATION FOR CERTIFICATES
(for CVM)**

1. The “**Certificate of a Pharmaceutical Product**” conforms to the format established by the World Health Organization (WHO) and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending or reviewing a license. WHO Certificate requests should include the information listed in **Supplementary Information – Certificate of a Pharmaceutical Product Requests**. Please ensure that the Exporter’s Certification Statement is signed by a responsible official of the exporting firm and is enclosed with the certificate request. Enclose labels for each product.
2. If the requested information on the application form is not provided by the exporting firm or if clarification is needed on the supplied information, the exporting firm will be contacted via telephone or FAX. If the exporting firm does not provide the necessary information within 48 hours, the request for certificates will be returned and will need to be resubmitted. You may enclose a completed UPS form and mailing supplies to expedite return of the Certificates. A certificate will be issued for each product.
3. Requests for certificates should be sent to:
Food and Drug Administration
Center for Veterinary Medicine
Division of Compliance (HFV-235)
7519 Standish Place
Rockville, MD 20855
(240-276-9227 or
CVMExportCertification@fda.hhs.gov – for inquiries)
4. Errors made by FDA during the preparation of export certificates will be corrected, at no cost to the applicant, within 45 days after issuance.
 - Errors made in the application, by the submitter, cannot be corrected. A new application must be submitted.
7. The fee for preparing and issuing a single certificate is \$175; 1st duplicate original \$155; and \$70 for each subsequent duplicate. Please do not include the fee payment with your requests; the exporting firm will be billed quarterly.

PLEASE NOTE: Making or submitting false statements on any documents submitted to FDA represents violations of the United States Code, Title 18, Chapter 47, Section 1001 with penalties including up to \$10,000 in fines and up to 5 years imprisonment.

Issuance of an Export Certificate for Approved Products or Certificate of Exportability will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate. Certificates issued by the FDA are solely for export purposes and may not be used for domestic advertising.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”