Form Approved: OMB No. 0910-0498; Expiration Date: 4/30/2024

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/oaa**. 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-234), 12225 Wilkins Avenue, MPN4 #133, Rockville, MD 20852. Please 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? ☐ Yes ☐ No

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

4. Billing and Shipping Account Information

Is the Billing Contact and Address the same as the applicant?

☐ Yes ☐ No *If no, please provide Billing Contact, Email address and Address below.*

Billing contact name	Address
Alternate Billing Email Address *(if not the same as requestor)*	
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) *(Enter either FDA Approval, Submission, License or New Drug Application Number, as applicable)*	Date of issue *(mm/dd/yyyy)*

Product-license holder	Address

Status of product license holder *(mark appropriate item(s))* ☐ Manufacturer ☐ Packager and/or Relabeler ☐ Neither

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

Applicant name	Address

Status of applicant *(mark appropriate item(s))*
☐ Manufacturer ☐ Packager and/or Relabeler ☐ Neither

For CVM unapproved biological drugs, mark the category that indicates why authorization is lacking *(mark appropriate item(s))*
☐ Not required ☐ Not requested ☐ Under consideration ☐ 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 *(if applicable)*	
Firm FDA Registration Number	Date of most recent inspection

Facility name (2)	Address
License number *(if applicable)*	
Firm FDA Registration Number	Date of most recent inspection

Facility name (3)	Address
License number *(if applicable)*	
Firm FDA Registration Number	Date of most recent inspection

Facility name (4)	Address
License number *(if applicable)*	
Firm FDA Registration Number	Date of most recent inspection

Do you want the manufacturing location(s) listed on the certificate?
☐ Yes ☐ No

8. Importing Countries *(list in columns)*	
9. Number of certificates requested: _____	

Department of Health and Human Services Food and Drug Administration	**EXPORTER'S CERTIFICATION STATEMENT** ***"CERTIFICATE OF A PHARMACEUTICAL PRODUCT"*** ***for CBER and CVM***

FIRM NAME

As a responsible official or designee authorized to represent and act on behalf of the facility named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the facility(s) and the products identified on the Supplementary Information are to the best of my knowledge in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations including the following:

1. All facilities that appear on the certificate are currently registered and each facility has listed each of its products identified for export as required by Section 510 of the Act and 21 CFR Part 207 or 607;
2. Each product(s) identified for export is legally marketed within the United States and is the subject of a Biologics License, NDA,or ANDA;
3. Each product(s) identified is not subject of an open recall or the subject of any current enforcement action initiated by FDA;
4. All manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process have been identified on the 3613b form;
5. The requesting facility and all facilities involved in the manufacturing process are operating in substantial compliance with Good Manufacturing Practices Regulation for the identified product(s); and
6. Each product(s) identified for export is being exported from the United States

I hereby make this certification of compliance statement for FDA with full knowledge that the making or submission of false statements represent violations of the United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to five years imprisonment.

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
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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 certifications 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 export certification issued.

General Instructions:

- The **"Certificate of a Pharmaceutical Product"** is an export certification that 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 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 requestor or if clarification is needed on the supplied information, the requestor will be contacted. If the requestor 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 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/oaa. 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.

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. 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-234)
   12225 Wilkins Avenue, MPN4 #133
   Rockville, MD 20852
   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.

5. 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.

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 Operations
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."