Form Approved: OMB No. 0910-0498; Expiration Date: 8/31/2021

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 No Changes

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

2. Section 1.0

Proprietary name and National Drug Code if available

Dosage form

3. Section 1.1

Active ingredient

Amount per unit dose

Is this product currently marketed in the United States? ☐ Yes ☐ No

Is the product licensed/approved to be placed on the market in the U.S.? ☐ 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 No Change

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

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

Billing contact name	Address
Alternate Billing Email Address *(if not the same as requestor)*	Phone number: Fax number:
~~Mail carrier name~~ Fedex or UPS label	~~Account number and/or Shipping Label~~

CBER instructions are on page 5. ***CVM instructions are on page 6.***

PSC Publishing Services (301) 443-6740 EF

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)* CVM will ask for date of approval instead
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))*~~ CVM will no longer ask ☐ 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~~ Firm Establishment Identifier (FEI)	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?~~ CVM will no longer ask ☐ Yes ☐ No	

8. Importing Countries *(list in columns)*	*No Changes*
9. Number of certificates requested: _____	**No Changes**

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 Application 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 Application 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 Application;
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

SIGNATURE	DATE

NAME AND TITLE

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.

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."