Form Approved: OMB No. 0910-0498; Expiration Date: 2/28/06

Department of Health and Human Services
Food and Drug Administration

SUPPLEMENTARY INFORMATION
CERTIFICATE OF A PHARMACEUTICAL PRODUCT

1. Requestor Information

Name	Address
Firm	
Telephone number	FAX number	Firm Tax ID code

2. Section 1.0

Proprietary name

Dosage form

3. Section 1.1

Active ingredient

Amount per unit dose

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.***

4. Section 2A.1 & 2A.2

Applicant name	Address
FDA product approval (AADA, ANDA, BLA/PLA, NADA, NDA)	Date of issue

Also, provide a copy of the approval letter as verification of the product license or NDA or NADA number and approval date.

5. Section 2A.3 or 2B.2

Status of Product license holder *(mark appropriate item(s))*:

☐ Manufacturer ☐ Packager and/or Relabeler ☐ Neither

6. Facilities involved in the manufacturing of the exported product *(a maximum of four facilities may be listed)*

Facility name (1)	Address
Liscense number *(if applicable)*	
Registration number	Date of most recent inspection
Facility name (2)	Address
Liscense number *(if applicable)*	
Registration number	Date of most recent inspection

CBER instructions begin on page 4. | ***CVM instructions begin on page 5.*** | ***CDER instructions begin on page 6.***

PSC Graphic Arts: (301) 443-1090 EF

6. Facilities involved in the manufacturing of the exported product *(continued)*

Facility name (3)	Address
Liscense number *(if applicable)*	
Registration number	Date of most recent inspection
Facility name (4)	Address
Liscense number *(if applicable)*	
Registration number	Date of most recent inspection

7. Section 2A.3.1

Do you want the manufacturing location(s) listed on the certificate?

☐ Yes ☐ No

8. Importing countries *(list in columns)*

9. Number of certificates requested: _____

10. Section 2B.3

For unapproved biological drugs, mark the category that indicates why authorization is lacking:

☐ Not required ☐ Not requested ☐ Under consideration ☐ Refused

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 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; and
- the product labeling provided with the Supplementary Information is a true and accurate representation of the product labeling approved by the FDA.

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

EXPORTER'S CERTIFICATION STATEMENT
"CERTIFICATE OF A PHARMACEUTICAL PRODUCT"
for CDER

The information, contained in this request for a Certificate of a Pharmaceutical Product, is true and accurate based upon the current approved application or other legal basis permitting marketing of the product. We acknowledge that any false or fictitious statements, made in the application, that are used by FDA to process the certificate, will be in violation of the United States Code Title 18, Section 1001.

AUTHORIZATION TO RELEASE STATEMENT

We authorize the Food and Drug Administration to release this information in the certificate format. I understand that we will be billed a fee for each certificate not to exceed $175.00. If you have any questions, or require additional information regarding this correspondence, please call me at _____ (phone number).

SIGNATURE	DATE

NAME AND TITLE

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 to Foreign Government"** is for the export of products legally marketed in the United States. Certificate requests should include the information listed in **Supplementary Information – Certificate to Foreign Government 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. Please ensure that the appropriate Exporter Certification Statements for Certificate to Foreign Government Requests for Human Cells, Tissues, and Cellular and Tissue-Based Products (procured prior to May 25, 2005, or on or after May 25, 2005) is signed by a responsible official of the exporting firm and is enclosed with the certificate request.

- The **"Certificate of Exportability"** is for the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of Sections 801(e) or 802 of the Act. Certificate requests should include the information listed in **Supplementary Information - Certificate of Exportability 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.

- 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.

- The **"Non-clinical Research Use Only Certificate** is for the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the Federal, Food, Drug and Cosemetic Act. Certificate requests should include the information listed in **Supplementary Information - Non-clinical Research Use Only Certificate 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.

- 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 PLA / BLA, NDA, PMA or 510(k) application or similar unapproved products 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 or FAX. 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 301-827-6201.

- 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
  1401 Rockville Pike, Attention: HFM-624
  Rockville, MD 20852-1448

  or via FAX at 301-594-0940

- 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.

- You may enclose a completed FEDEX form 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 Export Certificate to Foreign Governments is for the export of products legally marketed in the United States. An application form must be completed and signed. The form is to be completed by the responsible head or designee of the exporting firm. Please enclose labels for each product.

2. The Certificate of Exportability is for the export of products unapproved for distribution and sale in the United States. The requestor must meet the requirements of Section 801(e) of the Act.

3. 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.

4. 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 FEDEX form to expedite return of the Certificates. A certificate will be issued for each product.

5. Requests for certificates should be sent to:

   Kim Bell
   Center for Veterinary Medicine Division of Compliance (HFV-235)
   7519 Standish Place
   Rockville, MD 20855
   (240-276-9212- for inquiries)

6. The fee for preparing and issuing a single certificate is $175; 1st duplicate original $155 and $70 for each subsequent duplicate. No fee will be charged for animal food/feed products. Please do not include the fee payment with your requests; the exporting firm will be billed quarterly.

7. The instructions and applications will be available on the *CVM Home Page (www.fda.gov/cvm/export.certificate.htm).*

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.

Department of Health and Human Services
Food and Drug Administration

CERTIFICATE OF A PHARMACEUTICAL PRODUCT
APPLICATION INSTRUCTIONS (for CDER)

INTRODUCTION

The Food and Drug Administration has historically issued various types of certificates to firms exporting products to foreign countries. The Center for Drug Evaluation and Research (CDER) has revised its procedures for the issuance of Certificates of a Pharmaceutical Product (examples are attached) for the following types of requests:

- Drug products that are legally marketable in the US;
- Products not authorized for sale in the US which may be legally exported to foreign governments (Certificate of a Pharmaceutical Product for Export of an Unapproved Product under Sections 801(e) or 802 of the FD&C Act); and
- Foreign Manufacturer (products manufactured outside of the U.S.).

GENERAL INFORMATION

A separate application must be made for each drug product. However, before preparing your application, please consult with the importing country to determine exactly what type of information is being required for the certificate.

- Products approved with the same NDA number and the same dosage form, but with different potencies, can be processed on the same certificate.
- Foreign names for the drug products may be included and noted as "International Tradename" in the "Remarks" section of the certificate.
- DO NOT submit applications in binders or put the attachments in plastic sleeves.

Additional Information

To maintain conformity with the certificate format, additional information or statements must not exceed ***three*** lines of text. Text that exceeds three lines must be typed on a separate "8 ½ x 11" sheet of paper and will be attached to the certificate.

Attachments

All attachments must be sent in duplicate. For certificate requests, for more than one country, please provide the container label, package container, and package insert for each country as follows:

An application for **one** country requires **two** sets of attachments (one set for the certificate and one for our files).

- Requests for **two or more** countries require **one** set of attachments for each country, plus **one** additional copy for our files (e.g., for two certificates, provide three sets of attachments; one set for each certificate and one set for our files).
- Attachments must not exceed **five** pages per certificate.

Ribbons

The following colors are being used to designate the type of certificate requested:

- ***Red*** will be affixed to all (regular) Certificates of Pharmaceutical Product.
- ***Blue*** will be affixed to Certificates for Export of an Unapproved Products.
- ***Yellow*** will be affixed to Certificates with Foreign Manufacturing sites.

Fees

Under the FDA Export Reform and Enhancement Act of 1996, FDA is authorized to charge a fee for certificates issued within **20 calendar days** of receipt of an application. The fee, for each certificate, shall not exceed **$175.00**. ***Do NOT send payment with the application; invoices are issued quarterly***.

- Second certificate, for the same country, in the same application **$90.00**
- Third and subsequent certificates, for the same country, in the same application **$40.00**

Expiration Date

Certificates will expire **24** months from the date of notarization. After expiration, a new application must be submitted. Certificates cannot be reissued.

REQUIRED INFORMATION

An application for an export certificate ***must*** include, the following information:

Federal Tax Identification Number

To facilitate the billing process, the following information must be included in all certificate applications:

- Federal tax identification number
- Billing address and contact

Marketing Status in the exporting country (U.S.)

- Is the product currently marketed in the United States?
  Yes or **No**.

Certification of Exportation from the U.S. for Foreign Manufacturing Sites

Please include the following statement in the cover letter: *"We certify that (**Product Name**) is manufactured and/or packaged in (**Name***

***of Foreign Country**) and is exported from the United States*. Unless a product is sent from the U.S., directly to the requesting country, a Certificate of a Pharmaceutical Product (CPP) will not be issued.

Country of Destination

Certificate requests, for multiple countries, can be made in one application. A certificate will be issued for each country, but only one certificate number will be assigned per application.

US Tradename (the drug product's brand name) or Generic Name

- The trade or generic name on the product as it is marketed in the U.S.
- Labels with foreign tradenames must be accompanied by the U.S. equivalent.

Container Label(s)

- An original sample of the current product label, approved for marketing in the U.S., must be mounted on a plain sheet of 8½" x 11" paper. Loose, paper clipped, or labels in plastic sleeves will not be accepted. (***1 copy per certificate plus 1 copy for our files)***
- One label for each potency requested must be submitted. (***1 copy per certificate plus 1 copy for our files)***
- If the label is silk-screened onto the container, please send a copy of the silkscreen or the art layout of the label mounted on a plain sheet of 8½" x 11" paper. DO NOT send the container (e.g., bottles, tubes). (***1 copy per certificate plus 1 copy for our files)***
- To remain within the five-page attachment maximum, several container labels can be mounted on one sheet of paper. Labels can also be double mounted on both sides of the paper.

Package Container

- An original sample, of the current package container, must be mounted on a plain sheet of 8½" x 11" paper. If the package container is a box, collapse it before mounting. (***1 copy per certificate plus 1 copy for our files)***
- If the carton is bulky, please send the art layout of the container mounted on 8½" x 11" paper. (***1 copy per certificate plus 1 copy for our files)***

Package Insert

An original sample of the current package insert must be mounted on a plain sheet of 8½" x 11" paper. (***1 copy per certificate plus 1 copy for our files)***

NOTE: For OTC products, the product sample and promotional literature are no longer needed.

Name and Address of Manufacturing Facility, Including Zip Code

- Include the name of the manufacturing site, with a complete street address.
- Provide the registration number for the manufacturing facility.
- Provide a **brief** explanation, and/or documentation (e.g. FDA Form 356 H), if there have been any changes in the corporate structure or in the company name.

Marketing Authority

New drug and abbreviated new drug approval letters are considered to be the only "license" to market a drug product. If the product does not have an approval letter, provide the legal basis permitting marketing of the product. Over-the-Counter drugs and those with grandfathered status are marketed under OTC monographs and Compliance Program Guide (CPG 7132c.02), respectively.

NDA, ANDA, or AADA Approval Letter

- Copy of the *original* approval letter as verification of the NDA, ANDA, or AADA number, approval date, application holder, product name, dosage form, and potency of the drug product. ***If the NDA holder has changed, please provide the name of the new application holder***.
- Copy of ***supplemental*** approval letters for new dosage forms, new potencies, new indications, and Rx to OTC switches. DO NOT submit supplemental approval letters for new manufacturing sites or stability studies.

Over-the Counter (OTC)

- Provide the title and date of the applicable monograph. DO NOT attach a copy of the publication.

Grandfathered Status

- Provide a statement addressing the grandfathered status of the drug product.

Sections 801(e) and 802 of the Food, Drug and Cosmetic Act

- Export of unapproved drug products that are not authorized for sale in the U.S. may be legally exported to foreign countries under § 801(e) and 802 of the FD&C Act.
- A copy of the product formulation, to be attached to the certificate, must be included with the application.

Status of Product-license Holder

The product-license holder is the name of the company that owns the new drug or abbreviated new drug application. Please indicate, in the cover letter, the name of the **current** product-license holder of the NDA or ANDA. For purposes of complying with the WHO scheme, the product-license holder is classified as one of the following:

- Manufacturer
- Packager/Labeler
- Neither (Distributor)

Status of Applicant

The applicant is the name of the firm or person who submits an application for an export certificate. For purposes of complying with the WHO scheme, the applicant is classified as one of the following:

- Manufacturer
- Packager/Labeler
- Neither (Distributor)

Certification Statement

The information contained in this request for a Certificate of a Pharmaceutical Product is true and accurate and based upon the current approved application or other legal basis permitting marketing of the product. We acknowledge that any false or fictitious statements made in the application, which are used by FDA to process the certificate, will be in violation of the United States Code Title 18, Section 1001.

Product Identification Statement (required for unapproved products)

For certificate requests for unapproved drug products, a product identification statement must be included affirming that the company and the product to be exported are in compliance with applicable provisions of the Act as amended by the FDA Reform and Enhancement Act of 1996. This statement also identifies the provision of Sections 801 or 802 of the FD&C Act permitting export as follows:

> *We certify that the product to be exported is in compliance with the applicable provisions of § 801(e) and 802 of the Act as amended by the FDA Reform and Enhancement Act of 1996.*

Authorization to Release Information

Each application must include a statement authorizing release of the information contained in the certificate and attachment(s) as follows:

> *We authorize the Food and Drug Administration to release this information in the certificate format. I understand that we will be billed a fee for each certificate, not to exceed $175.00.*

ACTIVE PHARMACEUTICAL INGREDIENTS (API) and Excipients

The active pharmaceutical ingredient (API) is the bulk drug substance (raw material) that has not been processed into a final dosage form (e.g., tablet, capsule).

- Provide an original sample of the current bulk container label, for the API, mounted on a plain sheet of 8½ " x 11" paper.
- Export certificates are ***NOT*** issued for inactive ingredients (excipients).

INCOMPLETE APPLICATIONS

To obtain a certificate, all required information must be provided. An application with incomplete information, or improperly mounted labels, will be returned to the submitter.

CORRECTION OF ERRORS

- 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.

MAILING ADDRESS

Please include self-addressed return labels with your application and mail it to the following address. Please note that we are only able to accept FEDEX for overnight mailing of the export certificates.

Food and Drug Administration
Center for Drug Evaluation and Research
Export Certificate Program, HFD-323
Montrose Metro 2 Building
11919 Rockville Pike
Rockville, MD 20852

If additional information is needed, please call one of the members of the Export Certificate Team at the following telephone numbers:

1. Jocelyn Lewis ..... (301) 827-8983
2. Betty McRoy ..... (301) 827-8982
3. Scott Tokoli ..... (301) 827-8969
4. Roxana Newquist ..... (301) 827-8984

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the applicable address below.

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20857

Food and Drug Administration
Center for Drug Evaluation and Research (HFD-323)
11919 Rockville Pike
Rockville, MD 20852

Food and Drug Administration
Center for Veterinary Medicine (HFV-235)
Division of Compliance
7519 Standish Place
Rockville, MD 20855

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 control number.