August 4, 2003

Dear Sir or Madam:

The "Guidelines on the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce" was revised in 1997. As a result, the Center for Drug Evaluation and Research (CDER) revised its procedures for the issuance of Certificates for Pharmaceutical Products to firms that legally market drug products. Sections 801(e) and 802 of the Federal Food, Drug and Cosmetic Act (FD&C Act) provide for the issuance of Export Certificates for unapproved products, that are not authorized for sale in the United States, which may be legally exported to foreign governments.

Please find attached the revised *Certificate of a Pharmaceutical Product* application guidelines and instructions, which are required to submit requests for export certificates.

A copy of the FDA Export Reform and Enhancement Act of 1996 is available on the Web at the following site:

http://www.fda.gov/ora/import/impexp/ora_impexp_page.html.

If you have any questions or need additional information, please call the Export Certificate Team at the telephone numbers listed on page 8.

Sincerely yours,

Joseph C. Famulare, Director
Division of Manufacturing and Product Quality
Office of Compliance
Center for Drug Evaluation and Research

CERTIFICATE OF A PHARMACEUTICAL PRODUCT APPLICATION INSTRUCTIONS

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