July 22, 2002

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 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 complete export certificate requests. This document is available on the Internet at the following website:

http://www.fda.gov/cder/regguide.htm

A copy of the FDA Export Reform and Enforcement 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 Program, Import/Export International Drug Team at (301) 594-3150.

Sincerely yours,

William G. Nychis
Deputy Director
Division of Labeling and
Nonprescription Drug Compliance
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 801or 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.

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

Additional Information

To maintain conformity with the certificate format, additional information or statements must be limited to **one** line of text. Text that exceeds one line 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 requests.

Blue will be affixed to Certificates for Export of an Unapproved Product and for Foreign Manufacturers.

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:

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.

Marketing Authority (cont'd)

Sections 801 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 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

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

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

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 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 INGREDIENT (API)

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, cream, syrup).

Provide an original sample of the current bulk container label, for the API, mounted on a plain sheet of 8½ " x 11" paper.

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.

MAILING ADDRESS

Please include self-addressed return labels with your application and mail it to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Export Certificate Program, HFD-310
7520 Standish Place, Room 166
Rockville, MD 20855

If additional information is needed, please call (301) 594-3150.

EXAMPLE OF AN APPLICATION FOR A CERTIFICATE OF PHARMACEUTICAL PRODUCT

(APPLICANT'S LETTERHEAD)

Food and Drug Administration
Center for Drug Evaluation and Research
Certificate Program, HFD-310
7520 Standish Place, Room 166
Rockville, Maryland 20855

On behalf of **(firm name)**, I am requesting **(no. of certificates)** Certificate(s) of Pharmaceutical Product. The required information is provided below:

Country of destination:

US Tradename (brand name) or Generic Name:

Active Ingredient(s) (*quantitative formulation preferred*):

Container and Package Labeling: (*attached)*

Package Insert: (*attached*)

Name and Street Address of Manufacturing Facility, including Zip Code, and Registration #:

Registration #
ABC Pharmaceuticals
0000 Any Street
Anywhere, USA 11111

Status of product-license holder:

Status of applicant:

Marketing Authority: (*attached, if approval letter)*

Is this product actually on the market in the exporting country?

Approval Letter: ***(attached)***

If the product does not have an NDA, ANDA, or AADA number, please state legal basis permitting marketing of the drug product such as OTC monograph or "grandfather" status.

Tax Identification Number:

Billing Address and Contact:

Certification Statement:

The information contained in this request for a Certificate to Foreign Government 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, that are used by FDA to process the certificate, will be in violation of the United States Code Title 18, Section 1001.

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

Please contact me if you have any questions regarding this request on my direct line at **(phone number)**.

EXAMPLE OF AN APPLICATION FOR A CERTIFICATE OF PHARMACEUTICAL PRODUCT FOR EXPORT OF AN UNAPPROVED PRODUCT

(APPLICANT'S LETTERHEAD)

Food and Drug Administration
Center for Drug Evaluation and Research
Certificate Program, HFD-310
7520 Standish Place, Room 166
Rockville, Maryland 20855

On behalf of **(firm name)**, I am requesting **(no. of certificates)** Certificate(s) of Pharmaceutical Product for Exportability. The required information is provided below:

Country of destination:

US Tradename (brand name) or Generic Name:

Active Ingredient(s):

Container and Package Labeling: ***(If available, attached)***

Name and Address of Manufacturing Facility, including Zip Code, and Registration #:

Registration #
ABC Pharmaceuticals
0000 Any Street
Anywhere, USA 11111

Tax Identification Number:

Billing Address and Contact:

Status of Applicant:

Product Identification Statement:

We certify that the product(s) to be exported are in compliance with the applicable provisions of Section 801 or 802 of the Act as amended by the FDA Reform and Enhancement Act of 1996.

Certification Statement:

The information contained in this request for a Certificate to Foreign Government 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, that are used by FDA to process the certificate, will be in violation of the United States Code Title 18, Section 1001.

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

Please contact me if you have any questions regarding this request on my direct line at **(phone number)**.

United States Food and Drug Administration

Certificate of a Pharmaceutical Product

Certificate No.
Conforms to WHO format revised 10/1/97

Exporting Country: **United States of America**
Importing Country:

1. International or National Nonproprietary Names (if applicable) and dosage form:
1.1 Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): SEE ATTACHMENTS
1.2 Is this product **licensed** to be placed on the market for use in the exporting country? **NO - See Block B**
1.3 Is this product actually on the market in the exporting country? **Yes**

A	**B**
2A.1 Number of product-license and date of issue:	2B.1 Applicant for certificate (name and address):
2A.2 Product-license holder:	2B.2 Status of Applicant:
2A.3 Status of product-license holder	2B.3 Why is authorization lacking? not required **XXXX** not applicable under consideration refused
2A.4 Is an approved summary basis appended? **No**	2A.3.1 or 2B.2.1 Mfr:
2A.5 Is the attached product information complete and consonant with the license? **No**	**Remarks:**
2A.6 Applicant for certificate if different from the license holder (name and address):	The product is being marketed in the United States at this time; however, such Over-the-Counter drug products are marketed without prior clearance by this administration.

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**
3.1 Periodicity of routine inspection (years): Every 2 years per U.S.A. regulations
3.2 Has the manufacture of this type of dosage form been inspected: Yes
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? Yes, at time of inspection
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party? YES

Address of certifying authority: U.S. Food and Drug Administration
7520 Standish Place
Rockville, MD 20855, USA
Telephone: (301) 594-0063 Fax (301) 594-0165

Betty L. Jones, Deputy Director
Office of Compliance
Center for Drug Evaluation and Research

State of Maryland

Sworn and subscribed to before me this ____day of _____, 2002.

_____
Notary Public

This certificate expires 24 months from the date notarized.

United States Food and Drug Administration

Certificate of a Pharmaceutical Product

Export of an Unapproved Product

Certificate No.
Conforms to WHO format revised 10/1/97

Exporting Country: **United States of America**
Importing Country:

1. International or National Nonproprietary Names (if applicable) and dosage form:
1.1 Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): SEE ATTACHMENTS
1.2 Is this product **licensed** to be placed on the market for use in the exporting country? **NO - See Block B**
1.3 Is this product actually on the market in the exporting country? **No**

A	B
2A.1 Number of product-license and date of issue:	2B.1 Applicant for certificate (name and address):
2A.2 Product-license holder:	2B.2 Status of Applicant:
2A.3 Status of product-license holder	2B.3 Why is authorization lacking? not required **XXXX** not applicable under consideration refused
2A.4 Is an approved summary basis appended? **No**	2A.3.1 or 2B.2.1 Mfr:
2A.5 Is the attached product information complete and consonant with the license? **No**	**Remarks:**
2A.6 Applicant for certificate if different from the license holder (name and address):	The FDA certifies that this product may be legally exported pursuant to § 802 of the FD&C Act.

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**
3.1 Periodicity of routine inspection (years): Every 2 years per U.S.A. regulations
3.2 Has the manufacture of this type of dosage form been inspected: Yes
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? Yes, at time of inspection
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party? YES

Address of certifying authority: U.S. Food and Drug Administration
7520 Standish Place
Rockville, MD 20855, USA
Telephone: (301) 594-0063 Fax (301) 594-0165

Betty L. Jones, Deputy Director
Office of Compliance
Center for Drug Evaluation and Research

State of Maryland

Sworn and subscribed to before me this ____day of _____, 2002.

_____
Notary Public

This certificate expires 24 months from the date notarized.

United States Food and Drug Administration

Certificate of a Pharmaceutical Product

Export of an Unapproved Product

Certificate No.
Conforms to WHO format revised 10/1/97

Exporting Country: **United States of America**
Importing Country:

1. International or National Nonproprietary Names (if applicable) and dosage form:
1.1 Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): SEE ATTACHMENTS
1.2 Is this product **licensed** to be placed on the market for use in the exporting country? **YES - See Block A**
1.3 Is this product actually on the market in the exporting country? **Yes**

A	**B**
2A.1 Number of product-license and date of issue:	2B.1 Applicant for certificate (name and address):
2A.2 Product-license holder:	2B.2 Status of Applicant:
2A.3 Status of product-license holder **Manufacturer**	2B.3 Why is authorization lacking? not required / not applicable / under consideration / refused
2A.4 Is an approved summary basis appended? **No**	2A.3.1 or 2B.2.1 Mfr:
2A.5 Is the attached product information complete and consonant with the license? **Yes**	**Remarks:**
2A.6 Applicant for certificate if different from the license holder (name and address):	The FDA certifies that this product may be legally exported pursuant to § 801(e) of the FD&C Act.

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**
3.1 Periodicity of routine inspection (years): Every 2 years per U.S.A. regulations
3.2 Has the manufacture of this type of dosage form been inspected: Yes
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? Yes, at time of inspection
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party? YES

Address of certifying authority: U.S. Food and Drug Administration
7520 Standish Place
Rockville, MD 20855, USA
Telephone: (301) 594-0063 Fax (301) 594-0165

Betty L. Jones, Deputy Director
Office of Compliance
Center for Drug Evaluation and Research

State of Maryland Sworn and subscribed to before me this ____day of _____, 2002.

_____
Notary Public

This certificate expires 24 months from the date notarized.

United States Food and Drug Administration

Certificate of a Pharmaceutical Product

Foreign Manufacturer

Certificate No.
Conforms to WHO format revised 10/1/97

Exporting Country: **United States of America**
Importing Country:

1. International or National Nonproprietary Names (if applicable) and dosage form:
1.1 Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): SEE ATTACHMENTS
1.2 Is this product **licensed** to be placed on the market for use in the exporting country? **YES - See Block A**
1.3 Is this product actually on the market in the exporting country? **Yes**

A	B
2A.1 Number of product-license and date of issue:	2B.1 Applicant for certificate (name and address):
2A.2 Product-license holder:	2B.2 Status of Applicant:
2A.3 Status of product-license holder	2B.3 Why is authorization lacking? not required / not applicable / under consideration / refused
2A.4 Is an approved summary basis appended? **No**	2A.3.1 or 2B.2.1 Mfr:
2A.5 Is the attached product information complete and consonant with the license? **Yes**	**Remarks:** The FDA has no specific current knowledge of the CGMP's of this foreign manufactured product. For the current CGMP status contact the country of manufacturer. This FDA certification pertains to the product marketed in the United States.
2A.6 Applicant for certificate if different from the license holder (name and address):	

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **No for Foreign Manufacturer**
3.1 Periodicity of routine inspection (years): Every 2 years per U.S.A. regulations
3.2 Has the manufacture of this type of dosage form been inspected: Yes
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? Yes, at time of inspection
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party? YES

Address of certifying authority: U.S. Food and Drug Administration
7520 Standish Place
Rockville, MD 20855, USA
Telephone: (301) 594-0063 Fax (301) 594-0165

Betty L. Jones, Deputy Director
Office of Compliance
Center for Drug Evaluation and Research

State of Maryland

Sworn and subscribed to before me this ____day of _____, 2002.

_____
Notary Public

This certificate expires 24 months from the date notarized.