Department of Health and Human Services
Food and Drug Administration

REQUEST FOR CERTIFICATE OF A PHARMACEUTICAL PRODUCT FOR CDER PRODUCTS

GENERAL INFORMATION

Firms exporting FDA-regulated articles are often asked by foreign customers or foreign governments to supply a certification relating to articles subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other laws FDA administers. Section 801(e)(4)(A) of the FD&C Act, as amended by the FDA Export Reform and Enhancement Act of 1996 (Public Law 104-134) provides that FDA may issue certificates for food, drugs, animal drugs, and devices within 20 days of receipt of a request for such a certificate. FDA issues export certificates for approved or licensed drugs and for unapproved drugs that meet the requirements of Sections 801(e)(1) or 802 of the FD&C Act. Certificates of Pharmaceutical Product (CPPs), the only export certificate issued by CDER, are issued for drugs typically exported from the U.S. directly to the requesting country. CPPs conform to the format established by the World Health Organization (WHO) and are intended for use by importing countries when considering whether to license the product in question for sale in that country. CDER only issues CPPs for human drugs that it regulates. Certificates expire 24 months from the date of issuance, after which a new application must be submitted. Certificates cannot be reissued.

CPPs issued for drugs exported from the U.S. are printed on security paper and contain the signature of the authorized CDER Official, embossed federal seal, and ribbon. Different ribbon colors are used to designate the type of CPP issued, as follows:

- Red designates FDA-approved products, over-the-counter (OTC) products and homeopathic drugs;
- Blue designates unapproved products;
- Yellow designates drugs manufactured in foreign facilities; and
- Orange designates Active Pharmaceutical Ingredients (APIs).

Under Section 801(e)(4)(B) of the FD&C Act, FDA is authorized to charge a fee for CPPs issued within 20 days of receipt of an application, not to exceed $175.00. The fees are as follows:

- First certificate for the same country in the same application $175.00
- 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

PLEASE DO NOT send payment with the application; invoices are issued quarterly.

Send CPP Requests and supporting documents to the following address:

Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Export Certificate Program, 10903 New Hampshire Avenue, Building 51, Room 4249, Silver Spring, MD 20993-0002.

For inquiries about CPPs, please e-mail CDERExportCertificateProgram@fda.hhs.gov or call 301-796-4950.

1. Requestor Information

Name	Address
Firm	
Telephone number	E-mail address

2. Drug Information

Drug Proprietary name
Dosage form *(e.g. capsules, powder, drops)*

Instructions begin on page 5.

3. Active Ingredient Information

Active ingredient		
Amount per unit dose	FDA product listing number (e.g., NDC)	Is the product currently marketed in the United States? ☐ Yes ☐ No

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 and Address below.*

Billing contact name	Address
Firm Tax ID code	

5. Drug Marketing Information

FDA drug approval number (ANDA, BLA, NDA) or FDA OTC Monograph citation/title	Date of drug approval or OTC monograph ruling *(mm/dd/yyyy)*

Please provide a copy of the drug approval letter.
Also, please note that "licensed drug" refers to a drug with an FDA drug approval number.

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

6. Applicant for Certificate Information

Applicant for Certificate	Address
Status of the Applicant for Certificate *(mark appropriate item(s))* ☐ Manufacturer ☐ Packager and/or Relabeler ☐ Neither	For unapproved drugs and APIs, 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 three facilities and only one drug manufacturer may be listed per application.)*

Facility name (1) and role *(e.g., API manufacturer, labeler, drug manufacturer)*	Address
Firm FDA Registration Number *(FEI number and/or DUNS number)*	Date of most recent inspection

(Item 7 entry sets continued, next page)

7. Facilities Involved in the Manufacturing of the Exported Product *(Continued)*	
Facility name (2) and role *(e.g., API manufacturer, labeler, drug manufacturer)*	Address
Firm FDA Registration Number *(FEI number and/or DUNS number)*	Date of most recent inspection
Facility name (3) and role *(e.g., API manufacturer, labeler, drug manufacturer)*	Address
Firm FDA Registration Number *(FEI number and/or DUNS number)*	Date of most recent inspection

8. Importing Countries *(List in columns and indicate if multiple copies for a country are needed, please limit to 15 countries per application.)*	

9. Total number of certificates requested: _____

CERTIFICATION STATEMENTS *(Complete all that apply)*

EXPORTER'S CERTIFICATION STATEMENT

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

Signature	Date
Name and Title:	

AUTHORIZATION TO RELEASE STATEMENT

I 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 e-mail me at _____ (e-mail address).

Signature	Date
Name and Title:	

CERTIFICATION OF EXPORTATION FROM THE U.S. FOR FOREIGN MANUFACTURING SITES

for products manufactured in a country outside of the United States

I certify that _____
(Product Name)

is manufactured and/or packaged in _____
(Name of Foreign Country)

and is exported from the United States.

Signature	Date
Name and Title:	

CERTIFICATION OF EXPORTATION FROM THE U.S. FOR UNAPPROVED DRUG PRODUCTS

I certify that _____
(Product Name)

is intended for export and is in compliance with the applicable provisions of section 801(e) and section 802 of the FD&C Act, as amended by the FDA Reform and Enhancement Act of 1996.

Signature	Date
Name and Title:	

Department of Health and Human Services
Food and Drug Administration

CERTIFICATE OF A PHARMACEUTICAL PRODUCT
Application Instructions (for CDER)

General Information

- Before preparing your application, please consult with the importing country to determine exactly what type of information is required for the certificate.
- A US Tax Code/US Tax number is required to process your application.
- The "requestor" is the firm or person filling out the application. The "applicant" is the firm or person requesting the CPP. For example, a firm (applicant) may hire another firm (requestor) to fill out an application on its behalf.
- CDER recommends sending your application with confirmation of delivery receipt to ensure delivery.
- Provide a self-addressed return label with tracking information with your application to ensure delivery of the CPP.
- Do not submit applications in binders or place attachments in plastic sleeves.
- A separate application must be made for each pharmaceutical product.
- Multiple countries for each pharmaceutical product may be requested in one application.
- If requesting a CPP with more than one drug manufacturer, please submit separate applications for each drug manufacturer. You may include more than one labeler or packager on one application.
- Foreign names for the pharmaceutical products may be included and noted as "International Tradenames" in the remarks section of the CPP.
- Indicate clearly in a cover letter any special information regarding your application, for example, if you would like the full address of a manufacturing facility or shelf-life of the product included on the CPP.
- For container labels, please provide the actual label or a copy of the art layout. The label must be in color and legible. Do not include bottles or vials with your application.
- For package labels, please provide the actual package container (collapse box before mounting) or a copy of the art layout. The label must be in color and legible.
- An API is the bulk drug substance (or raw material) that has not been processed into a final dosage form (e.g., tablet, capsule). CDER does not issue CPPs for intermediates or inactive ingredients (also known as excipients).
- For API CPP requests, the CPP will list the drug's International Nonproprietary Name (INN) or National Nonproprietary name.
- Your application may be returned if the manufacturing facility is not registered and the pharmaceutical product is not listed pursuant to section 510 of the FD&C Act. Drug listing is required for approved drugs, OTC drugs, unapproved drugs, bulk APIs, and products for export only.
- Incomplete applications may be returned.
- FDA will not issue a CPP for products that do not meet the applicable requirements of the FD&C Act.
- Errors made by FDA during the preparation of CPPs will be corrected at no cost to the applicant, if requested within 45 days after issuance.
- Errors made in the application by the requestor cannot be corrected. A new application must be submitted.
- Issuance of a CPP for CDER-regulated drugs will not preclude regulatory action by FDA, if warranted, against products covered by the CPP.

CPP Requests for FDA Approved Drugs

- Complete Form 3613f (sections 1, 2, 3, 4, 5, 6, 7, 8 and 9).
- Provide a copy of the FDA approval letter and/or supplemental letter.
- For drug products under the President's Emergency Plan for AIDS Relief (PEPFAR), include a copy of the full or tentative approval letter.
- Provide a set of attachments for each country requested and an additional set for FDA records (e.g., a CPP request for 3 countries will require providing 4 sets of attachments with your application).
- You are required to provide the following attachments: FDA-approved container label, package label, and package insert.
- You may include additional documents for attachment such as a drug formulation page or other information required by the importing country.
- Attachments must not exceed 20 pages per CPP, be legible and in color, and fit on a 8-1/2" X 11" page. You may mount package inserts on the paper and use both sides of the paper.
- Complete and sign exporter's certification statement and authorization to release statement.
- Complete and sign certification statement for foreign manufacturing facilities, if applicable.
- Include self-addressed return labels and mailing supplies with your application.
- Mail application with the original signature (no photocopies).

CPP Requests for OTC Drug Products or Homeopathic Drugs

- Complete Form 3613f (sections 1, 2, 3, 4, 5, 6, 7, 8 and 9).
- Provide a set of attachments for each country requested and an additional set for FDA records (e.g., a CPP request for 3 countries will require providing 4 sets of attachments with your application).
- You are required to provide the following attachments: container label that complies with the requirements of the applicable OTC monograph.
- You may include additional documents for attachment, such as a drug formulation page or other information required by the importing country.

- Attachments must not exceed 20 pages per CPP, be legible and in color, and fit on a 8-1/2" X 11" page. You may use both sides of the paper.
- Complete and sign exporter's certification statement and authorization to release statement.
- Complete and sign certification statement for foreign manufacturing facilities, if applicable.
- Include self-addressed return labels and mailing supplies with your application.
- Mail application with the original signature (no photocopies).

CPP Requests for APIs

- Complete Form 3613f (sections 1, 3, 4, 6, 7, 8 and 9).
- Provide a set of attachments for each country requested and an additional set for FDA records (e.g., a CPP request for 3 countries will require providing 4 sets of attachments with your application).
- You are required to provide the following attachment: package or container label that complies with the labeling requirements of 21 Code of Federal Regulations (CFR) 201.122.
- You may include additional documents for attachment, such as a drug formulation page or other information required by the importing country.
- Attachments must not exceed 20 pages per CPP, be legible and in color, and fit on a 8-1/2" X 11" page. You may use both sides of the paper.
- Complete and sign exporter's certification statement and authorization to release statement.
- Complete and sign certification statement for foreign manufacturing facilities, if applicable.
- Complete and sign certification statement for unapproved drugs.
- Include self-addressed return labels and mailing supplies with your application.
- Mail application with the original signature (no photocopies).

CPP Requests for Unapproved Drugs

- Complete Form 3613f (sections 1, 2, 3, 4, 6, 7, 8 and 9).
- Provide a set of attachments for each country requested and an additional set for FDA records (e.g., a CPP request for 3 countries will require providing 4 sets of attachments with your application).
- You are required to provide the following attachments: container label and drug formulation page.
- You may include additional documents for attachment, such as ones containing other information required by the importing country.
- Attachments must not exceed 20 pages per CPP, be legible and in color, and fit on a 8-1/2" X 11" page. You may use both sides of the paper.
- Complete and sign exporter's certification statement and authorization to release statement.
- Complete and sign certification statement for foreign manufacturing facilities, if applicable.
- Complete and sign certification statement for unapproved drugs.
- Include self-addressed return labels and mailing supplies with your application.
- Mail application with the original signature (no photocopies).

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 Chief Information Officer
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."