FDA Export Certificate Program for Human Drugs Overview

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U.S. Food and Drug Administration

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Overview

- What are export certificates?
- Why are export certificates issued?
- Types of export certificates issued by CDER
- Legal authority to issue export certificates
- How to request an export certificate from CDER
- CDER eCATS benefits
- CDER eCATS application and review process
- Resources

What are Export Certificates?

A document prepared by FDA containing information about a product's regulatory or marketing status.

Under section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), upon request, FDA is required to issue certificates for human drugs and biologics, animal drugs, and devices that meet the applicable requirements of the FD&C Act.

Why CDER Issues Export Certificates?

- Issued to provide information about the drug's U.S. marketing status and the manufacturer's compliance with quality manufacturing requirements.

- Requested by companies to help them qualify their product for importation into a foreign market or to receive approval, licensing or registration of the drug abroad.

What Legal Authority Does CDER have to issue Export Certificates?

Under Section 801(e)(4)(B) of the FD&C Act, the FDA is authorized to issue within 20 business days of receipt of an application.

Under Section 801(e)(4)(B) of the FD&C Act, the FDA is authorized to charge a fee for CPPs issued within 20 business 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

Export Certificates of Pharmaceutical Product (CPP)

- Only issues CPPs for human drugs exported from the United States directly to the requesting country.
- Follows the format established by the World Health Organization (WHO).
- CPPs expire 24 months from the date of issuance.
- CPPs are printed on security paper and contain the signature of the authorized CDER Official, embossed federal seal and ribbon.
- Each CPP issued includes only one drug product, one dosage form, one dosage strength, one country, and one finished dose manufacturer.

What types of CPPs Does CDER Issue?

APPROVED

RED Ribbon, Attachments and Seal

United States Food and Drug Administration

Center for Drug Evaluation and Research

10903 New Hampshire Ave, Silver Spring, MD 20993, United States of America

CDERExportCertificateProgram@fda.hhs.gov - Telephone (301) 796-4950

Certificate of a Pharmaceutical Product - Approved Drug Product

Certificate Number: Certificate Issue Date: Certificate Expiration Date:

Importing Country: Exporting Country:

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form:
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred):
1.2	Is this product licensed to be placed on the market for use in the exporting country?
1.3	Is this product actually on the market in the exporting country?
2.A.1	Product license number & date of issue:
2.A.2	Product license holder name & address:
2.A.3	Status of Product license holder:
2.A.3.1	Manufacturer name & address:
2.A.4	Is a summary basis for approval appended?
2.A.5	Is the attached product information, complete and consonant with the license?
2.A.6	Applicant name & address for certificate (if different from the license holder):
2.B.4	Remarks:
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
3.1	Periodicity of routine inspections (years):
3.2	Has the manufacture of this type of dosage form been inspected?
3.3	Do the facilities and operations conform to GMPs as recommended by the WHO? (GMPs including 21 Code of Federal Regulations parts 210, 211, or ICH Q7A):
3.4	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party?

, Branch Chief
Drug Import/Export Compliance Branch
Division of Imports, Exports & Recalls
Office of Drug Security, Integrity & Response

This certificate conforms to the format recommended by the World Health Organization format revised October 1, 1997. Website: www.who.int

F O R E I G N MANUFACTURER

YELLOW Ribbon, Attachments and Seal

U N A P P R O V E D

BLUE Ribbon, Attachments and Seal

United States Food and Drug Administration

Center for Drug Evaluation and Research

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Certificate of a Pharmaceutical Product - Unapproved Drug Product

Certificate Number: | Certificate Issue Date: | Certificate Expiration Date

Importing Country: | Exporting Country:

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form:
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred):
1.2	Is this product licensed to be placed on the market for use in the exporting country?
1.3	Is this product actually on the market in the exporting country?
2.B.1	Applicant for certificate name & address:
2.B.2	Status of Applicant:
2.B.2.1	Manufacturer name & address:
2.B.3	Why is marketing authorization lacking?
2.B.4	Remarks:
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
3.1	Periodicity of routine inspections (years):
3.2	Has the manufacture of this type of dosage form been inspected?
3.3	Do the facilities and operations conform to GMPs as recommended by the WHO? (GMPs including 21 Code of Federal Regulations parts 210, 211, or ICH Q7A)
3.4	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party?

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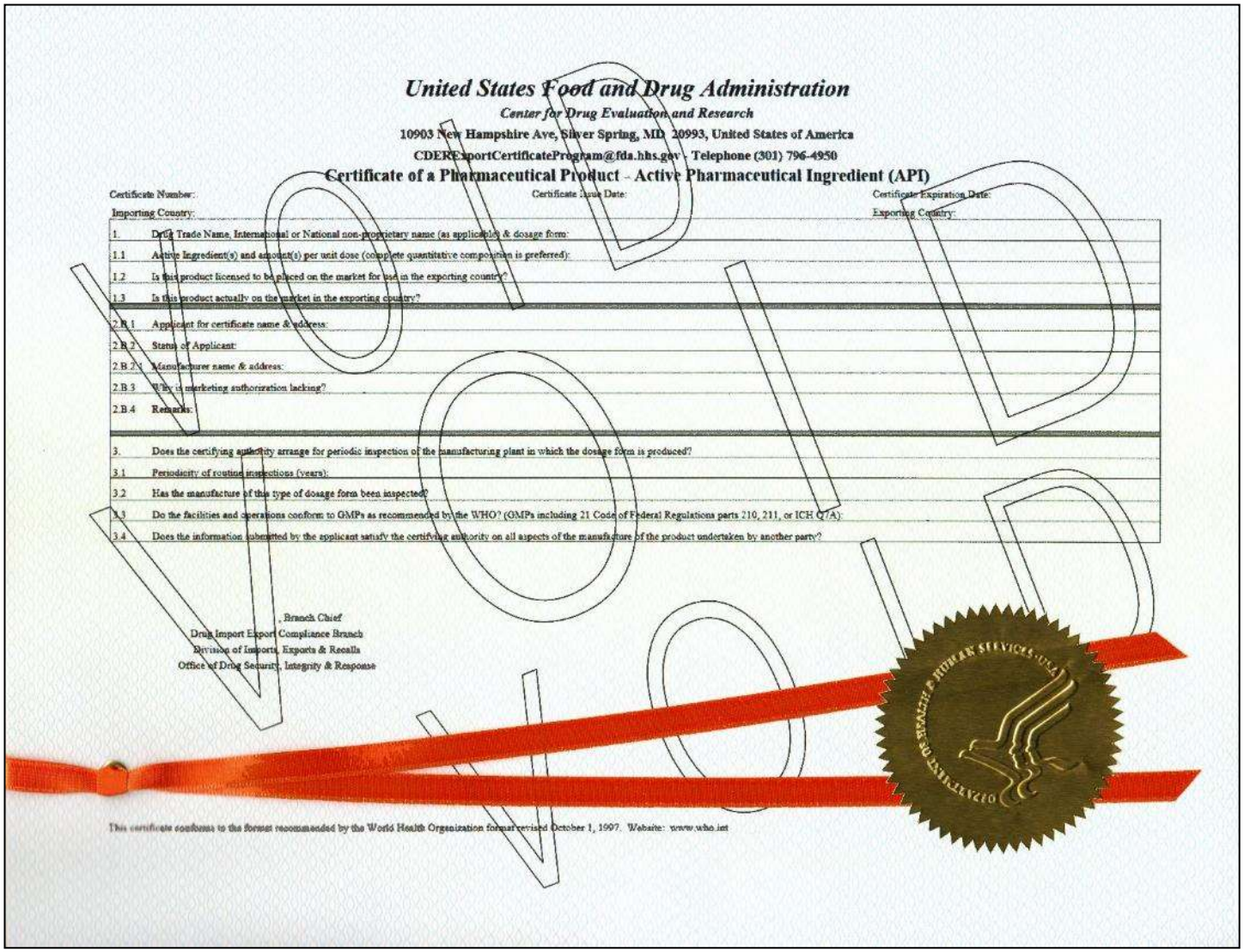
ACTIVE PHARMACEUTICAL INGREDIENT (API)

ORANGE Ribbon, Attachments and Seal



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Certificate of a Pharmaceutical Product - Active Pharmaceutical Ingredient (API)

Certificate Number: Certificate Issue Date: Certificate Expiration Date:

Importing Country: Exporting Country:

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form:
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred):
1.2	Is this product licensed to be placed on the market for use in the exporting country?
1.3	Is this product actually on the market in the exporting country?
2.B.1	Applicant for certificate name & address:
2.B.2	Status of Applicant:
2.B.2.1	Manufacturer name & address:
2.B.3	Why is marketing authorization lacking?
2.B.4	Remarks:
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
3.1	Periodicity of routine inspections (years):
3.2	Has the manufacture of this type of dosage form been inspected?
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Challenge Question 1

CDER issues the following combinations of CPPs and ribbon colors:

A. Approved-red ribbon, Foreign Manufacturer-yellow ribbon, Unapproved-blue ribbon and Active Pharmaceutical Ingredient-orange ribbon

B. Unapproved-yellow ribbon, Approved-green ribbon, Foreign Manufacturer-pink ribbon and Active Pharmaceutical Ingredient- black ribbon

C. Unapproved-orange ribbon, Foreign Manufacturer-blue ribbon, Approved-yellow ribbon and Active Pharmaceutical Ingredient-red ribbon

D. All of the above

E. None of the above

How to Request a Certificate of Pharmaceutical Product (CPP)?

U.S. Department of Health and Human Services

FDA FURLS

CDER eCATS

CDER Export Certification Application and Tracking System

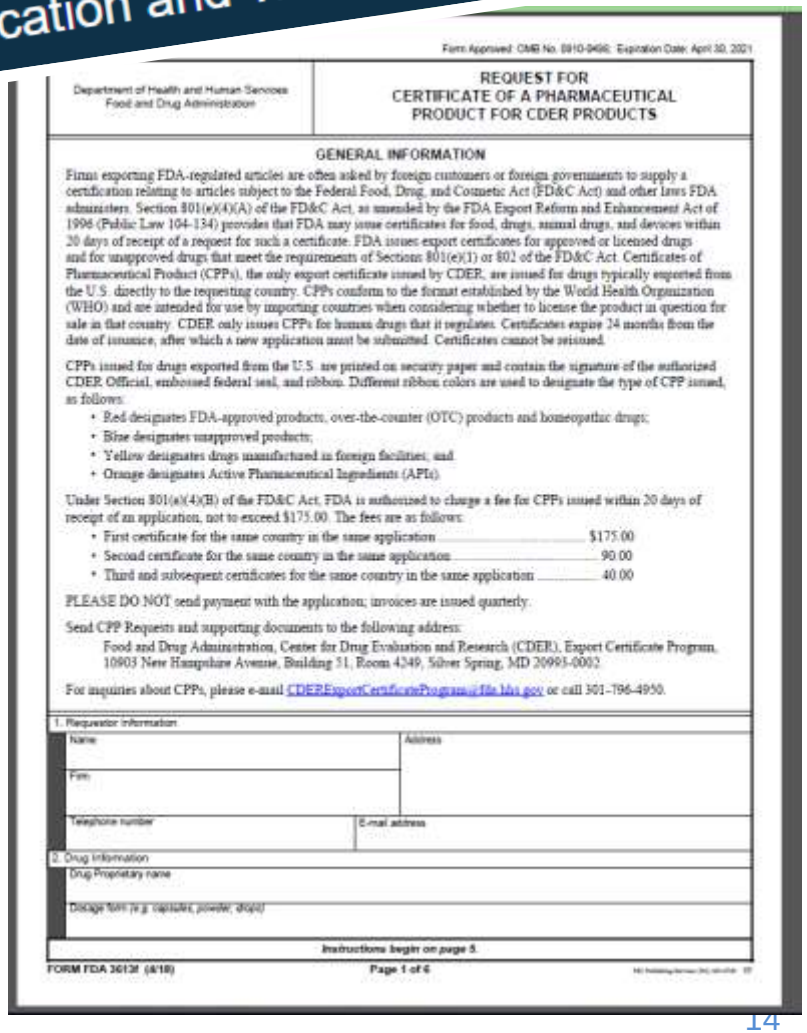
FDA

CDER eCATs

Electronic submission

Form 3613f

Paper Application



Form Approved: OMB No. 0910-0498; Expiration Date: April 30, 2021

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 CDERExportCertificatesProgram@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.

FORM FDA 3613f (4/19) Page 1 of 6

Benefits of CDER eCATS

Guided step-by-step instructions and real-time validation of data.

Email notification of the status throughout the entire application process.

Email communication between FDA and applicant to resolve potential issues/concerns.

Faster delivery of CPP application versus mailing the application.

CDER eCATs Application Process

General Application Information

- **Per Application request**

- ✓ One drug product
- ✓ One dosage form
- ✓ One dosage strength
- ✓ One finished dose manufacturer [or active pharmaceutical ingredient (API) manufacturer]

- ✓ Applicant may select a MAXIMUM of fifteen (15) countries per application
- ✓ If additional countries are needed, submit a new application

Any field with an asterisk (*) indicates a required field.

Application Information

- **Have the following information available before applying for CPP:**
  - ❑ FEI numbers for all manufacturing facilities
  - ❑ FDA product listing number (NDC number)
  - ❑ Tax ID code or EIN number
  - ❑ FDA drug approval number and approval date (if applicable)
  - ❑ OTC monograph citation and approval date (if applicable)

- **Have the following information available via PDF for upload before applying for CPP:**
  - ❑ Color Labels of drug item
  - ❑ Return Postage label
  - ❑ Drug Approval document (if required)
  - ❑ Package insert (if required)
  - ❑ Drug Composition/Formulation (if required)
  - ❑ Other Attachments (if required by the importing country)

Application Information

- **Certificate of Pharmaceutical Product (CPP) Delivery Information**
  - Upload self-paid return shipping label
  - Receiver can only be a **U.S. address**
  - Return label can only be **UPS** and **FEDEX**

- **Product-Specific Information**
  - Include proprietary name (if applicable), active ingredient, unit dose and dosage form

- **Finish Dosage Manufacturer Information**
  - Listed in section 2.A.3.1 on CPP
  - Can only list one finished dose manufacturer per CPP
  - If CPP is for API, API manufacturer will be listed in section 2.A.3.1

- **Additional Manufacturers**
  - May be included in the remarks section or as an attachment
    - API manufacturer
    - Packager
    - Re-labeler
    - Testing manufacturer

Application Information

- **Labeling and Attachments**
  - Upload inner label.
  - Upload outer label (if no outer label, upload inner label)
  - Upload package insert (if applicable)

- **Additional Attachments (e.g., formulation page)**
  - Inclusion of additional attachments not required as part of application is at the discretion of CDER

- **Remarks**
  - Inclusion of remarks not required as part of application is at the discretion of CDER

Application Review Process

Review Process

- **Manufacturing Facilities**

  - ✓ Facility name and location
  - ✓ Facility inspection history
  - ✓ Facility type

- **Product Information**

  - ✓ Product type
  - ✓ Product marketing status
    - Approval number
    - BLA license number
    - Monograph

Review Process

- **Labeling**
  - ✓ Must be legible
  - ✓ Most recent label must be listed in the Electronic Drug Registration and Listing System (eDRLS)
  - ✓ For API applications, **the non-proprietary name must be prominent**

- **Remarks**
  - ✓ Limited space
  - ✓ CDER has standard remarks for certain CPP types that will be printed on the CPP
  - ✓ CDER will consider inclusion of applicant remarks if appropriate and if space available

General Application Information/Tips

Our review compares your application information with information in FDA databases.

Please make sure your drug approval documentation is current.

Drugs manufactured in the U.S. must be listed and all manufacturing facilities must be registered in the Electronic Drug Registration and Listing System (eDRLS).

CDER does not make determinations of cGMP compliance for facilities.

Three days to respond to Return for Action Letters.

Challenge Question 2

If a labeling submitted by the applicant does not match the labeling found in FDA databases, which of the following is true?

A. CDER will issue the CPP and ask the applicant to send updated labeling as soon as possible.

B. CDER will cancel the application.

C. CDER will return the application to applicant so that it can be modified and resubmitted.

D. All of the above

E. None of the above

Application Status

Received	An application has been received by CDER.
Ready to Review	Data pull from relevant CDER databases has occurred.
Under Review	CDER data retrieval process is complete and application is ready to be reviewed.

Application Status

Ready to Print	Application is ready for printing.
Printing in Progress	Certificate is printed and prepared for mailing.
Completed	CDER has completed the review process and certificate has been mailed.

Application Status

Cancelled	Application is cancelled per internal/external reasons.
Return for Action	Application requires modification.
Rejected	Application information does not align with CDER's authority to issue a CPP.

Application Status Email Notification

Received

Under Review

Printing in Progress

Completed

Email notification will be sent when the application status changes

Cancelled

Rejected

Return for Action

Challenge Question 3

You apply for a CPP. You receive an email notification through CDEReCATS that the review process is complete.

A. This means that you must make a correction and submit a new application.

B. This means that the export certificate review is complete and that the CPP has been printed and mailed.

C. Your application review process is on hold until further notice.

D. All of the above

E. None of the above

Resources

If you have questions regarding the online CDER eCATS application process, please email the CDER Export Certificate Program at:

CDERExportCertificateProgram@fda.hhs.gov

or refer to our website at:

https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-exports

U.S. FOOD & DRUG
ADMINISTRATION

FDA Export Certificate Program for Human Drugs Overview