Export Certificates

Center for Drug Evaluation and Research

CDER eCATS
CDER Export Certification Application and Tracking System

API
Active Pharmaceutical Ingredient
ONLINE ACCOUNT ADMINISTRATION (OAA)

NAVIGATE to FDA ONLINE ACCOUNT ADMINISTRATION (OAA)

URL
https://www.access.fda.gov/oaa

If the user has an existing online account:
ENTER ACCOUNT ID and PASSWORD
CLICK the box “I Understand”
CLICK “Login”

If the user does not have an existing online account:
SELECT “Create New Account”
Create New Account

You cannot use your Food Facility or Tobacco Registration and Product Listing account to register a Medical Device establishment and vice versa. You must create a separate account to register your Medical Device establishment, Food Facility and Tobacco Registration and Product Listing.

Step 1: Select Applicable Center for Account Creation

- Center for Biological Evaluation & Research (Export Certification Application and Tracking)
- Center for Device & Radiological Health (Device Registration and Listing / Export Certification Application and Tracking)
- Center for Drug Evaluation & Research (Export Certification Application and Tracking)
- Center for Food Safety & Applied Nutrition (FFRM, FSMA, LACF, SEPRM, SFCN, NDIN, PNSI etc. / Certification Application Program)
- Center for Tobacco Products (Tobacco Registration and Product Listing)

CLICK CENTER FOR DRUG EVALUATION & RESEARCH (Export Certification Application and Tracking)
Enter ALL REQUIRED DATA

**Create New Account**

You cannot use your Food Facility or Tobacco Registration and Product Listing account to register a Medical Device establishment, and vice versa. You must create a separate account to register your Medical Device establishment, Food Facility and Tobacco Registration and Product Listing.

- **Step 1: Select Applicable Center for Account Creation**
  - Center for Epidemiological Evaluation and Response
  - Center for Devices and Radiological Health
  - Center for Drug Evaluation and Research
  - Center for Food Safety and Applied Nutrition
  - Center for Tobacco Products

- **Select the systems you will need to access**
  - COH Import Certification Application and Tracking System

- **Step 2: Enter Your Account Information**

  **Account Information**
  - First Name
  - Middle Initial (Optional)
  - Last Name / Surname
  - Job Title
  - Company Name
  - Phone Number
  - Country / Area
  - Phone Number
  - Extension
  - Fax Number
  - E-mail Address
  - Confirm E-mail Address

  **Physical Address**
  - Address Line 1
  - Address Line 2 (Optional)
  - City
  - State / Province / Territory
  - Zip Code (Postal Code)

  **Extra Information**
  - Password
  - Confirm Password
  - Secret Question 1
  - Secret Question 2
  - Secret Question 3
  - Secret Question 4
  - Secret Question 5

  **Additional Information**
  - Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

  **Understand**
  - Yes
  - No
**ONLINE ACCOUNT ADMINISTRATION (OAA)**

**Account Information**
- First Name
- Middle Initial
- Last Name / Surname
- Title
- Company Name
- Phone Number
- FAX Number
- E-mail Address
- Secret Question 1
- Secret Answer 1
- Secret Question 2
- Secret Answer 2
- Secret Question 3
- Secret Answer 3

**Physical Address (Business) of Account Holder**
- Address Line 1
- Address Line 2
- City
- State / Province / Territory
- Zip Code (Postal Code)
- Country / Area

Click the **Submit** button to create an account, or click the **Modify** button to return and edit your account profile.

**REVIEW ALL REQUIRED DATA BEFORE SUBMISSION**
You have successfully created an account.
Your account ID is

YOU WILL NEED TO REMEMBER YOUR ACCOUNT ID AND PASSWORD TO LOGIN TO THE SYSTEM IN THE FUTURE.
Dear FDA Industry Systems Account User,

Please do not reply to this notification/e-mail.

You have created a new account. The Account ID is
Thank you for using the FDA Industry Systems website.

If you need further assistance, please go to
Export Certificates

Center for Drug Evaluation and Research

CDER eCATS
CDER Export Certification Application and Tracking System

API
Active Pharmaceutical Ingredient
Each application entered must be for:
- A single API (e.g., Acetaminophen USP)
- A single dosage form (e.g., powder)
- A single amount/dose (e.g., 5 grams)
- A single API manufacturer
- Up to MAXIMUM of fifteen (15) countries

Each certificate issued will have an unique certificate number (each country will have a single certificate)

Any field with an asterisk (*) indicates a required field. You will not be able to proceed without filling out that field.

If this office RETURNS your application to you due to discrepancies, you will have 3 business days to resolve and resubmit your application in CDEReCATs. The return notification will be sent via email.

If you do not resolve discrepancies within 3 business days, your application will be cancelled.
### APPLICATION INFORMATION

- **Have the following information available before applying for CPP:**
  - FEI numbers for all manufacturing facilities
  - FDA product listing number (NDC number)
  - Firm Tax ID code or EIN number

- **Have the following information available via PDF for upload before applying for CPP:**
  - Legible **Color Labels** of drug item
  - **Return Postage** label (USP or FEDEX)
  - Drug **Composition/Formulation** (if required)
  - **Any Other Attachment** required by the importing country (if required)
If you have questions regarding the online CDEReCATS application process, please email the CDER Export Certificate Program at: CDERExportCertificateProgram@fda.hhs.gov

For more information on the CDER Export Certificate Program, Please visit: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm (under “Drug Exports”)
NAVIGATE and LOG IN to the Food and Drug Administration (FDA) ONLINE ACCOUNT ADMINISTRATION (OAA) webpage

URL: https://www.access.fda.gov/oaa
Click "CDER Export Certification Application and Tracking System"

Once you have selected CDER Export Certification Application & Tracking System, the system will take you to the CDEReCATS Main Menu.
**GENERAL NAVIGATION BUTTONS**

**Back**
Go back one screen and continue entering application information. Information entered on the current screen will **NOT** be saved.

**Save & Exit**
Information entered up to this point will be saved. The system will provide you with an application number and your application will be in a “Draft” status in the system for **30 days**. After 30 days the application will be deleted from the system. When you log into the CDEReCATS system, any applications that are in a “Draft” status will be displayed after selecting the “Enter New Application” option from the main menu.

**Continue**
Go to the next screen and continue entering the application form.

**Cancel & Start Again**
The system will return you to the screen where you selected the Certificate Type. Any information you have entered will **NOT** be saved.
MAIN MENU

Enter New Application
To start a new application

Modify Application
To edit or change an existing saved application

Search Application
To look at existing applications and to clone applications
GENERAL INFORMATION

Before preparing your application, please consult with the importing country to determine exactly what type of information is required for the certificate.

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.

Provide a self-addressed return label with tracking information with your application to ensure delivery of the CPP.

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 the remarks section 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.

Clearance of a CPP for CDER-regulated drugs will not preclude regulatory action by FDA, if warranted, against products covered by the CPP.
GENERAL/CONTACT 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 (FDCA) and other laws, FDA administrator Section 801(a)(1) of the FDCA Act, as amended by the FDA, the Reform Act and Enhancement Act of 1995 (Public Law 104-134) provides that FDA may issue certificates for lead, 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 510 or 580 of the FDCA 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 exporting 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:

- Black designates FDA-approved products, over-the-counter (OTC) products that follow an FDA monograph,
- Blue designates unapproved products,
- Yellow designates drugs manufactured in foreign facilities, and
- Orange designates Active Pharmaceutical Ingredients (APIs).

Under Section 801(a)(1)(B) of the FDCA 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 $100.00
- Third and subsequent certificates for the same country in the same application $45.00

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 Certification Program, 10901 New Hampshire Avenue, Building 8, Room 833, Silver Spring, MD 20993-8000.

For inquiries about CPPs, please email CDEREExportCertificateProgram@fda.hhs.gov or call 301-796-4850.

Registration and Listing
Section 510 of the Federal Food, Drug, and Cosmetic Act (the FDCA Act) requires every person who owns or operates any establishment in the United States engaged in the manufacture, preparation, propagation, compounding, or processing of drugs, unless exempt under section 510(B) of the FDCA Act, to register their establishment(s) and submit a listing of every drug and device in commercial distribution to the FDA. Failure to register or list as required by section 510 is a prohibited act under section 301(g) of the FDCA Act. Expanding a drug without registering and listing may result in FDA enforcement action.

An introduction to the FDCA Act can be found at http://www.ohiogov.com/revisions/federal/foodanddrugs/contents.html.

Registration and listing instructions can be found at www.fda.gov/cder/certification.

Output Good Manufacturing Practices
Certificate of Pharmaceutical Products (CPPs) generally attest to compliance with the current good manufacturing practices (cGMPs) of manufacturing facilities. Therefore, one requirement for a CPP to be issued is that the manufacturing facility must operate in compliance with cGMP (unless the particular exported product is not affected by the specific cGMP deficiencies). The cGMP regulations can be found but not limited to the 21 Code of Federal Regulations (CFR) part 210, part 211, part 223, part 225, and parts 210 and 211. The Title 21 CFR can be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfm/def/cfdefindex.cfm.
CERTIFICATE TYPE SELECTION

Please select the certificate type you are applying for. If you are unsure as to which one to select, please click on the ? for a description of each certificate type.

* - This field is required.

*Certificate Type

- Please Select-

- Please Select-

- Certificate of Pharmaceutical Product (CPP)

- Foreign Exported Certificate of Pharmaceutical Product

- Simple Notification

Back to Main Menu  Back  Continue

To return to CDEReCATS MAIN MENU

To proceed to GENERAL/CONTACT INFORMATION

To proceed to SECTION 1A – APPLICANT INFORMATION

SELECT “Certificate of Pharmaceutical Product (CPP)”
Most of the fields in section one of the CPP application process are automatically populated based on the information from your Online Administration Account (OAA) and cannot be edited in CDEReCATS.
APPLICANT ADDRESS VERIFICATION

This address has been verified. However, minor modifications were made to the information you entered. Please indicate whether you wish to accept the validated address or continue to use the existing address you entered.

YOUR ADDRESS
Address Line 1: 10903 New Hampshire Avenue
Address Line 2: Building 51
City: Silver Spring
State: Maryland
Zip Code: 20993
Country: UNITED STATES

VALIDATED ADDRESS
Address Line 1: 10903 New Hampshire Ave Bldg 51
Address Line 2:
City: Silver Spring
State: Maryland
Zip Code: 20993-0002
Country: UNITED STATES

* - These fields are required.

<Select>
- Continue to use the existing address
- Accept validated address and continue

SELECT “Continue to use the existing address” or “Accept validated address and continue”
SECTION 1B – BILLING INFORMATION

If the billing address is the same as the Applicant’s address:

SELECT “Yes”

ENTER Tax ID Code or EIN number

To return to SECTION– APPLICANT ADDRESS VALIDATION
To proceed to SECTION 1C– DELIVERY INFORMATION
Cancel the current activity and start the application process from the beginning
If the billing address is **different** from the Applicant’s address:

- **SELECT “No”**
- **ENTER Billing name and address**
- **ENTER Tax ID Code or EIN number**

To return to **SECTION– APPLICANT ADDRESS VALIDATION**

To proceed to **SECTION 1C– DELIVERY INFORMATION**

Cancel the current activity and start the application process from the beginning
SECTION 1C – DELIVERY INFORMATION

SELECT “FEDEX” or “UPS”

CLICK “Browse” button to locate the return label and CLICK “Upload” button to attach the return label (PDF) to the application.

*Method of Delivery –Please Select–

*Return Label

Back | Continue
Cancel & Start Again

To return to SECTION 1B– BILLING INFORMATION

To proceed to SECTION 2A– GENERAL PRODUCT INFORMATION

Cancel the current activity and start the application process from the beginning

CLICK “Browse” button to locate the return label and CLICK “Upload” button to attach the return label (PDF) to the application.
**SECTION 2A – GENERAL PRODUCT INFORMATION**

- **Select “No”**
- **Select “Active Pharmaceutical Ingredient (API)”**
- **Select “Yes” or “No”**

**U.S. License**
*Is this product licensed or approved to be placed on the market for use in the United States?*

--Please Select--
- Approved Drug Product
- Over-the-Counter Drug (OTC)
- **Active Pharmaceutical Ingredient (API)**
- Unapproved Drug Product

**Product on the market in USA?**
*Is this product actually on the market in the United States?*

**Back**
**Continue**
**Cancel & Start Again**

To return to **SECTION 1C– DELIVERY INFORMATION**
To proceed to **SECTION 2B– PRODUCT SPECIFIC INFORMATION**

**Cancel & Start Again**
Cancel the current activity and start the application process from the beginning
SECTION 2B – PRODUCT SPECIFIC INFORMATION

**ENTER FDA Product Listing Number (NDC number)**

*These fields are required.*

- **FDA Product Listing Number (e.g., NDC)**
  - [Input field]

- **What is the Applicant Status?**
  - [Input field]

- **Why is marketing authorization lacking?**
  - [Input field]

Acceptable NDC configurations: 4-4-2, 5-3-2 or 5-4-1

- **Back**
- **Continue**
- **Cancel & Start Again**

---

To return to **SECTION 2A – GENERAL PRODUCT INFORMATION**

To proceed to **SECTION 2D – PRODUCT CHARACTERISTICS**

Cancel the current activity and start the application process from the beginning
ENTER Active Ingredient name (Nonproprietary name)

ENTER the Amount and SELECT Dosage Form and Unit Dose from dropdown list

To return to SECTION 2B – PRODUCT SPECIFIC INFORMATION

To proceed to SECTION 3B – ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURER

Cancel the current activity and start the application process from the beginning
If you SELECT “Yes,” certain API Manufacturer Information will automatically populate.

If you SELECT “No,” ENTER API Manufacturer Information.

ENTER Registration Number (optional)

ENTER FEI Number

To return to SECTION 2D– PRODUCT CHARACTERISTICS

To proceed to SECTION 3C– PACKAGER/RELABELER

Cancel the current activity and start the application process from the beginning.
If you SELECT “Yes,” certain Packager/Relabeler Manufacturer Information will automatically populate.

If you SELECT “No,” ENTER Packager/Relabeler Manufacturer Information.

SELECT “Yes” or “No”
SECTION 3 – SUMMARY

CDER eCATS
CDER Export Certification Application And Tracking System

To return to SECTION 3C – PACKAGER/RELABELER

To proceed to SECTION 4A – IMPORTING COUNTRY LIST

Cancel the current activity and start the application process from the beginning
SECTION 4A – IMPORTING COUNTRY LIST

HIGHLIGHT the Country or Countries from drop down list and CLICK the “Add” button

To return to SECTION 3– SUMMARY

To proceed to SECTION 4B – NUMBER OF CERTIFICATES

Cancel the current activity and start the application process from the beginning
SECTION 4B – NUMBER OF CERTIFICATES

Enter the number of certificates requested. (Maximum of 50 including original and additional copies)

Country  Original Certificate
ALBANIA  1

Total Certificates = 1
Total = $175.00

ENTER the number of additional copies requested

Back  To return to SECTION 4A – IMPORTING COUNTRY LIST
Continue  To proceed to SECTION 5A – DRUG LABELS
Cancel & Start Again  Cancel the current activity and start the application process from the beginning
CLICK “Browse” to locate the label and CLICK “Upload” to attach to the application.
**SECTION 5A – DRUG LABELS**

*These fields are required.*

Please ensure that each label attachment is legible, in color and fits within an 8½ x 11 inch paper to expedite the application process.

NOTE: All attached documents for this page cannot exceed 50 MB.


Documents Uploaded:

<table>
<thead>
<tr>
<th>Label Type</th>
<th>File Name</th>
<th>File Size (KB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Package or Container Label</td>
<td>1457124837777_package_or_container_label.jpg</td>
<td>826.114</td>
</tr>
<tr>
<td></td>
<td>1457124837777_package_or_container_label.jpg</td>
<td>826.114</td>
</tr>
</tbody>
</table>

Total Size (KB): 826.114

**CLICK “Remove” and then CLICK “Back” to upload new labels**

---

**To return to SECTION 4B – NUMBER OF CERTIFICATES**

**To proceed to SECTION 5B – SUPPLEMENTAL DOCUMENTS**

**Cancel the current activity and start the application process from the beginning**
SECTION 5B – SUPPLEMENTAL DOCUMENTS

Would you like to attach supplemental documents?

- These fields are required.

Supplemental Documents
*Do you want to attach supplemental documents?

Yes
No

Back
Continue
Cancel & Start Again
**SECTION 5C – SUPPLEMENTAL DOCUMENT DETAILS**

- **SELECT** Attachment Type from drop down list
- **CLICK** “Browse” to locate the label and **CLICK** “Upload” to attach to the application
- **CLICK** “Yes” or “No” if you want attachment included with the certificate

**HIGHLIGHT** the Country or Countries from drop down list and **CLICK** “Add” button

---

**To return to** SECTION 5B – SUPPLEMENTAL DOCUMENTS

**To proceed to** SECTION 5D – REMARKS (OPTIONAL)

**Cancel the current activity and start the application process from the beginning**
SECTION 5D – REMARKS (OPTIONAL)

To return to SECTION 5C – SUPPLEMENTAL DOCUMENT DETAILS

To proceed to SECTION 5E – REMARKS ENTRY

Cancel the current activity and start the application process from the beginning
**SECTION 5E – REMARKS ENTRY**

**ENTER remarks**

**SELECT “Yes” or “No”**

**HIGHLIGHT the Country or Countries from drop down list and CLICK “Add” button**

---

**To return to** SECTION 5D – REMARKS (OPTIONAL)

**To proceed to** SECTION 6A – EXPORTER’S CERTIFICATION STATEMENT

**Cancel the current activity and start the application process from the beginning**
SECTION 6A – EXPORTER’S CERTIFICATION STATEMENT

ENTER your name

ENTER your title

CLICK “I Agree” button

To return to SECTION 5E – REMARKS ENTRY

To proceed to APPLICATION REVIEW

Cancel the current activity and start the application process from the beginning
APPLICATION REVIEW

**SECTION 6.A. EXPORTER'S CERTIFICATION STATEMENT**

**Firm Name:**

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.

We certify that the drug to be exported is in compliance with the applicable provisions of § 801 or 802 of the Food, Drug and Cosmetic Act as amended by the FDA Reform and Enhancement Act of 1996.

**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.

**I Agree.**

Name:  
Title:  
Date:  

---

**Cancel and Start Again**
Cancel the current activity and start the application process from the beginning

**Print**
Print application

**Preview Certificate**
View PDF copy of draft certificate

**Back to Main Menu**
To return to the CDEReCATS MAIN MENU screen

**Submit**
Submit application to CDER for review
**APPLICATION REVIEW**

**SECTION 6A**  EXPORTER'S CERTIFICATION STATEMENT

_Firm Name:_

_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._

_We certify that the drug to be exported is in compliance with the applicable provisions of § 801 or 802 of the Food, Drug and Cosmetic Act as amended by the FDA Reform and Enhancement Act of 1996._

_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._

*I Agree._

**| Name: | Title: |
---|---|
**| Date: |

**Buttons:**

- **Cancel & Start Again**: Cancel the current activity and start the application process from the beginning.
- **Print**: Print application.
- **Preview Certificate**: View PDF copy of draft certificate.
- **Back to Main Menu**: To return to the CDEReCATS MAIN MENU screen.
- **Submit**: Submit application to CDER for review.
APPLICATION REVIEW

Submit application to CDER for review

Preview Certificate

Print application

Cancel and Start Again

Print

Preview Certificate

Back to Main Menu

Submit

Cancel the current activity and start the application process from the beginning

Print application

View PDF copy of draft certificate

To return to the CDEReCATS MAIN MENU screen

Submit application to CDER for review
## DRAFT CERTIFICATE

**United States Food and Drug Administration**

**Center for Drug Evaluation and Research**

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

CDEExportCertificateProgram@fda.hhs.gov - Telephone (301) 796-4050

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

<table>
<thead>
<tr>
<th>Certificate Number: XXXX-XXXX</th>
<th>Certificate Issue Date: Month DD, YYYY</th>
<th>Certificate Expiration Date: Month DD, YYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Importing Country:</td>
<td>Expiring Country: UNITED STATES of AMERICA</td>
<td></td>
</tr>
</tbody>
</table>

The actual certificate issued by the FDA may be different from this preview certificate.

| 1.1 Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: |
| 1.2 Active Ingredient(s) and amount(s) for unit dose (correct quantitative composition is preferable. See Attachments) |
| 1.3 Is this product licensed to be placed on the market for use in the exporting country? |
| 1.4 Is this product actually on the market in the exporting country? |

| 2.1 Applicant for certificate name & address: |
| 2.2 Status of Applicant: |
| 2.3 Manufacturer name & address: |
| 2.4 Is it marketing authorized |

| 2.5.1.1 Is the manufacturing facility |
| 2.5.1.2 Has the manufacture of this type of dosage form been inspected? |
| 2.5.1.3 Do the facilities and operations conform to GMPs as recommended by WHO? (GMPs including 21 Code of Federal Regulations parts 210, 211, or ICH Q7A): |

| 3.1 Does the certifying authority for periodic inspection of the manufacturing plant in which the dosage form is produced? |
| 3.2 Periodicity of routine inspections (years): |
| 3.3 Has the manufacture of this type of dosage form been inspected? |
| 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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**Director**

Drug Imports and Exports Compliance Branch

Office of Drug Security, Integrity & Recalls

Office of Compliance

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

Submit application to CDER for review

Preview Certificate

Print

Back to Main Menu

Cancel and Start Again

Cancel the current activity and start the application process from the beginning

Print application

View PDF copy of draft certificate

To return to the CDEReCATS MAIN MENU screen

Submit

Submit application to CDER for review
APPLICATION SUBMISSION NOTIFICATION

Your Application Number is

Please keep the Application Number for your records. The Application Number is required for all communications with FDA regarding this application. Please refer to the help section for more details.

Back to Main  View Complete Application
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Export Certificate Program
10903 New Hampshire Avenue, Building 51, Room 4249
Silver Spring, MD 20993-0002
(301) 796-4950

{MAILING DATE}

Your application number {APPLICATION NUMBER} has been received.

Pursuant to 801(e)(4) of the Food, Drug and Cosmetic Act, drug export certificates shall be issued within 20 days of receipt of this request, unless there are issues with the CPP application (e.g. applicant did not provide proper information in application, GMPs are not acceptable). CDER export certificate program defines "days" as business days (weekends, federal holidays and FDA closures are not counted as business days). For Applications received before 2:00pm EST, the clock will start on the day we received your application. For Applications received after 2:00pm EST, the clock will start the following business day.

If you have any questions regarding your application, please contact the CDER Export Certificate Program at <a href="mailto:CDERExportCertificateProgram@fda.hhs.gov">CDERExportCertificateProgram@fda.hhs.gov</a>.

Regards,
CDER Export Certificate Program
If you have questions regarding the online CDEReCATS application process, please email the CDER Export Certificate Program at: CDERExportCertificateProgram@fda.hhs.gov

For more information on the CDER Export Certificate Program, Please visit:
END

API
Active Pharmaceutical Ingredient