Export Certificates

Center for Drug Evaluation and Research

CDER eCATS

CDER Export Certification Application and Tracking System

APPROVED

DRUG PRODUCT

FDA
Export Certificates

Center for Drug Evaluation and Research

Online Account Administration (OAA)

U.S. Department of Health and Human Services

FDA
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”**

**WARNING:** You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

**Getting Started**
To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select “Create New Account” towards the bottom left side of this page.

If you already have an account, enter your account ID and password.

If your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact FDA FURLS Help Desk at 1-800-216-7331 to confirm that the caller is acting on behalf of FDA.
CLICK CENTER FOR DRUG EVALUATION & RESEARCH (Export Certification Application and Tracking)
FDA ONLINE ACCOUNT ADMINISTRATION (OAA)

Enter ALL REQUIRED DATA
ONLINE ACCOUNT ADMINISTRATION (OAA)

REVIEW ALL REQUIRED DATA BEFORE SUBMISSION

CLICK “Submit”
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

APPROVED
DRUG PRODUCT

FDA logo
• Each application entered must be for:
  - A single drug product
  - A single dosage form (e.g. capsules)
  - A single amount/dose (e.g. 10 grams)
  - A single finished dose 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.
• 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
  - 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:
  - Legible Color Labels of drug item
  - Return Postage label (USP or FEDEX)
  - Drug Approval Letter document
  - Package Insert
  - 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 CDER eCATS 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.
<table>
<thead>
<tr>
<th><strong>Enter New Application</strong></th>
<th>To start a new application</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Modify Application</strong></td>
<td>To edit or change an existing saved application</td>
</tr>
<tr>
<td><strong>Search Application</strong></td>
<td>To look at existing applications and to clone applications</td>
</tr>
</tbody>
</table>
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 Trade Names" 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 drugs 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.
- Dissuance of a CPP for CDER-regulated drugs will not preclude regulatory action by FDA, if warranted, against products covered by the CPP.
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 administrators, Section 801(a)(4)(A) of the FD&C Act, as amended by the FDA Export Reform and Enhancement Act of 1996 (Public Law 104-154) 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 505(c)(1) or 505 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 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)(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: $200.00
- 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 Certificate Program, 10903 New Hampshire Avenue, Building 51, Room 2305, Silver Spring, MD 20993-0002.

For inquiries about CPPs, please e-mail CDERExportCertificateProgram@fda.hhs.gov or call 301-796-4955.

Registration and Listing
Section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C 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(g) of the FD&C Act, to register their establishment(s) and submit a listing of the FDA. Failure to register or list as required by section 510(g) is a prohibited act under section 301(g) of the FD&C Act. Exporting a drug without registering and listing may result in FDA enforcement action.

An introduction to the FD&C Act can be found at:
http://www.6e.gov/RegulatoryInformation/RegulationsOverview/FoodDrugCosmeticAct/FDACActChapterVIIAppsAndDevices/default.htm.

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

Current Good Manufacturing Practices
Certification 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 Title 21 Code of Federal Regulations (CFR) part 210, part 211, part 225, part 226, and parts 600-680. The Title 21 CFR can be found at:

To return to GENERAL INFORMATION
To proceed to CERTIFICATE TYPE SELECTION
SELECT “Certificate of Pharmaceutical Product (CPP)” or “Foreign Exported Certificate of Pharmaceutical Product”
FOREIGN EXPORTED CPP INFORMATION

Foreign Exported CPPs will be issued on security paper and signed by the CDER approving official. They will not contain attachments, a ribbon, or embossed federal seal. You may request a Foreign Exported CPP using FDA Form 3613f if you meet the following criteria:

1. The product is approved by the FDA under a New Drug Application, an Abbreviated New Drug Application, or a Biologics Licensing Application regulated by CDER;
2. The product is not approved by the exporting country, and it is not possible for the manufacturer
   To obtain the necessary CPP from a country other than the United States;
3. The product is manufactured according to the requirements of its FDA approval;
4. A signed cover letter with the application requesting the Foreign Exported CPP should state
   That the above requirements are met and include the following statement:

   “We certify that [product name] is manufactured in [name of foreign country of manufacture] according to the requirements of its approval in the United States and will be exported from [name of foreign country of manufacture] to [name of importing country]. We further certify that [product name] is not authorized for marketing in [name of foreign country of manufacture] and that the necessary Certificate of Pharmaceutical Product cannot be obtained from that country or any other country”

5. The product meets all other requirements for issuance of a CPP.
ENTER Applicant information

Most of the fields in Section 1 of the CPP application process are automatically populated based on the information from your Online Administration Account (OAA) and cannot be edited in CDEReCATS.

To return to SECTION– CERTIFICATE TYPE SELECTION

To proceed to SECTION – APPLICANT ADDRESS VALIDATION

Cancel the current activity and start the application process from the beginning
APPLICANT ADDRESS VALIDATION

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.

Address Validation Decision
- [ ] Continue to use the existing address
- [ ] Accept validated address and continue

SELECT “Continue to use the existing address” or “Accept validated address and continue”
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 & Start Again

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.

To return to SECTION 1B– BILLING INFORMATION

To proceed to SECTION 2A– GENERAL PRODUCT INFORMATION

Cancel & Start Again

Cancel the current activity and start the application process from the beginning.
SECTION 2A – GENERAL PRODUCT INFORMATION

SELECT “Yes” or “No”

To return to SECTION 1C– DELIVERY INFORMATION

To proceed to SECTION 2B– PRODUCT SPECIFIC INFORMATION

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

ENTER the FDA Approval Number

CLICK the “Browse” button to locate the Approval Letter and CLICK the “Upload” button to attach the Approval Letter (PDF) to the application

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

To return to SECTION 2A– GENERAL PRODUCT INFORMATION

To proceed to SECTION 2C– PRODUCT LICENSE HOLDER INFORMATION

Cancel the current activity and start the application process from the beginning
If you SELECT “Yes,” certain Product License Holder Information will automatically populate. If you SELECT “No,” ENTER Product License Holder Information.

SELECT Status of License holder from drop down box.

- To return to SECTION 2B – PRODUCT SPECIFIC INFORMATION
- To proceed to SECTION 2D – PRODUCT CHARACTERISTICS
- Cancel the current activity and start the application process from the beginning.
SECTION 2D – PRODUCT CHARACTERISTICS

ENTER Proprietary Name or Brand Name

ENTER Active Ingredient Name (Nonproprietary Name)

ENTER the Amount and SELECT Dosage Form and Unit Dose from drop down list

To return to SECTION 2C – PRODUCT LICENSE HOLDER INFORMATION
To proceed to SECTION 3A – FINISHED DOSAGE MANUFACTURER
Cancel the current activity and start the application process from the beginning
SECTION 3A – FINISHED DOSAGE MANUFACTURER

If you SELECT “Yes,” certain Finished Dosage Manufacturer Information will automatically populate.

If you SELECT “No,” ENTER Finished Dosage Manufacturer Information.

ENTER Registration Number (optional)

ENTER FEI Number

Back
Continue
Cancel & Start Again

To return to SECTION 2D– PRODUCT CHARACTERISTICS
To proceed to SECTION 3B– ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURER
Cancel the current activity and start the application process from the beginning.
SECTION 3B – ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURER

To return to SECTION 3A – FINISHED DOSAGE MANUFACTURER

To proceed to SECTION 3C – PACKAGER/RELABELER

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.

SELECT “Yes” or “No.”

To return to SECTION 3A– FINISHED DOSAGE MANUFACTURER

To proceed to SECTION 3C– PACKAGER/RELABELER

Cancel the current activity and start the application process from the beginning.
SECTION 3C – PACKAGER/RELABELER

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

CLICK "Edit" to change information

Back
Continue
Cancel & Start Again

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

Selected Countries will appear here

Back
Continue
Cancel and Start Again

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
ENTER the number of additional copies requested

Country: ALGERIA
Original Certificate: 1

Total Certificates = 1
Total = $175.00

To return to SECTION 4A – IMPORTING COUNTRY LIST
To proceed to SECTION 5A – DRUG LABELS
Cancel the current activity and start the application process from the beginning
SECTION 5A – DRUG LABELS

CLICK “Browse” to locate the label and CLICK “Upload” to attach to the application.

Back | To return to SECTION 4B – NUMBER OF CERTIFICATES
Continue | To proceed to SECTION 5B – SUPPLEMENTAL DOCUMENTS
Cancel & Start Again | Cancel the current activity and start the application process from the beginning
SECTION 5A – DRUG LABELS

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 5C – SUPPLEMENTAL DOCUMENT DETAILS**

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

---

- **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 to have attachment to be included with the certificate

**HIGHLIGHT the Country or Countries from the list and **CLICK “Add”** button**
SECTION 5D – REMARKS (OPTIONAL)

- These fields are required.

Optional Remarks

*Do you want to add remarks?  
○ Yes  ○ No

Back  Continue  Cancel & Start Again

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
ENTER remarks

SELECT “Yes” or “No”

HIGHLIGHT the Country or Countries from the 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

Back
To return to SECTION 5E – REMARKS ENTRY

Continue
To proceed to APPLICATION REVIEW

Cancel & Start Again
Cancel the current activity and start the application process from the beginning
### APPLICATION REVIEW

**SECTION 3A** APPLICATION INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Created Date</td>
<td>Certificate Type</td>
</tr>
</tbody>
</table>

**SECTION 1A** APPLICANT INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>First Name</td>
<td>Address</td>
</tr>
<tr>
<td>Middle Initial</td>
<td>Last Name</td>
</tr>
<tr>
<td>Firm Name</td>
<td></td>
</tr>
<tr>
<td>Telephone Number</td>
<td>Email Address</td>
</tr>
</tbody>
</table>

**SECTION 1B** BILLING INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the Billing Name and Address the same as the Applicant Name and Address?</td>
<td>Yes No</td>
</tr>
<tr>
<td>Tax ID Code</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 1C** DELIVERY INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method of Delivery</td>
<td>UPS</td>
</tr>
<tr>
<td>Return Label Attachment</td>
<td>Yes No</td>
</tr>
</tbody>
</table>

**SECTION 2A** GENERAL PRODUCT INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this product licensed to be placed on the market for use in the United States?</td>
<td>Yes No</td>
</tr>
<tr>
<td>FDA Approval Number</td>
<td></td>
</tr>
<tr>
<td>FDA Date of Approval</td>
<td></td>
</tr>
<tr>
<td>FDA Product Listing Number (e.g., NDC)</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 2B** PRODUCT SPECIFIC INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Product Type</td>
<td>Direct Approved Drug Type</td>
</tr>
<tr>
<td>Product on the market in USA?</td>
<td>Yes No</td>
</tr>
<tr>
<td>Is the product a PEPFAR (Presidential Emergency Plan For AIDS Relief)</td>
<td>Yes No</td>
</tr>
</tbody>
</table>

**SECTION 2C** PRODUCT LICENSE HOLDER INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the Product License Holder Name and Address the same as the Applicant Name and Address?</td>
<td>Yes No</td>
</tr>
<tr>
<td>Product License Holder Name</td>
<td>Address</td>
</tr>
</tbody>
</table>

**SECTION 2D** PRODUCT CHARACTERISTICS

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary Name</td>
<td></td>
</tr>
<tr>
<td>Active Ingredient</td>
<td></td>
</tr>
<tr>
<td>Dosage Form</td>
<td></td>
</tr>
<tr>
<td>Amount per Unit Dose</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 3A** FIXED DOSAGE MANUFACTURER

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the Finished Dosage Manufacturer Name and Address the same as the Applicant Name and Address?</td>
<td>Yes No</td>
</tr>
<tr>
<td>Registration Number (DUNS)</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 3B** ACTIVELY PHARMACEUTICAL INGREDIENT MANUFACTURER

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there an active Pharmaceutical Ingredient Manufacturer associated with this drug product?</td>
<td>Yes No</td>
</tr>
<tr>
<td>The Active Pharmaceutical Ingredient Manufacturer Name and Address are the same as the Applicant Name and Address?</td>
<td>Yes No</td>
</tr>
<tr>
<td>Registration Number (DUNS)</td>
<td></td>
</tr>
<tr>
<td>FEI Number</td>
<td></td>
</tr>
<tr>
<td>Do you want the Active Pharmaceutical Ingredient Manufacturer Name and Address to be printed on the certificate?</td>
<td>Yes No</td>
</tr>
</tbody>
</table>

**SECTION 3C** PACKAGE/REPACKER

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there a Package/Repacker associated with this drug product?</td>
<td>Yes No</td>
</tr>
</tbody>
</table>

**SECTION 4A** IMPORTING COUNTRY LIST

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of Countries for which certificates are requested</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 4B** NUMBER OF CERTIFICATES

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter the number of certificates requested (maximum of 50 including original and additional copies)</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Original Certificates</td>
</tr>
<tr>
<td>Total &lt; 5</td>
<td></td>
</tr>
<tr>
<td>Total Certificates</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 5A** DRUG LABELS

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label Type</td>
<td>File Name</td>
</tr>
<tr>
<td>Package or Container Label</td>
<td></td>
</tr>
<tr>
<td>Outer Package Label</td>
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<td>Package Insert</td>
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</table>

**SECTION 5B** SUPPLEMENTAL DOCUMENTS

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Do you want to attach supplemental documents?</td>
<td>Yes No</td>
</tr>
</tbody>
</table>

**SECTION 5C** SUPPLEMENTAL DOCUMENTS DETAILS

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Type</td>
<td>File Name</td>
</tr>
<tr>
<td>Formulation Page</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Firm Name</td>
<td>Food Industry</td>
</tr>
</tbody>
</table>

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 1004.

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 1999.

**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.

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
</tr>
</tbody>
</table>

Cancel & Start Again  Print  Preview Certificate
APPLICATION REVIEW

SECTION 6A  EXPORTER’S CERTIFICATION STATEMENT

Firm Name:

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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
- 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
APPLICATION REVIEW

Submit application to CDER for review

Preview Certificate

Back to Main Menu

Submit

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
APPLICATION REVIEW

Welcome to the Application Review page. Here, you can submit your application to CDER for review, preview the draft certificate, or cancel and start again.

**Firm Name:**
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**I Agree.**

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

**Options:**
- **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.

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# 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

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

### Certificate of a Pharmaceutical Product - Approved Drug Product

**Certificate Number:** XXXX-XXXX  
**Certificate Issue Date:** Month DD, YYYY  
**Certificate Expiration Date:** Month DD, YYYY

**Importing Country:**  
**Exporting Country:** UNITED STATES OF AMERICA

---

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

<table>
<thead>
<tr>
<th>1</th>
<th>Drug Trade Name, International or National non-proprietary name (as applicable) &amp; dosage form:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Active ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred). See Attachments</td>
</tr>
<tr>
<td>1.2</td>
<td>Is this product licensed to be placed on the market for use in the exporting country?</td>
</tr>
<tr>
<td>1.3</td>
<td>Is this product actually on the market in the exporting country?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.A</th>
<th>Product license number &amp; date of issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.A.1</td>
<td>Product license holder name &amp; address:</td>
</tr>
<tr>
<td>2.A.2</td>
<td>Status of Product license holder:</td>
</tr>
<tr>
<td>2.A.3</td>
<td>Manufacturer name &amp; address:</td>
</tr>
<tr>
<td>2.A.4</td>
<td>Is a summary basis for approval appended?</td>
</tr>
<tr>
<td>2.A.5</td>
<td>Is attached product Information, complete and consistent with the license?</td>
</tr>
<tr>
<td>2.A.6</td>
<td>Applicant name &amp; address for certificate (if different from the license holder):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.B</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Does the certifying authority for periodic inspection of the manufacturing plant in which the dosage form is produced?</td>
</tr>
<tr>
<td>3.1</td>
<td>Periodicity of routine inspections (please):</td>
</tr>
<tr>
<td>3.2</td>
<td>Has the manufacturer of this type of dosage form been inspected?</td>
</tr>
<tr>
<td>3.3</td>
<td>Do the facilities and operations conform to GMPs as recommended by the WHO, CGMP, including 21 Code of Federal Regulations parts 210, 211, or ICH Q7A? Yes, at time of inspection, site complies with FDA cGMP</td>
</tr>
<tr>
<td>3.4</td>
<td>the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party?</td>
</tr>
</tbody>
</table>

---

**Director**

Drug Imports and Exports Compliance Branch  
Office of Drug Security, Integrity & Recall  
Office of Compliance

---

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

**SECTION 6A**

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</tbody>
</table>

- **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
ENTER APPLICATION SUCCESSFUL!

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
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: CDEREExportCertificateProgram@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”)
END

APPROVED

DRUG PRODUCT