

APPROVED DRUG FLOW

CDER eCATS

CDER Export Certification
Application And Tracking System



FDA

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- 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.
- Cissuance of a CPP for CDER-regulated drugs will not preclude regulatory action by FDA, if warranted, against products covered by the CPP.

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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 (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 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(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.

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 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(p) 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.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapters/DrugsandDevices/default.htm>.

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

Current Good Manufacturing Practices

Certificates 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

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>.



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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

Certificate of Pharmaceutical Product (CPP) ?

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Certificate to a Pharmaceutical Product (CPP)

An export certificate is a document prepared by FDA certifying that the food, drug, animal drug, or device being exported meets the applicable requirements of the Federal Food, Drug, and Cosmetic Act. In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States or meet specific U.S. regulations, for example current Good Manufacturing Practice (cGMP) regulations. At the current time CDER only issues one type of export certificate, the Certificate of a Pharmaceutical Product (CPP). CPPs issued conform to the format established by the World Health Organization (WHO) and are intended for use by the importing country when considering whether to license the product in question for sale in that country.

Foreign Exported Certificate of a Pharmaceutical Product (CPP)

CDER's Export Certificate Program currently issues CPPs for FDA-approved products that are exported from one foreign country to another. This program began as a pilot in February 2005, and continues to date. CDER implemented the program to accommodate industry's request to provide foreign importing countries with FDA-issued CPP for FDA-approved products, even though the product is not manufactured and exported from the United States. Foreign Exported CPPs will be issued on security paper and signed by the CDER approving official. The CPP will not contain attachments, a ribbon, or embossed federal seal. The criteria for applying for a foreign exported CPP:

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.
- Please share notice of this procedural change with others in your firm who have a reason to know and with the foreign governmental authorities with whom you do the business.



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SECTION 1A APPLICANT INFORMATION

* - These fields are required.

Title
--Please Select--

*First Name

Middle Initial

*Last Name

*Firm Name

*Address Line 1

Address Line 2

*Country
UNITED STATES

*Zip Code Extension

*City
--Please Select--

*State
--Please Select--

Numbers only. No spaces, dashes or parentheses.

*Area Code (e.g.101)	*Phone Number (e.g.5551111)	Extension (e.g.1111)
*Phone Number		

*Email Address

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Cancel & Start Again



Step 01

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APPLICANT ADDRESS VALIDATION

YOUR ADDRESS

Address Line 1:

Address Line 2:

City:

State:

Zip Code:

Country:

VALIDATED ADDRESS

Address Line 1:

Address Line 2:

City:

State:

Zip Code:

Country:

* - These fields are required.

*Address Validation Decision

Return to Step 1 and make changes

Continue to use the existing address

Continue



Back Continue
Cancel & Start Again

SECTION 1B BILLING INFORMATION

* - These fields are required.

Billing Name and Address
Is the Billing Name and Address the same as the Applicant Name
and Address? Yes No

*Tax ID Code
11 1234567

Back Continue
Cancel & Start Again



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SECTION 1B BILLING INFORMATION

* - These fields are required.

Billing Name and Address
Is the Billing Name and Address the same as the Applicant Name
and Address? Yes No

*First Name

Middle Initial

*Last Name

*Firm Name

*Country
UNITED STATES

*Address Line 1

Address Line 2

*Zip Code
 -

*City
--Please Select--

*State
--Please Select--

Numbers only. No spaces, dashes or parentheses.

*Area Code (e.g. 101)	*Phone Number (e.g. 5551111)	Extension (e.g. 1111)
<input type="text"/>	<input type="text"/>	<input type="text"/>

*Email Address

*Tax ID Code
11 1234567

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Cancel & Start Again



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SECTION 1C DELIVERY INFORMATION

* - These fields are required.

Please complete and attach a return label to expedite the application process.
The label cannot exceed 50MB.
Allowed file types are *.png, *.jpeg, *.jpg, *.gif, *.bmp, *.dif, *.jif, *.tif, *.tiff, and *.pdf.

*Method of Delivery

*Return Label

Back Continue
Cancel & Start Again



Get Help ?

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Cancel & Start Again

SECTION 2A GENERAL PRODUCT INFORMATION

* - These fields are required.

U.S. License

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

Yes No

--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?

Yes No

**Definition of Licensed and Approved**

Licensed products are biological products that have been determined by FDA to be safe, pure, and potent. Biological products, once licensed, may be marketed in the United States. Some biological products are regulated by CDER, while others are regulated by CBER. Licensed biological products are subject to BLAs (biologic license applications). Approved drug products have been determined by FDA to be safe and effective. Approved drugs (regulated by CDER) have been evaluated and reviewed by CDER for safety and effectiveness and may be marketed in the United States. Approved drugs are subject to the following types of drug applications: NDA (new drug application) and ANDA (abbreviated new drug application).



Get Help ?

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SECTION 2A GENERAL PRODUCT INFORMATION

* - These fields are required.

U.S. License

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

Yes No

*Product Type

Approved Drug Product

- Please Select--
- AADA (Abbreviated Antibiotic Drug Application)
- ANDA (Abbreviated New Drug Application)
- NDA (New Drug Application)
- BLA (Biologics License Application)

Select Type of Approved Drug Product. Webpage will reload after selection.

Product Types

FDA's Center for Drug Evaluation and Research (CDER) issues certificates of pharmaceutical products (CPPs) for the following types of human drug items:

Approved Drugs and Licensed Biological Products

Approved new drugs (regulated by CDER) have been evaluated and reviewed by CDER for safety and effectiveness and may be marketed in the United States. Approved drugs are subject to the following types of drug applications: NDA (new drug applications); ANDA (abbreviated new drug application); and certain licensed biological products regulated by CDER under BLAs (biologic license applications).

Nonprescription ("Over the Counter (OTC)") Drugs

An OTC drug can be brought to the market if it is the subject of an approved NDA or ANDA or if it conforms to a final or pending OTC monograph. Each OTC drug monograph is a kind of "recipe book" covering acceptable ingredients, doses, formulations, labeling, and, in some cases, testing parameters. Products conforming to a monograph are not considered approved drugs but they may be marketed without FDA pre-approval. FDA defines OTC drugs as safe and effective for use by the general public without a doctor's prescription.

The OTC monographs can be found at the following website:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/default.htm>

Active Pharmaceutical Ingredients (API)

An active pharmaceutical ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

Unapproved New Drugs

Unapproved New Drugs have not been approved or evaluated by CDER for safety and effectiveness and cannot be marketed in the United States. Exportation of these drugs is permitted only in accordance with the requirements found in sections 801 and 802 of the Food Drug and Cosmetic Act. In addition, when export is permitted, pursuant to 21 CFR 1.101(d), a simple notification is required when first exporting your unapproved new drug.



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Cancel & Start Again

SECTION 2A GENERAL PRODUCT INFORMATION

* - These fields are required.

U.S. License

*Is this product [licensed or approved](#) to be placed on the market for use in the United States?

Yes No

*Product Type

Approved Drug Product

*Type of Approved Drug Product

AADA (Abbreviated Antibiotic Drug Application)

Product on the market in USA?

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

Yes No

PEPFAR?

*Is the product a PEPFAR?
(Presidential Emergency Plan For AIDS Relief)
For more information, select [PEPFAR](#).

Yes No

Back Continue
Cancel & Start Again



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SECTION 2B PRODUCT SPECIFIC INFORMATION

* - These fields are required.

The FDA Approval Number must contain six digits. If your FDA Approval Number is less than six digits, please enter one or more zeros in front of your Approval Number. (Ex. 001111)

*FDA Approval Number

Allowed file types are *.png, *.jpeg, *.jpg, *.gif, *.bmp, *.dif, *.jif, *.tif, *.tiff, and *.pdf.
The file size cannot exceed 50MB.

*Approval Letter Attachment

*FDA Date of Approval (MM/DD/YYYY)

*FDA Product Listing Number (e.g., NDC)



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Cancel & Start Again

SECTION 2C PRODUCT LICENSE HOLDER INFORMATION

* - These fields are required.

Product License Holder

*Is the Product License Holder Name and Address
the same as the Applicant Name and Address? Yes No

*Status of License Holder

--Please Select--

Back Continue
Cancel & Start Again



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Cancel & Start Again

SECTION 2C PRODUCT LICENSE HOLDER INFORMATION

* - These fields are required.

Product License Holder

*Is the Product License Holder Name and Address the same as the Applicant Name and Address? Yes No

*Product License Holder Name

*Country

*Address Line 1 (Domestic Only)

Address Line 2

*Zip Code

Extension

*City

*State

*Status of License Holder

Back Continue
Cancel & Start Again



SECTION 20 PRODUCT CHARACTERISTICS

* - These fields are required.

Note: Please copy and paste any copyright name, trademark or registered trademark symbols for inclusion on the certificate. Example: DRUGNAME©, DRUGNAME™, DRUGNAME®

*Proprietary Name (Drug, Trade or Brand Name) (Maximum 100 characters)

*Active Ingredient (Maximum 100 characters)

*Dosage Form

--Please Select--

*Amount

Unit Dose

per --Please Select--



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Cancel & Start Again

SECTION 3A FINISHED DOSAGE MANUFACTURER

* - These fields are required.

Finished Dosage Manufacturer

*Is the Finished Dosage Manufacturer Name and Address the same as the Applicant Name and Address? Yes No

*Registration Number (DUNS)

*FEI Number

Back Continue
Cancel & Start Again



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Cancel & Start Again

SECTION 3A FINISHED DOSAGE MANUFACTURER

* - These fields are required.

Finished Dosage Manufacturer

*Is the Finished Dosage Manufacturer Name and Address the same as the Applicant Name and Address? Yes No

*Finished Dosage Manufacturer Name

*Address Line 1

Address Line 2

*Country
UNITED STATES

*Zip Code Extension

*City
--Please Select--

*State/Province
--Please Select--

*Registration Number (DUNS)

*FEI Number

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Cancel & Start Again



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Cancel & Start Again

SECTION 3B ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURER

* - These fields are required.

API Manufacturer

Is there an Active Pharmaceutical Ingredient
Manufacturer associated with this drug product? Yes No

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Cancel & Start Again



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Cancel & Start Again

SECTION 3B ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURER

* - These fields are required.

API Manufacturer
*Is there an Active Pharmaceutical Ingredient
Manufacturer associated with this drug product? Yes No

API Manufacturer Name and Address
*Is the Active Pharmaceutical Ingredient
Manufacturer Name and Address the same as the
Applicant Name and Address? Yes No

*API Manufacturer Name

*Address Line 1

Address Line 2

*Country
UNITED STATES

*Zip Code Extension

*City
--Please Select--

*State/Province
--Please Select--

*Registration Number (DUNS)

*FEI Number

API Name and Address on the certificate
*Do you want the Active Pharmaceutical Ingredient
Manufacturer Name and Address to be printed on
the certificate? Yes No

Back Continue
Cancel & Start Again



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SECTION 3C PACKAGER/RELABELER

* - These fields are required.

Packager/Relabeler Information

*Is there a Packager/Relabeler associated with this drug product? Yes No

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SECTION 3C PACKAGER/RELABELER

* - These fields are required.

Packager/Relabeler Information

*Is there a Packager/Relabeler associated with this drug product? Yes No

*Packager/Relabeler Name

*Address Line 1

Address Line 2

*Country
UNITED STATES

*Zip Code Extension

*City
--Please Select--

*State/Province
--Please Select--

*Registration Number (DUNS)

*FEI Number

Packager/Relabeler Name and Address on the certificate
*Packager/ Relabeler Name and Address to be printed on the certificate? Yes No

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Cancel & Start Again



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Cancel & Start Again

SECTION 3 SUMMARY

Manufacturer Type	Name	Registration Number (DUNS)	FEI Number	Address
Finished Dosage Manufacturer Edit	Same as Applicant firm.	123456789	3004013308	Same as Applicant address.
API Manufacturer Edit	Same as Applicant firm.	123456789	3004013308	Same as Applicant address.
Packager/Relabeler Edit	N/A	N/A	N/A	N/A

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SECTION 4A IMPORTING COUNTRY LIST

* - These fields are required.

*Name of Country or Countries

AFGHANISTAN
ALAND ISLANDS
ALBANIA
ALGERIA
ANDORRA



>> Add

<< Remove

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Cancel & Start Again



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SECTION 4B NUMBER OF CERTIFICATES

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

Country	Original Certificate	Additional Copies
ALGERIA	1	<input type="text"/>

Total Certificates = 1

Total = \$175.00 ?

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Cancel & Start Again

Fee Calculation

The fee for preparing and issuing a single export certificate for each product per each country is \$175. For requests for additional copies for the same country, the second copy certificate will cost \$90, and subsequent copies (e.g. third copy, fourth copy etc.) will cost \$40 each. You will receive an invoice from the Food and Drug Administration within the next 90 days for the billing of the fees for the issuance and processing of the enclosed export certificate.



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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.

Allowed file types are *.png, *.jpeg, *.jpg, *.gif, *.bmp, *.dif, *.jif, *.tif, *.tiff, and *.pdf.
The file size cannot exceed 50MB.

*Package or Container Label
 Browse... Upload

*Outer Package Label
 Browse... Upload

*Package Insert
 Browse... Upload

Back Continue
Cancel & Start Again



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Cancel & Start Again

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.

Allowed file types are *.png, *.jpeg, *.jpg, *.gif, *.bmp, *.dif, *.jif, *.tif, *.tiff, and *.pdf.
The file size cannot exceed 50MB.

Documents Uploaded:

Label Type	File Name	File Size (KB)	
Package or Container Label	1457109279967_package_or Container Label.jpg	826.114	Remove
Outer Package Label	1457109287144_Outer Package Label.jpg	826.114	Remove
Package Insert	1457109294012_Package Insert.jpg	826.114	Remove
Total Size (KB):		2,478.343	

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SECTION 5C SUPPLEMENTAL DOCUMENT DETAILS

* - 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.

Allowed file types are *.png, *.jpeg, *.jpg, *.gif, *.bmp, *.dif, *.jif, *.tif, *.tiff, and *.pdf.
The file size cannot exceed 50MB.

*Attachment Type



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SECTION 5B SUPPLEMENTAL DOCUMENTS

* - These fields are required.

Supplemental Documents

*Do you want to attach supplemental documents?

Yes No

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SECTION 5C SUPPLEMENTAL DOCUMENT DETAILS

* - 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.

Allowed file types are *.png, *.jpeg, *.jpg, *.gif, *.bmp, *.tif, *.tiff, and *.pdf.
The file size cannot exceed 50MB.

*Attachment Type
Formulation Page

Supplemental Attachment:
[1457109650325_package_or_Container_Label.jpg](#) Remove

Country Specific

*Do you want to associate countries to this attachment? Yes No

Print Attachment

*Do you want the attachment printed with the certificate? Yes No

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SECTION 5B SUPPLEMENTAL DOCUMENTS

* - These fields are required.

Supplemental Documents

*Do you want to attach supplemental documents? Yes No

Documents Uploaded:

Select	Document Type	File Name	Countries	Print
<input type="radio"/>	Formulation Page	1457109857409_Supplemental_attachment.jpg	Not Selected	No

Add Remove

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SECTION 5D REMARKS (OPTIONAL)

* - These fields are required.

Optional Remarks

*Do you want to add remarks?

Yes No

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SECTION 5E REMARKS ENTRY

*** - These fields are required.**

Disclaimer
The FDA has the right to remove and or update any remarks provided by industry to be printed on the certificate.

Your remarks cannot exceed 250 characters.

***Enter your remarks**

Country Specific

***Do you want to associate countries to these remarks?** Yes No

Print Remarks

***Do you want the remarks printed on the certificate?** Yes No



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SECTION 5D REMARKS (OPTIONAL)

* - These fields are required.

Optional Remarks

*Do you want to add remarks?

Yes No

Remarks entered:

Select	Remarks	Country	Print
<input type="radio"/>	Test remarks	Not Selected	No

Add Remove

Back Continue

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SECTION 6A EXPORTER'S CERTIFICATION STATEMENT

* - These fields are required.

Firm Name: Test Food Industry

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.

*Name:

*Title:

*I Agree

March 4, 2016

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Date: March 4, 2016
 Created Date: March 4, 2016 Certificate Type: Certificate of Pharmaceutical Product (CPP)

SECTION 1A APPLICANT INFORMATION FINI

Title: Mr.
 First Name: John Address: Potomac Blvd
 Middle Initial: N Bethesda, MD 20852
 Last Name: Doe United States of America
 Firm Name: Test Food Industry Email Address: testdoe@test.com
 Telephone Number: 2407111111

SECTION 1B BILLING INFORMATION

Is the Billing Name and Address the same as the Applicant Name and Address?
 Yes No
 Firm Tax ID Code: 11 1234567

SECTION 1C DELIVERY INFORMATION

Method of Delivery: UPS Return Label Attachment: 147210211006_UPS Return Label.jpg

SECTION 2A GENERAL PRODUCT INFORMATION FINI

Is this product licensed to be placed on the market for use in the United States?
 Yes No
 Selected Product Type: Approved Drug Product
 Selected Approved Drug Type: ANDA (Abbreviated New Drug Application)
 Product on the market in US?
 Yes No
 Is the product a PEPPART (Pediatric Emergency Plan For AIDS Relief)?
 Yes No

SECTION 2B PRODUCT SPECIFIC INFORMATION

FDA Approval Number: 99999
 Approval Letter Attachment: 147210206660_Approval Letter.pdf
 FDA Date of Approval: January 1, 2015
 FDA Product Listing Number (e.g., NDC): 0000-1020-11

SECTION 2C PRODUCT LICENSE HOLDER INFORMATION

Is the Product License Holder Name and Address the same as the Applicant Name and Address?
 Yes No
 Address: 11020 1st Street
 Product License Holder Name: Product License Holder Name N Bethesda, MD 20852
 United States of America
 Status of Product License Holder: Manufacturer

SECTION 3B PRODUCT CHARACTERISTICS

Proprietary Name (Drug, Trade or Brand Name): Metropolis Tablets, USP
 Active Ingredient: Metropolis Tablets, USP
 Dosage Form: Injection, emulsion
 Amount per Unit Dose: 5 Milligram/5mL

SECTION 3A FINISHED DOSEAGE MANUFACTURER FINI

Is the Finished Dosage Manufacturer Name and Address the same as the Applicant Name and Address?
 Yes No
 Registration Number (DUNS): 123456789
 FI Number: 303401300

SECTION 3B ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURER

Is there an Active Pharmaceutical Ingredient Manufacturer associated with this drug product?
 Yes No
 Is the Active Pharmaceutical Ingredient Manufacturer Name and Address the same as the Applicant Name and Address?
 Yes No
 Registration Number (DUNS): 123456789
 FI Number: 303401300

SECTION 3C PACKAGING RELABELER

Is there a Packaging/Relabeler associated with this drug product?
 Yes No

SECTION 4A IMPORTING COUNTRY LIST FINI

List of Countries for which certificates are requested: ALGERIA

SECTION 4B NUMBER OF CERTIFICATES

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

Country	Original Certificates	Additional Copies	Total Copies
ALGERIA	1		1
Total	1		Total Certificates: 1

SECTION 5A ENCL LABELS FINI

Label Type	File Name	File Size (KB)
Package or Container Label	1472100773901_1472100773901_1472100773901_Label.jpg	826,114
Outer Package Label	1472100773901_1472100773901_Label.jpg	826,114
Package Insert	1472100773901_1472100773901_Insert.pdf	826,114
Total	Total Size (KB):	2,478,342

SECTION 5B SUPPLEMENTAL DOCUMENTS

Do you want to attach supplemental documents?
 Yes No

SECTION 5C SUPPLEMENTAL DOCUMENTS DETAILS

Document Type	File Name	Country	Print
Formulation Page	1472100773901_Supplemental.pdf	Not Selected	No

SECTION 5D REMARKS (OPTIONAL)

Do you want to add remarks (Optional)?
 Yes No

SECTION 5E REMARKS ENTRY

Remarks	Associate to Country?	Country	Print to Certificate?
Test remarks	No	Not Selected	No

SECTION 6A EXPORTER'S CERTIFICATION STATEMENT FINI

Firm Name: Test Food Industry

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: John Doe Title: Global Regulatory Affairs
 Date: March 4, 2016