APPROVED DRUG FLOW


CDER eCATS
CDER Export Certification
Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Get Help
GENERAL INFORMATION
Back to Main Menu
Continue
• 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 drugâs 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.
Back to Main Menu
Continue

CDER eCATS CDER Export Certification Application And Tracking System

FDA

Get Help

GENERAL/CONTACT INFORMATION

Back Continue

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

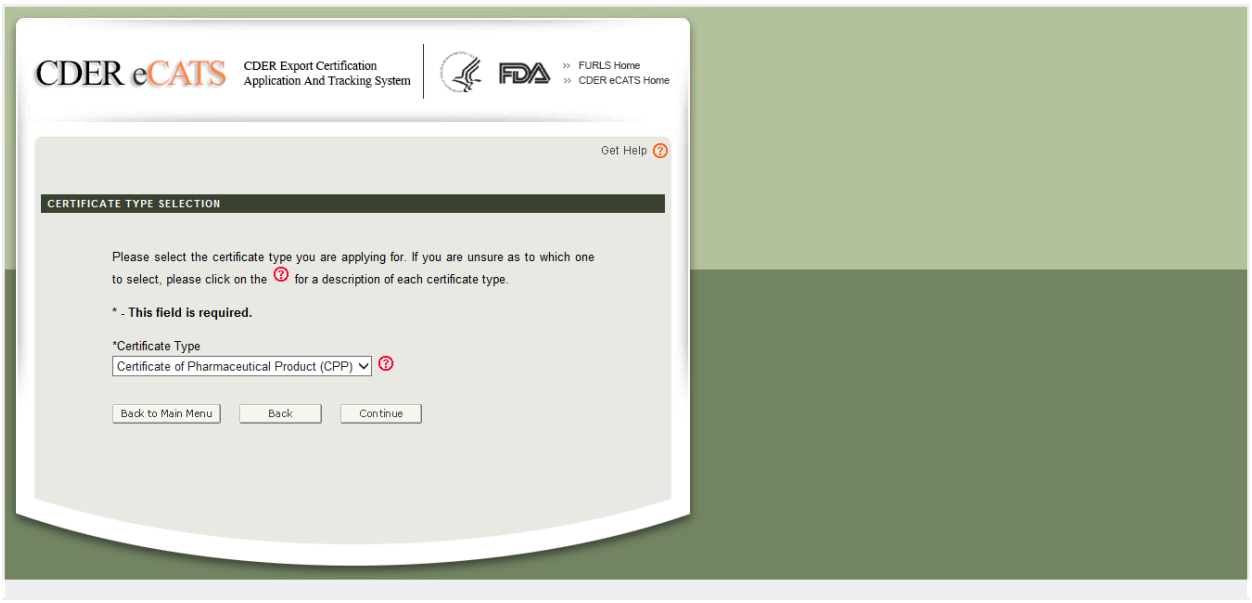
Section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires every person who owns or operates any establishment in the United States engaged in the manufacture, preparation, propagation, compounding, or processing of drugs, unless exempt under section 510(g) of the FD&C Act, to register 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/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/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.

Back Continue


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Get Help
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)
Back to Main Menu
Back
Continue

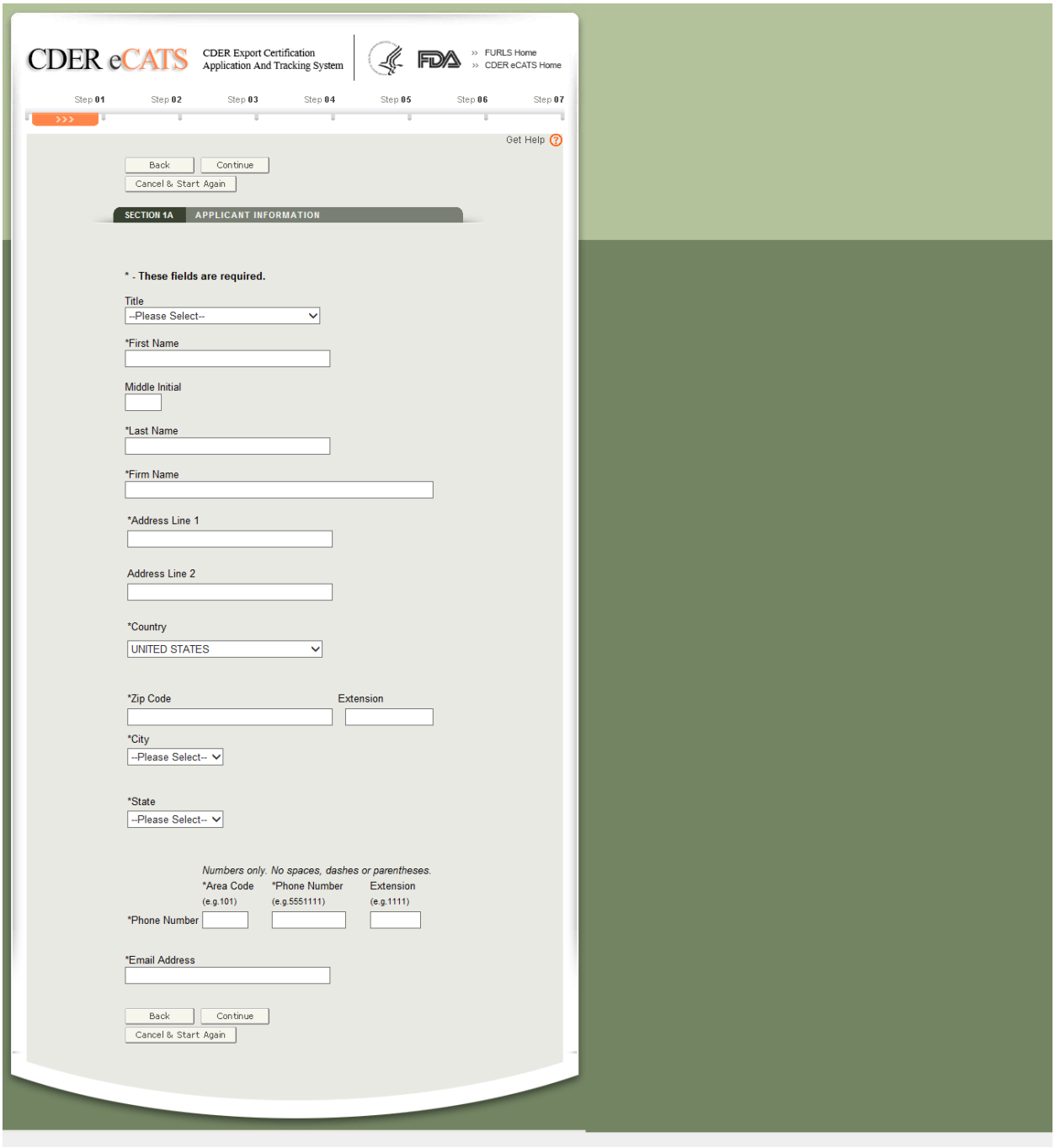
Certificate to a Pharmaceutical Product (CPP)

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.


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07
Get Help
Back
Continue
Cancel & Start Again
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
Back
Continue
Cancel & Start Again

CDER eCATS

CDER Export Certification Application And Tracking System

» FURLS Home
» CDER eCATS Home

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07

APPLICANT ADDRESS VALIDATION

YOUR ADDRESS	VALIDATED ADDRESS
Address Line 1:	Address Line 1:
Address Line 2:	Address Line 2:
City:	City:
State:	State:
Zip Code:	Zip Code:
Country:	Country:

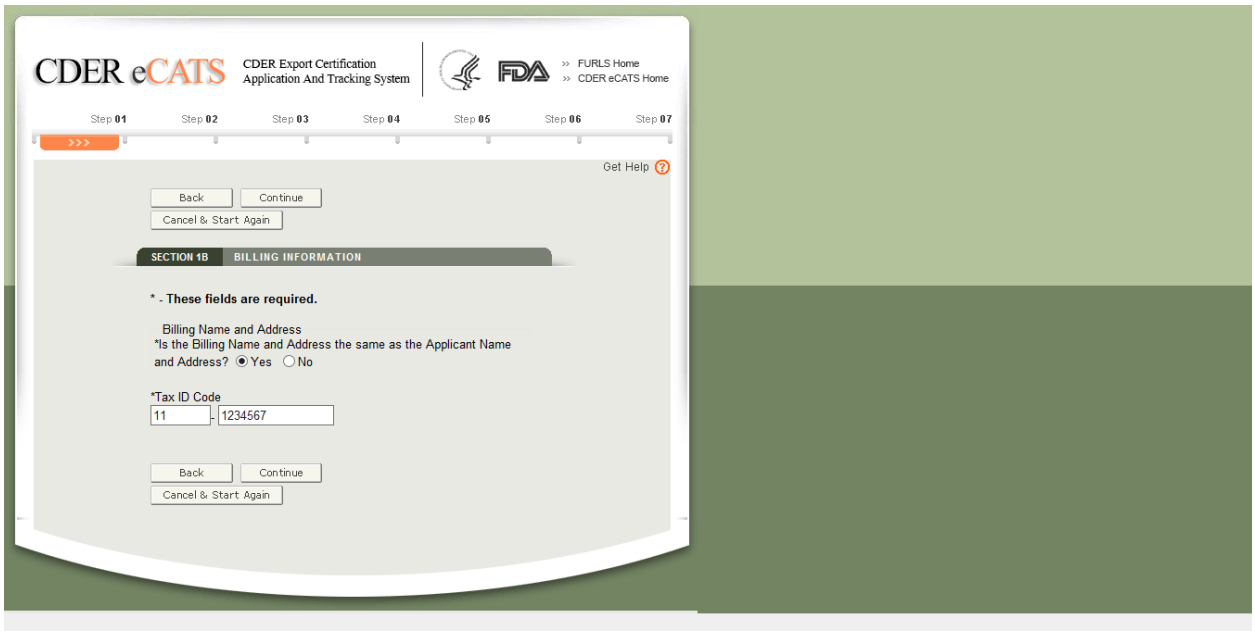
* - **These fields are required.**

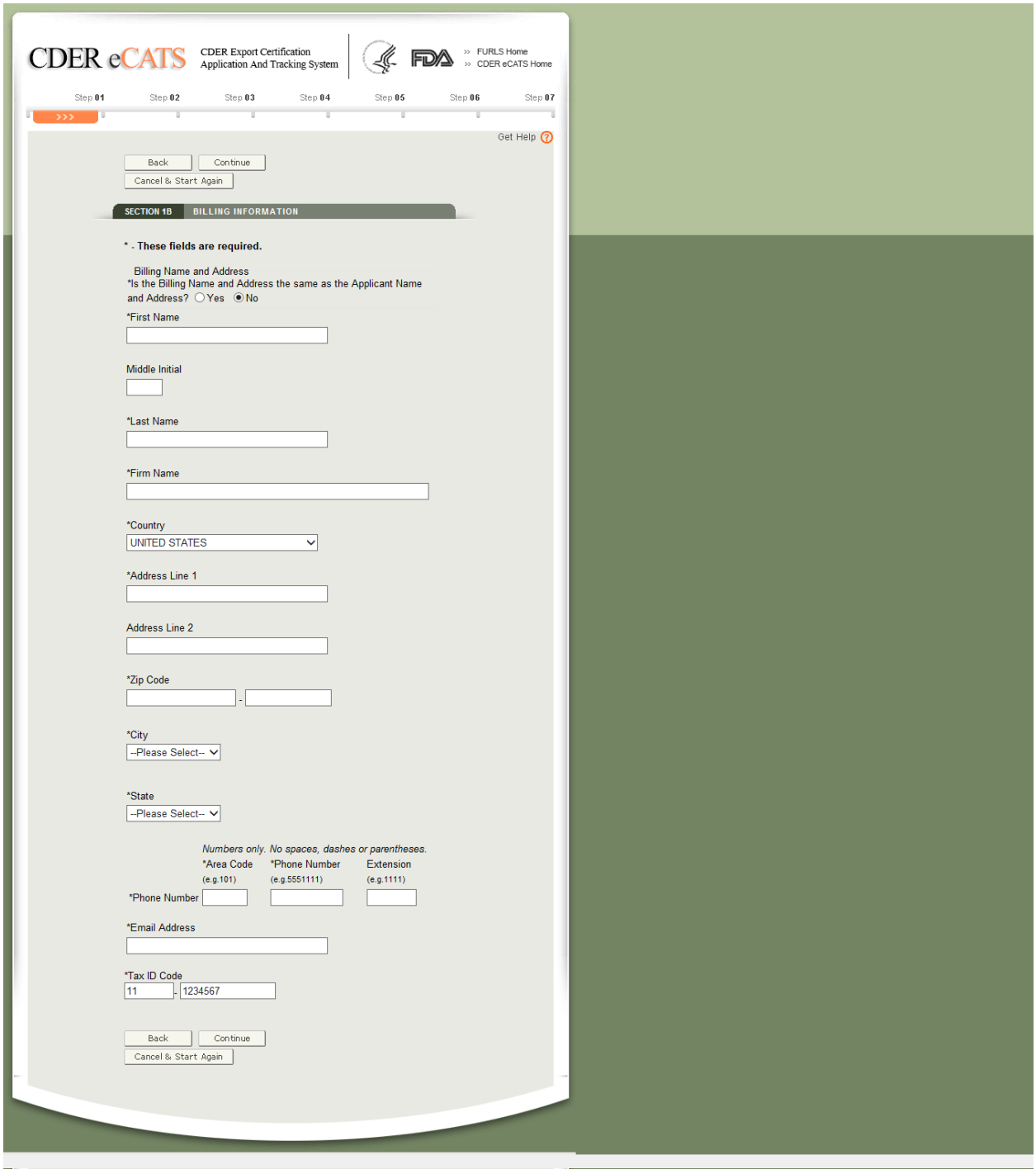
*Address Validation Decision

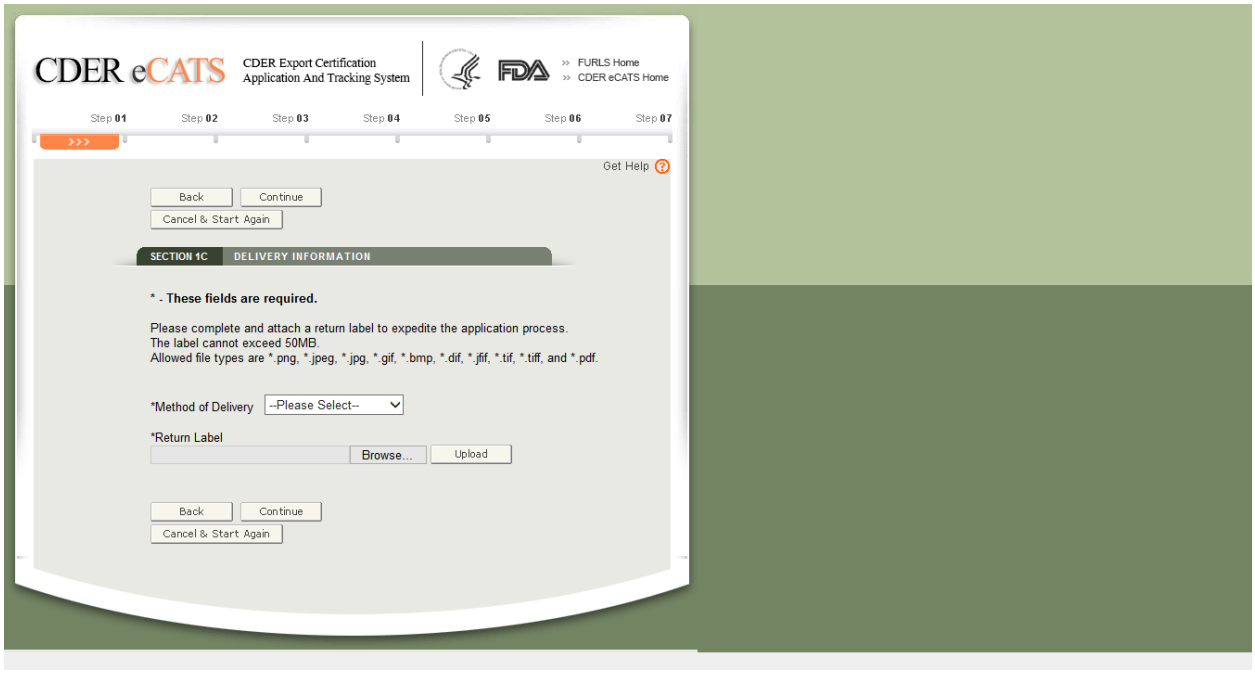
○ Return to Step 1 and make changes

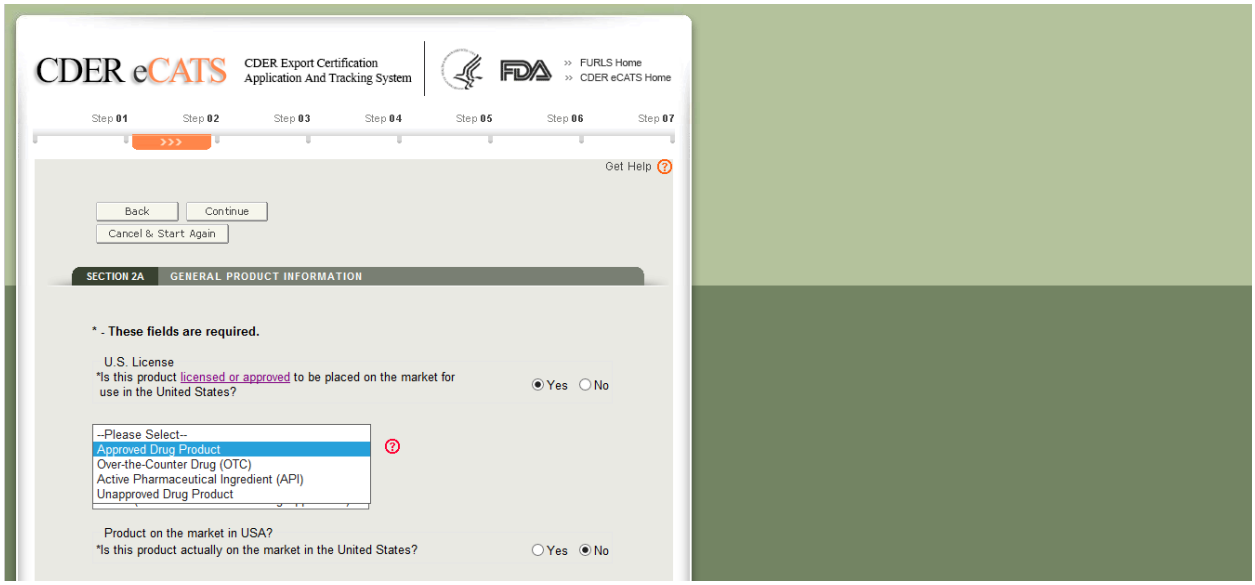
◉ Continue to use the existing address

Continue


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
Get Help
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


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07
Get Help
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
*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)
*Phone Number
*Email Address
*Tax ID Code
11
1234567
Back
Continue
Cancel & Start Again

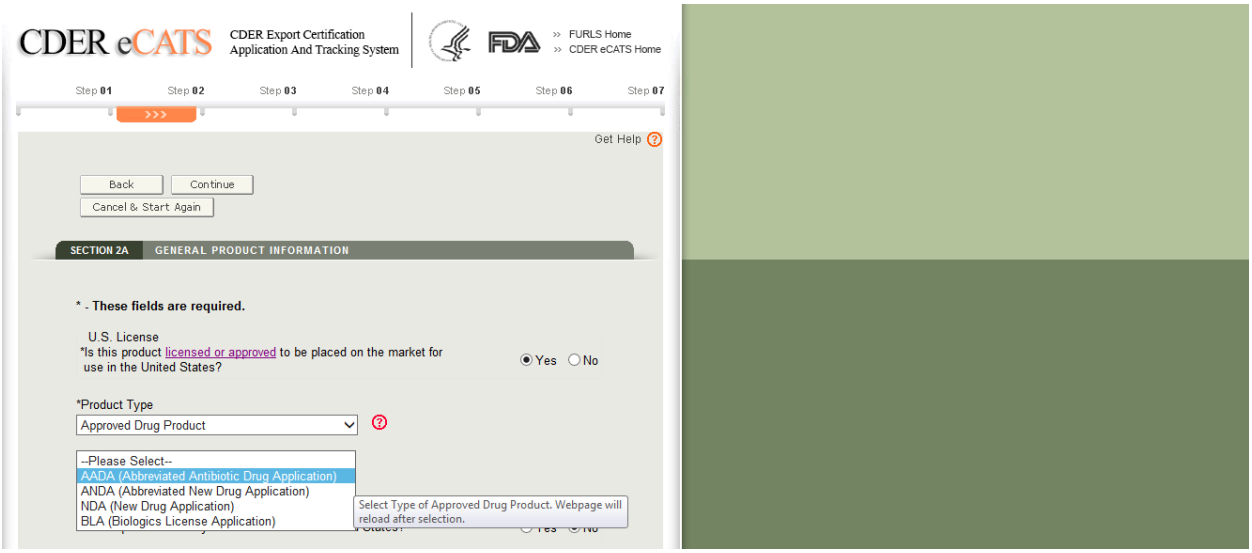

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
Get Help
Back
Continue
Cancel & Start Again
SECTION 1C
DELIVERY INFORMATION
* - These fields are required.
Please complete and attach a return label to expedite the application process.
The label cannot exceed 50MB.
Allowed file types are *.png, *.jpeg, *.jpg, *.gif, *.bmp, *.dif, *.jfif, *.tif, *.tiff, and *.pdf.
*Method of Delivery
--Please Select--
*Return Label
Browse...
Upload
Back
Continue
Cancel & Start Again


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
Get Help
Back
Continue
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 is 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).

Close ✕


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
Get Help
Back
Continue
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
--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.

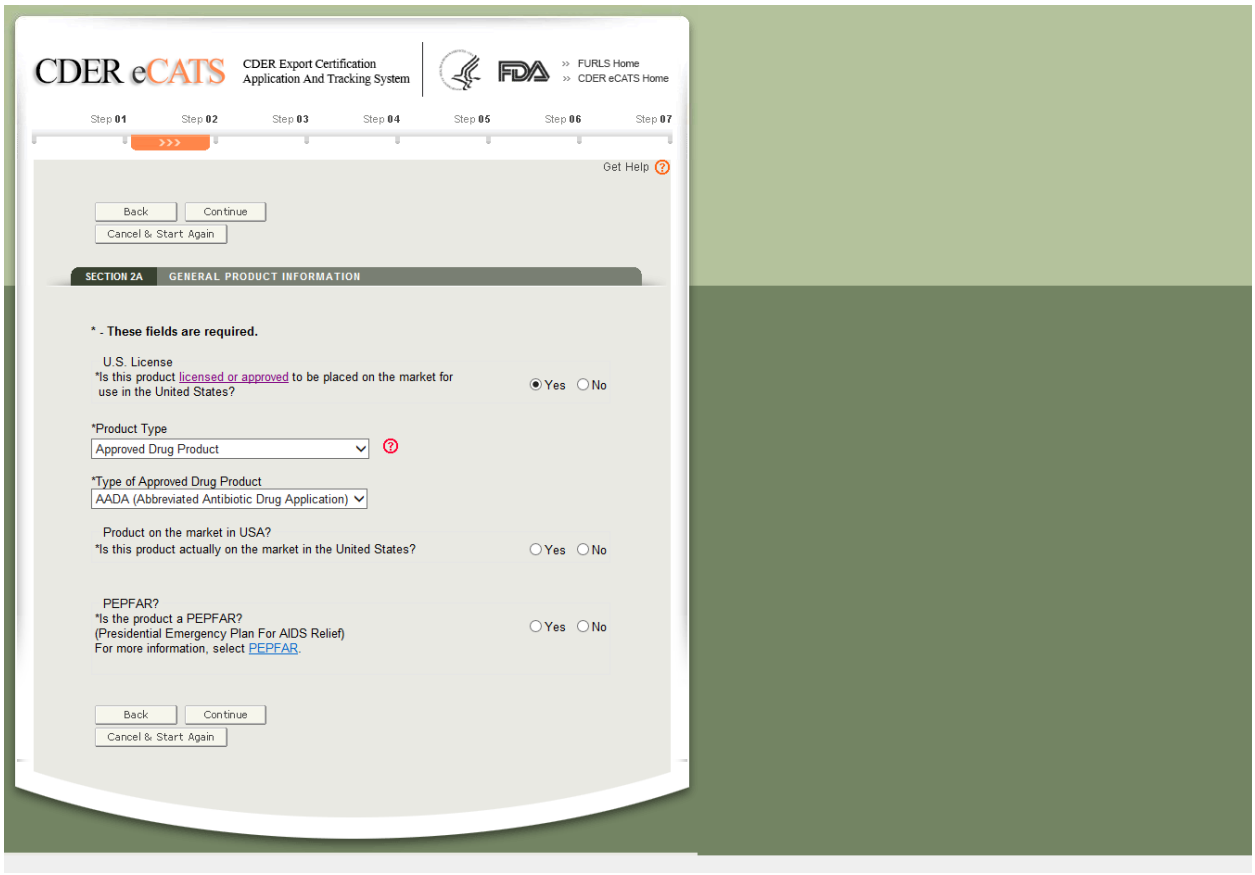
The OTC monographs can be found at the following website:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/default.htm

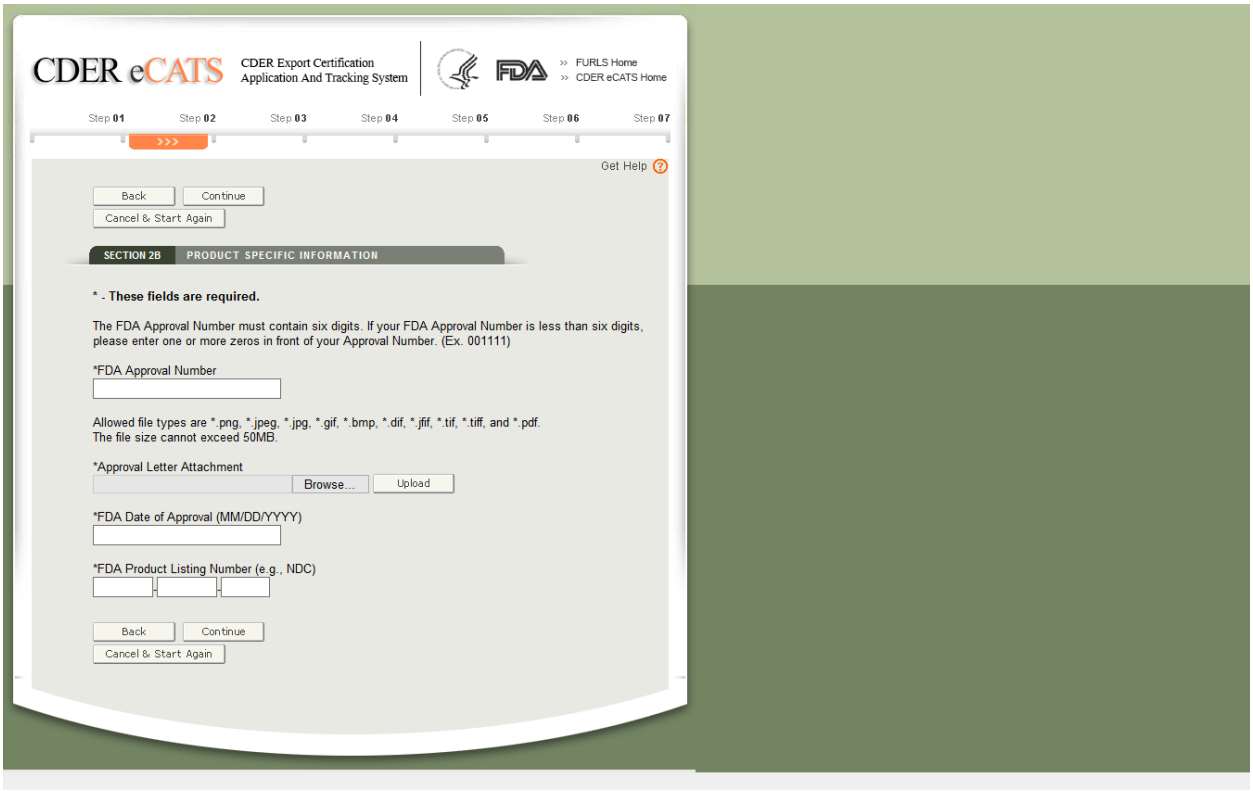
Active Pharmaceutical Ingredients (API)

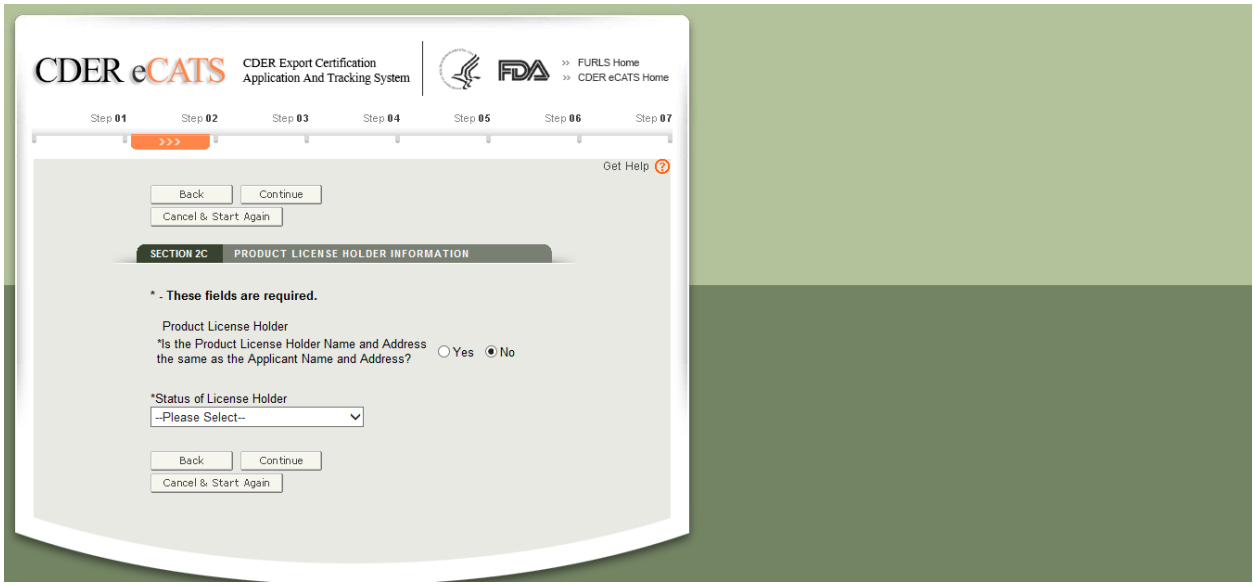
An active pharmaceutical ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

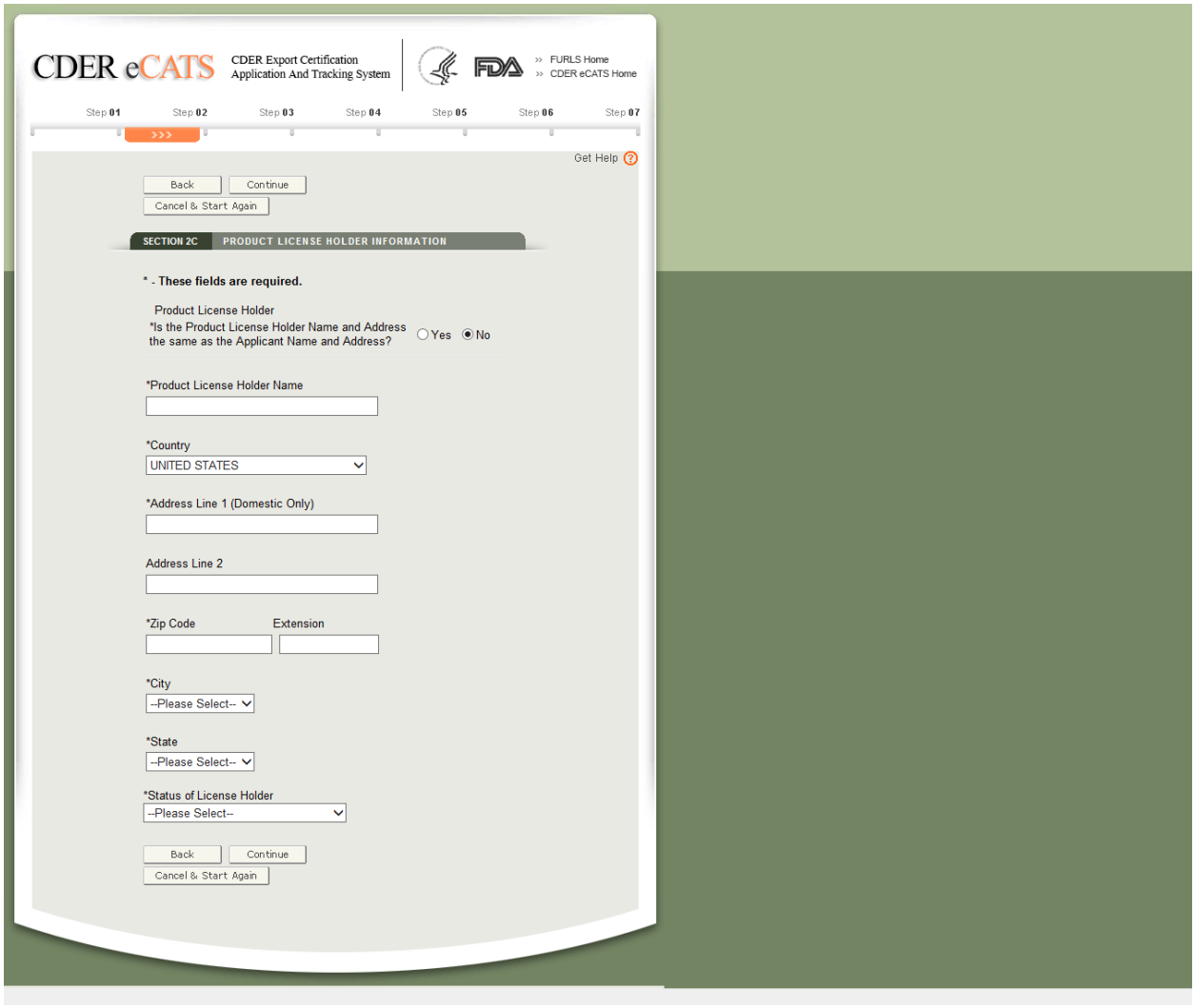
Unapproved New Drugs

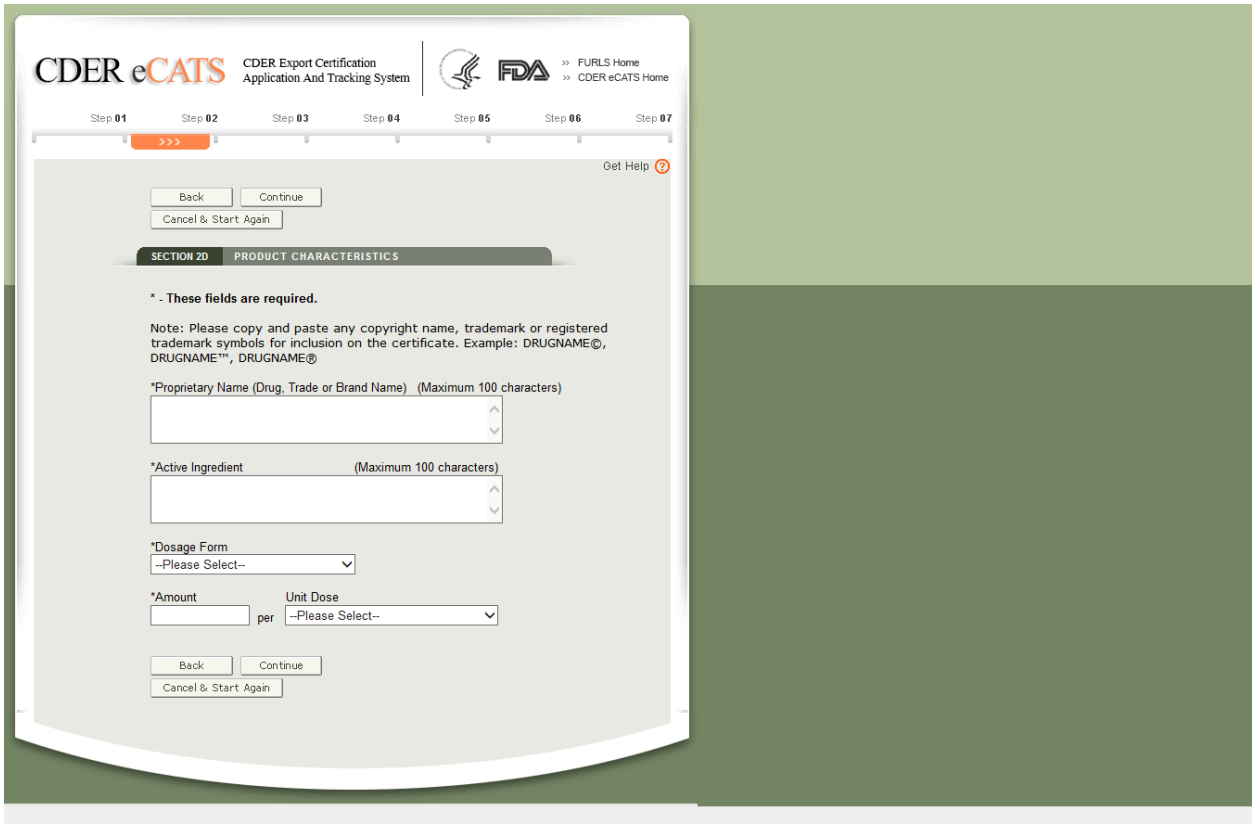
Unapproved New Drugs have not been approved or evaluated by CDER for safety and effectiveness and cannot be marketed in the United States. Exportation of these drugs is permitted only in accordance with the requirements found in sections 801 and 802 of the Food Drug and Cosmetic Act. In addition, when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

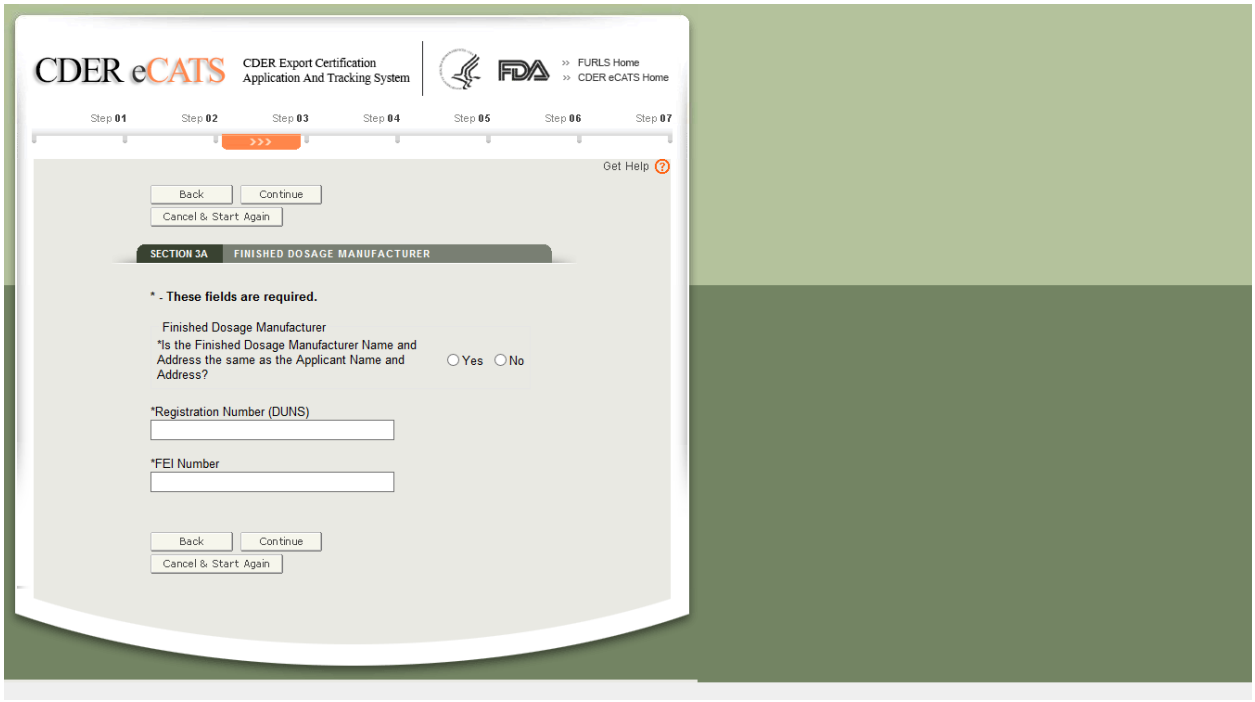

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07
Get Help
Back
Continue
Cancel & Start Again
SECTION 2A GENERAL PRODUCT INFORMATION
* - These fields are required.
U.S. License
*Is this product 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

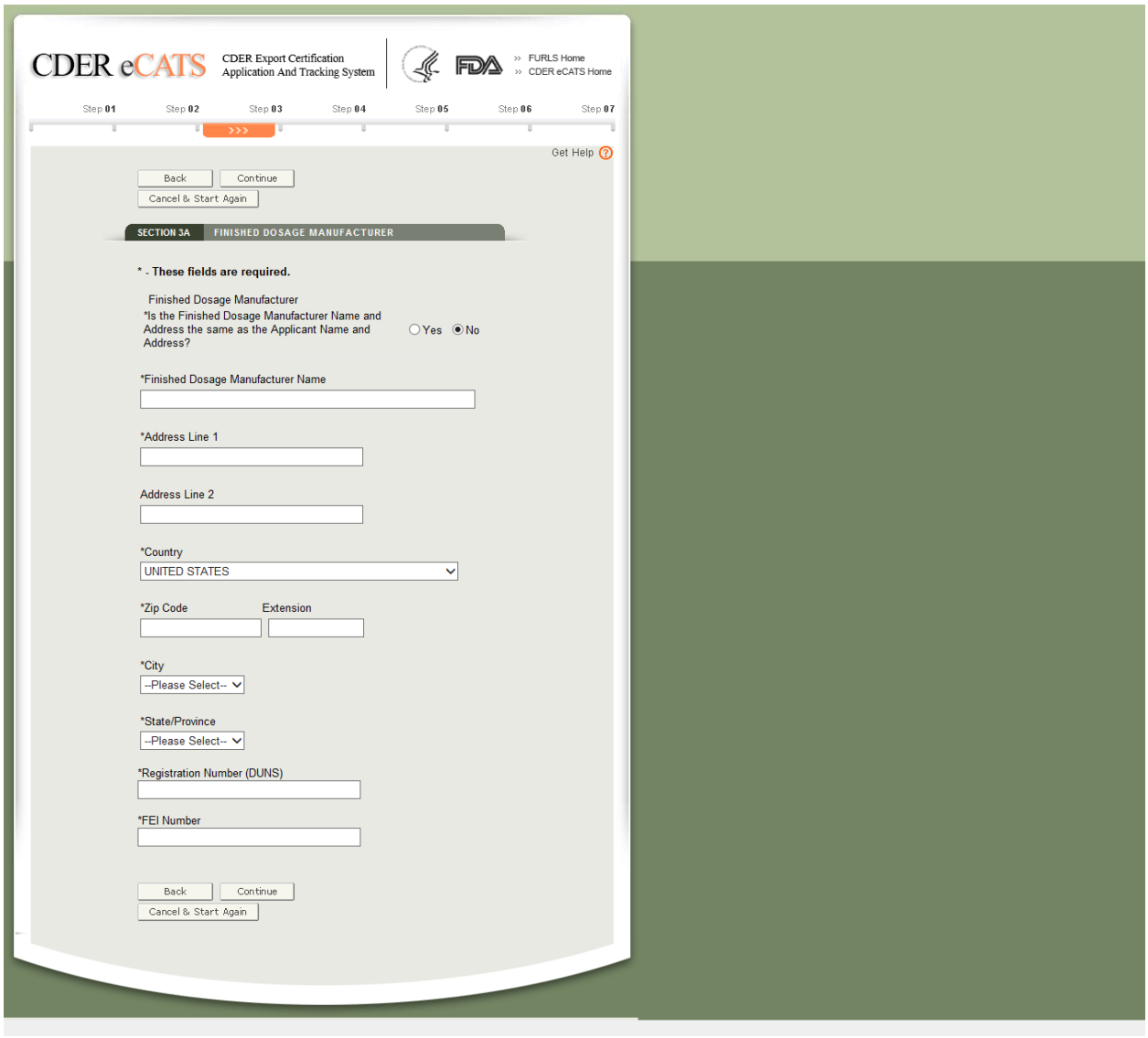

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
SECTION 2B
PRODUCT SPECIFIC INFORMATION
* - These fields are required.
The FDA Approval Number 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, *.jfif, *.tif, *.tiff, and *.pdf.
The file size cannot exceed 50MB.
*Approval Letter Attachment
Browse...
Upload
*FDA Date of Approval (MM/DD/YYYY)
*FDA Product Listing Number (e.g., NDC)
Back
Continue
Cancel & Start Again

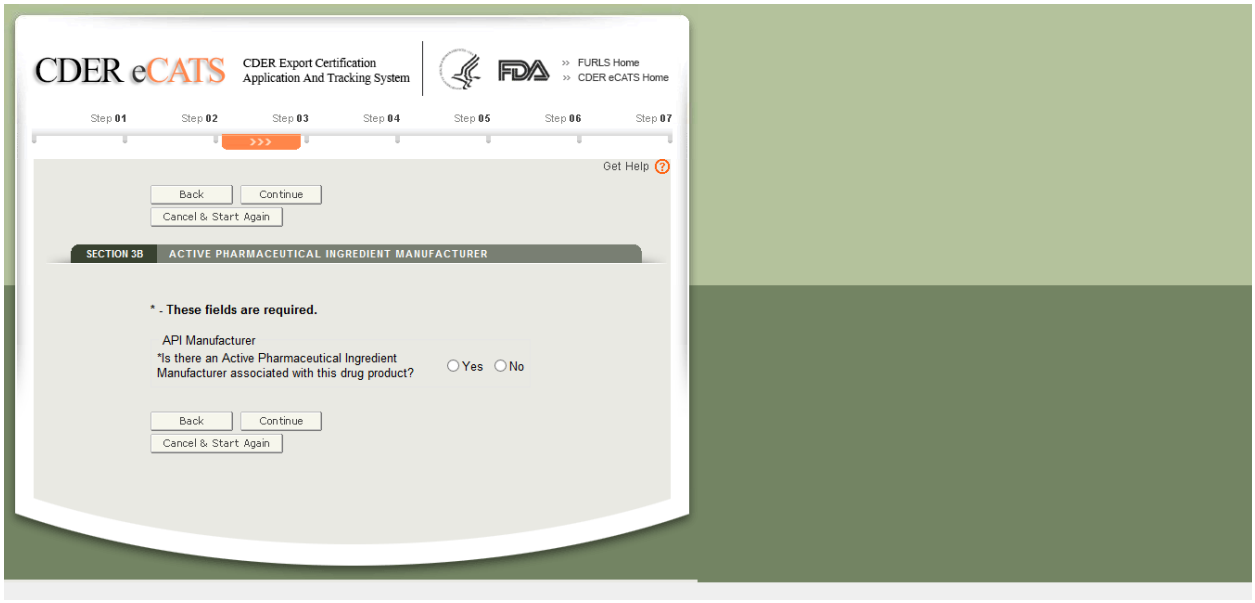

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
SECTION 2C
PRODUCT LICENSE HOLDER INFORMATION
* - These fields are required.
Product License 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


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07
>>>
Get Help
Back
Continue
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
UNITED STATES
*Address Line 1 (Domestic Only)
Address Line 2
*Zip Code
Extension
*City
--Please Select--
*State
--Please Select--
*Status of License Holder
--Please Select--
Back
Continue
Cancel & Start Again


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
SECTION 2D
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
per
Unit Dose
--Please Select--
Back
Continue
Cancel & Start Again

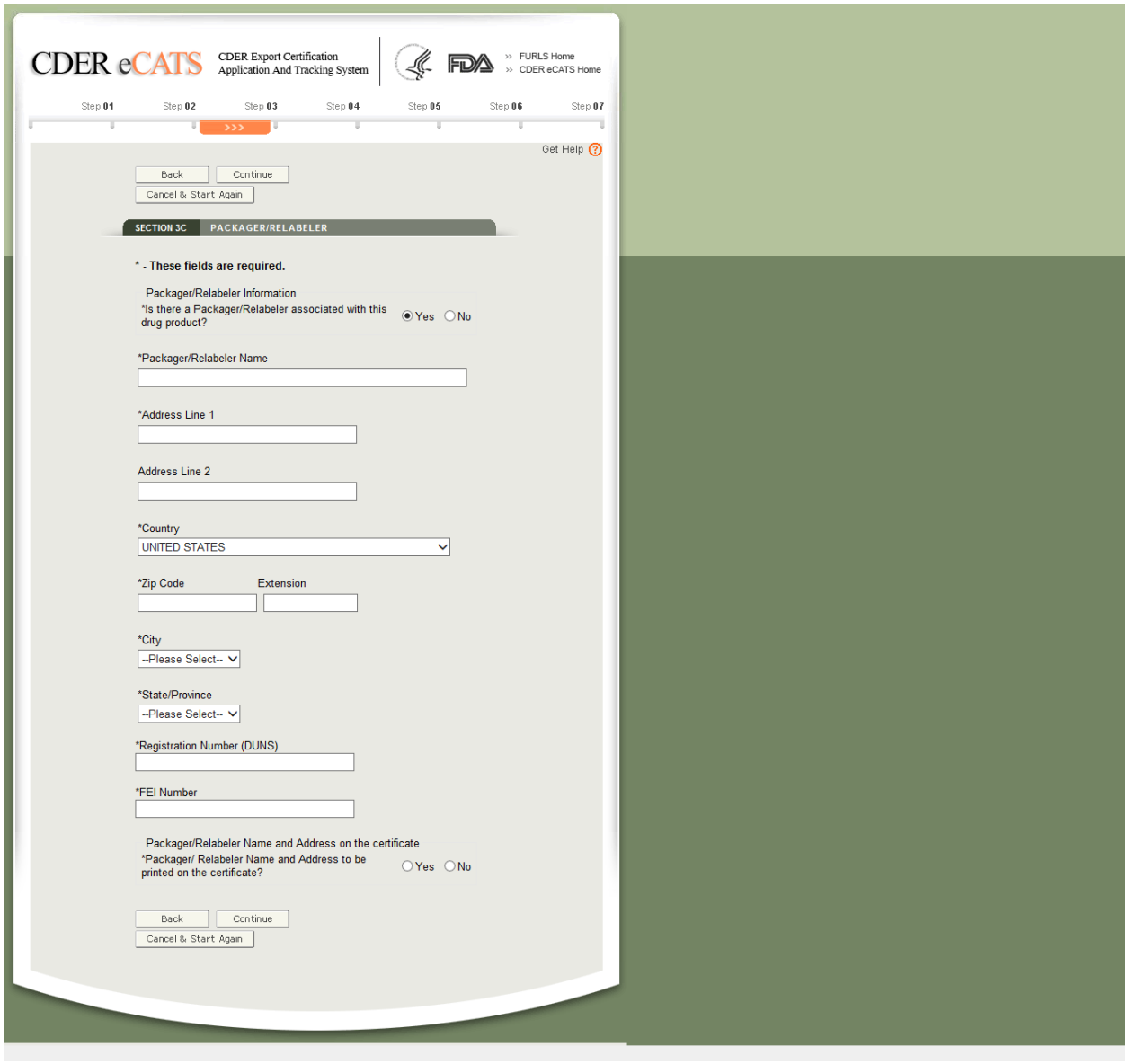

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
SECTION 3A
FINISHED DOSAGE MANUFACTURER
* - These fields are required.
Finished Dosage Manufacturer
*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

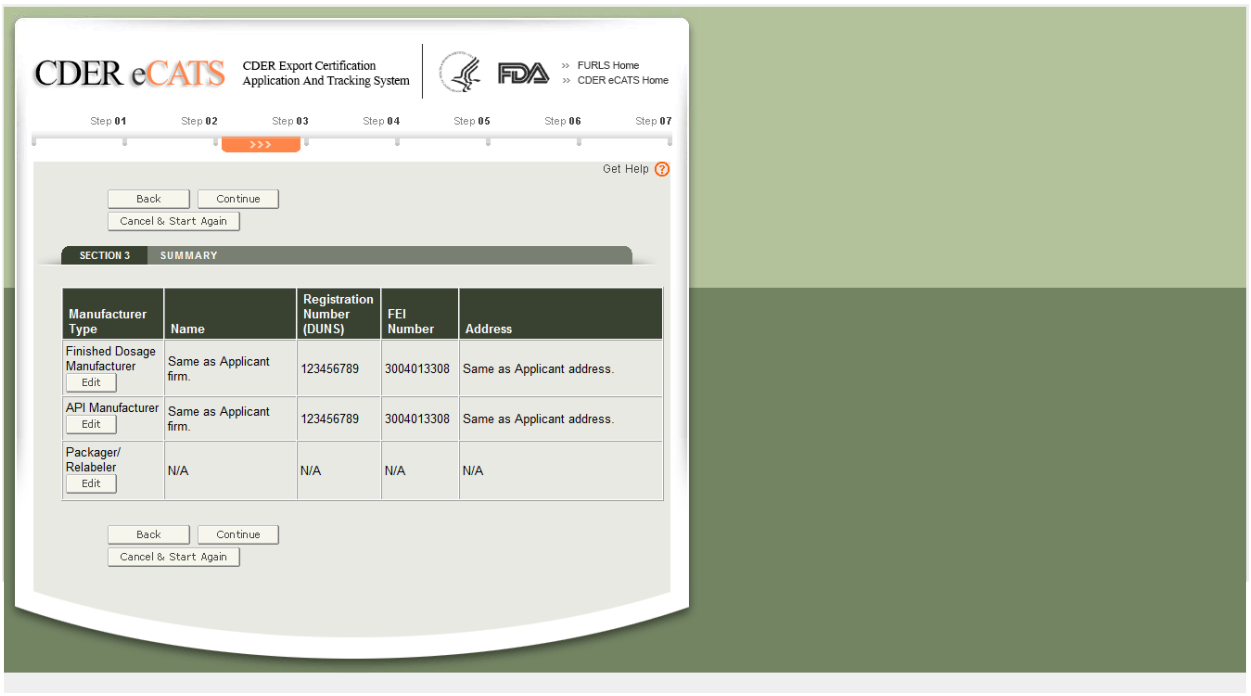

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07
Get Help
Back
Continue
Cancel & Start Again
SECTION 3A FINISHED DOSAGE MANUFACTURER
* - These fields are required.
Finished Dosage Manufacturer
*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
Back
Continue
Cancel & Start Again

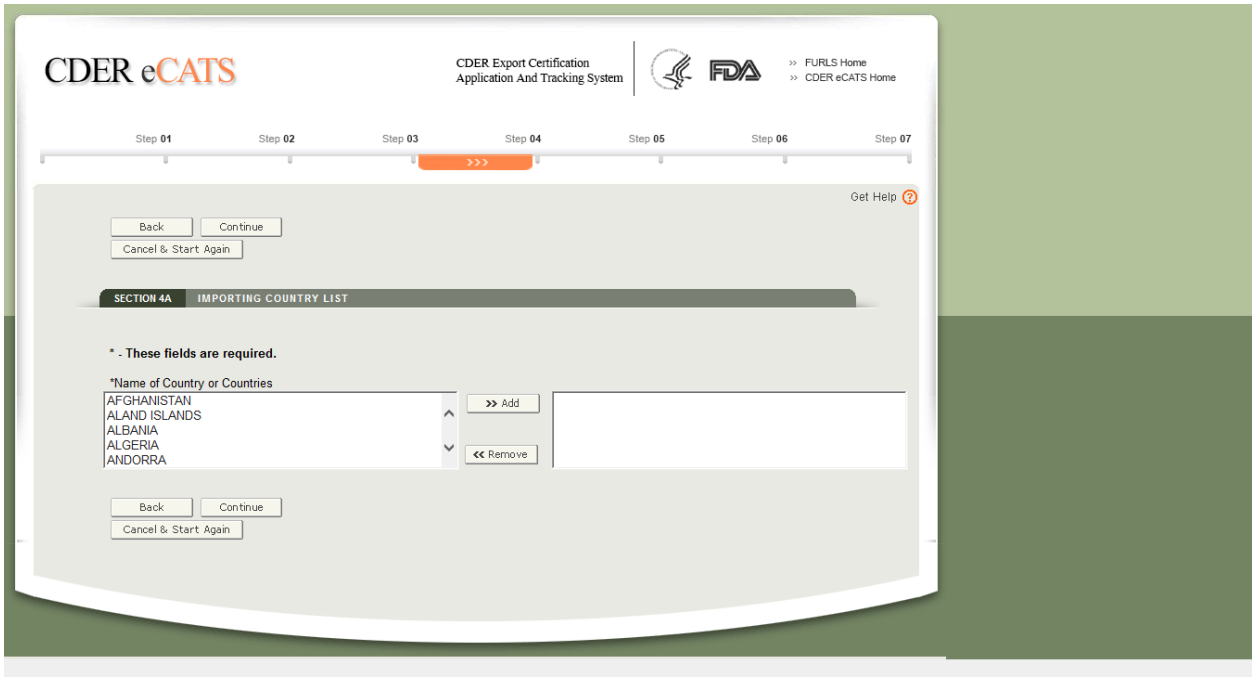

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
SECTION 3B
ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURER
* - These fields are required.
API Manufacturer
*Is there an Active Pharmaceutical Ingredient Manufacturer associated with this drug product?
Yes
No
Back
Continue
Cancel & Start Again

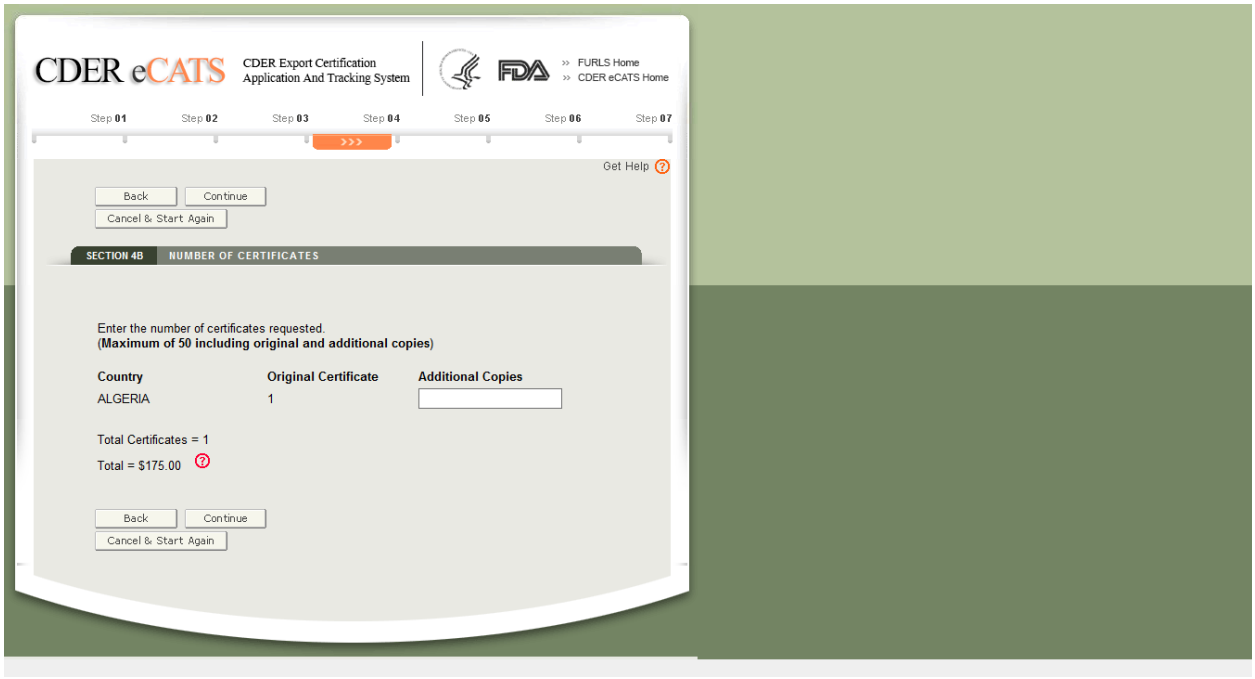

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
SECTION 3B
ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURER
* - These fields are required.
API Manufacturer
*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


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
SECTION 3C
PACKAGER/RELABELER
* - These fields are required.
Packager/Relabeler Information
*Is there a Packager/Relabeler associated with this drug product?
Yes
No
Back
Continue
Cancel & Start Again


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
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
Back
Continue
Cancel & Start Again

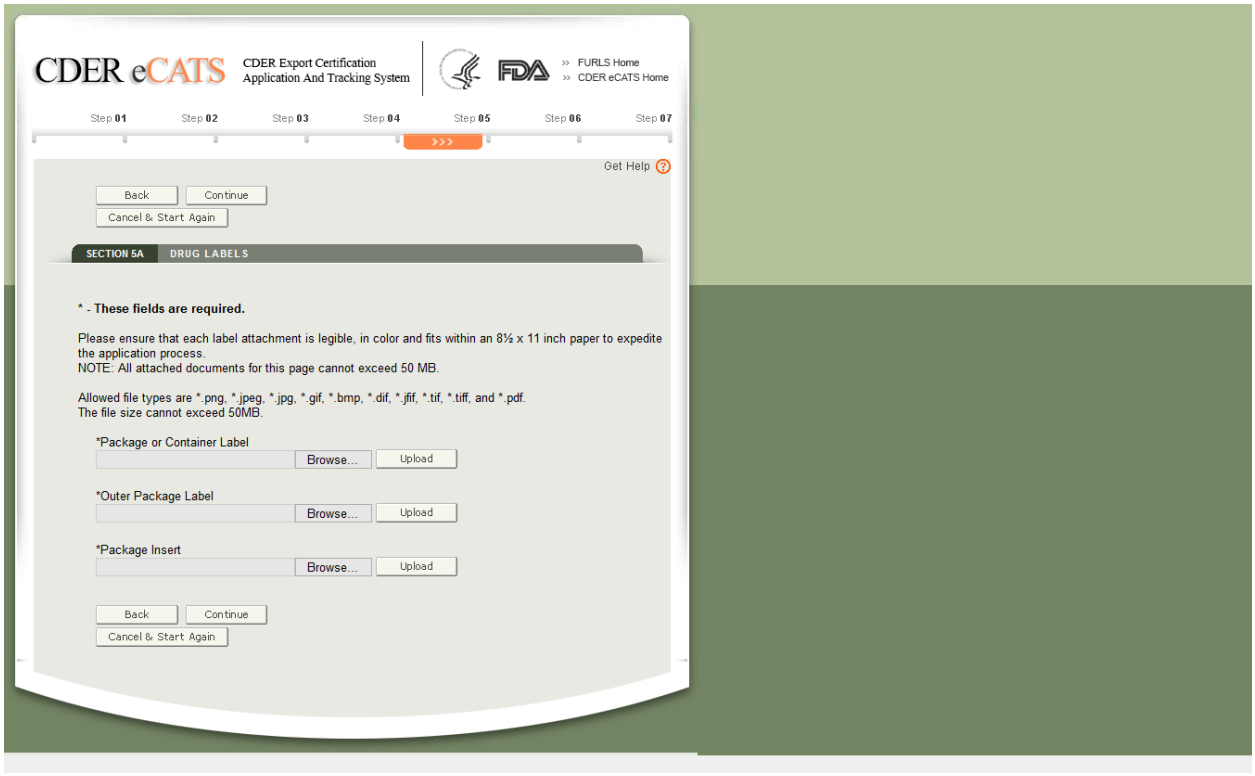

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
SECTION 3
SUMMARY
Manufacturer Type
Name
Registration Number (DUNS)
FEI Number
Address
Finished 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
Back
Continue
Cancel & Start Again

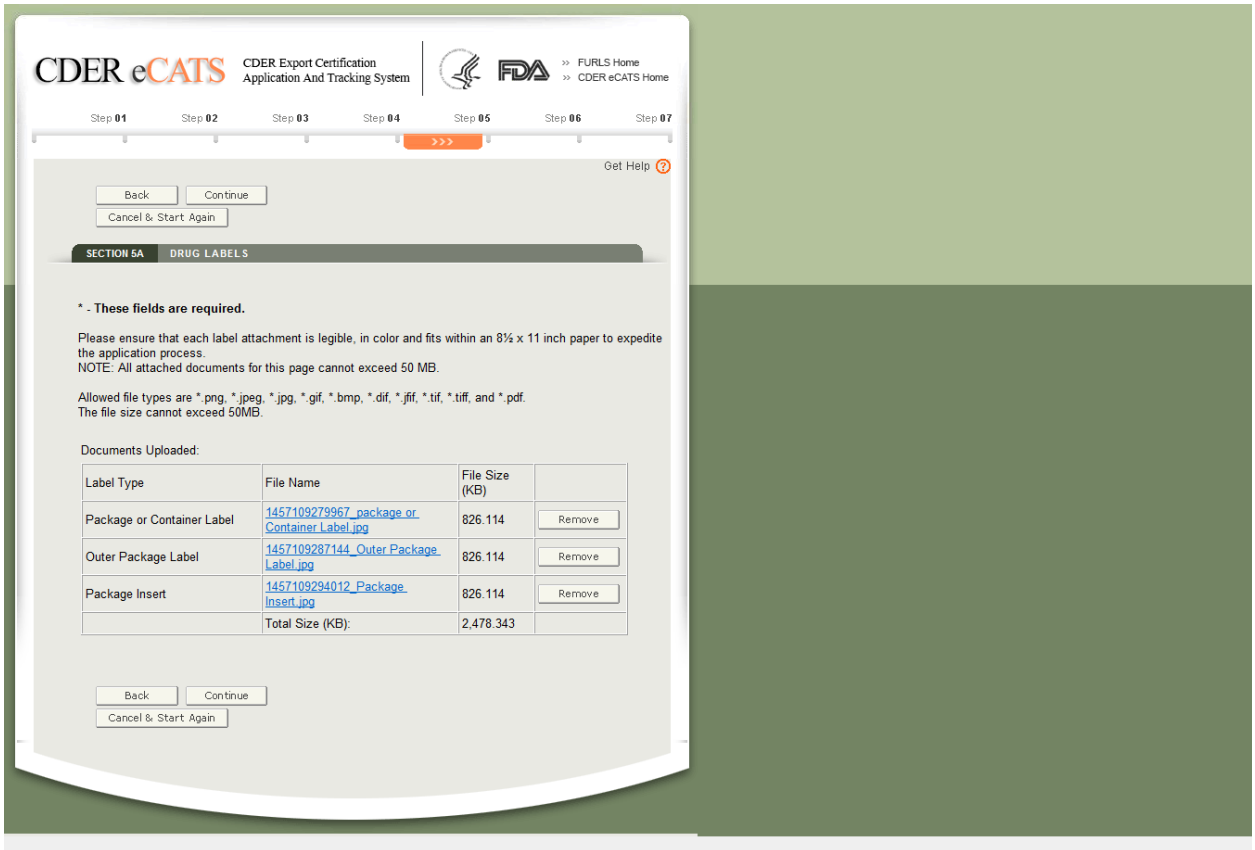

CDER eCATS
CDER Export Certification
Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
SECTION 4A
IMPORTING COUNTRY LIST
* - These fields are required.
*Name of Country or Countries
AFGHANISTAN
ALAND ISLANDS
ALBANIA
ALGERIA
ANDORRA
>> Add
<< Remove
Back
Continue
Cancel & Start Again


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
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
Total Certificates = 1
Total = $175.00
Back
Continue
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.


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07
Get Help
Back
Continue
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, *.jfif, *.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


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07
Get Help
Back
Continue
Cancel & Start Again
SECTION 5A DRUG LABELS
* - These fields are required.
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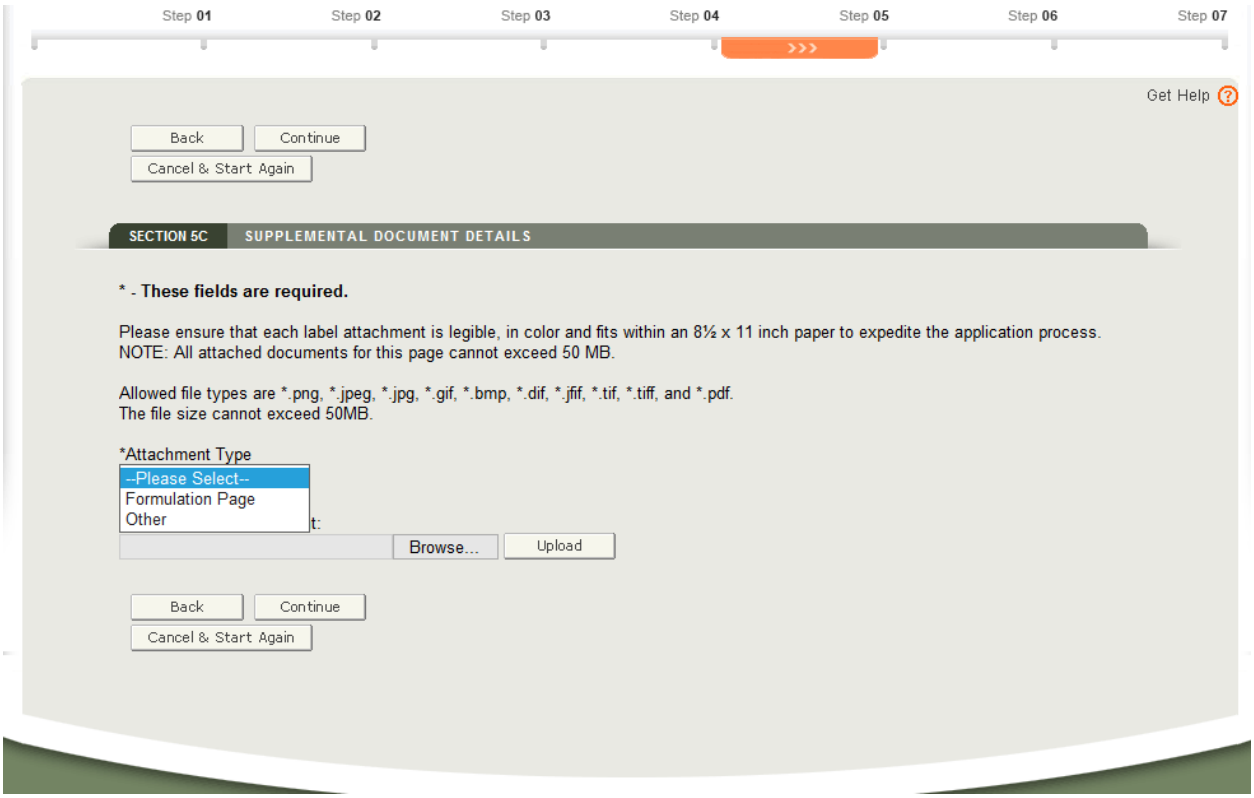
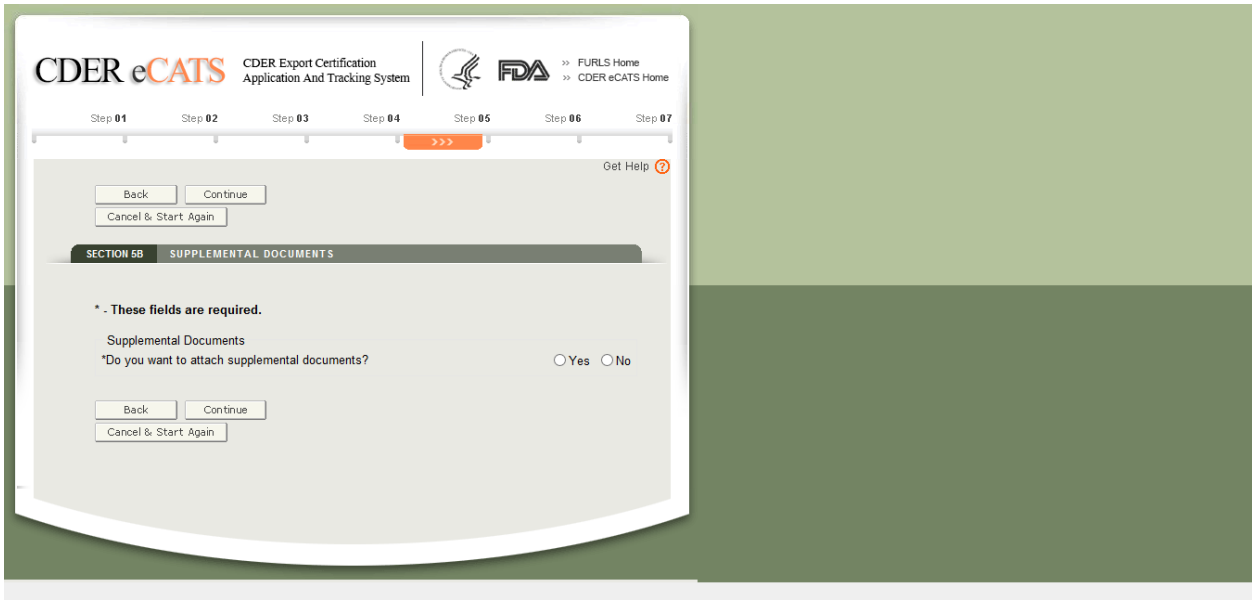
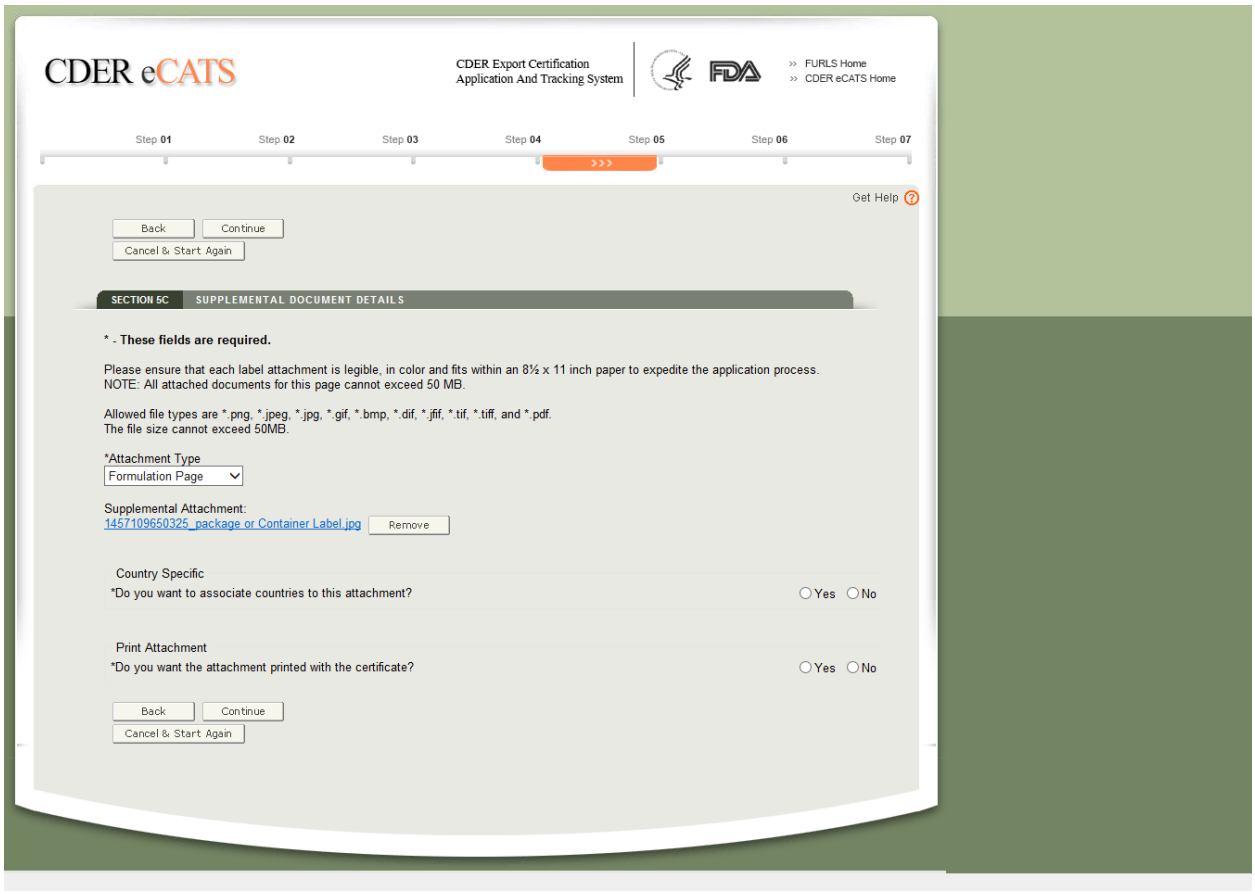
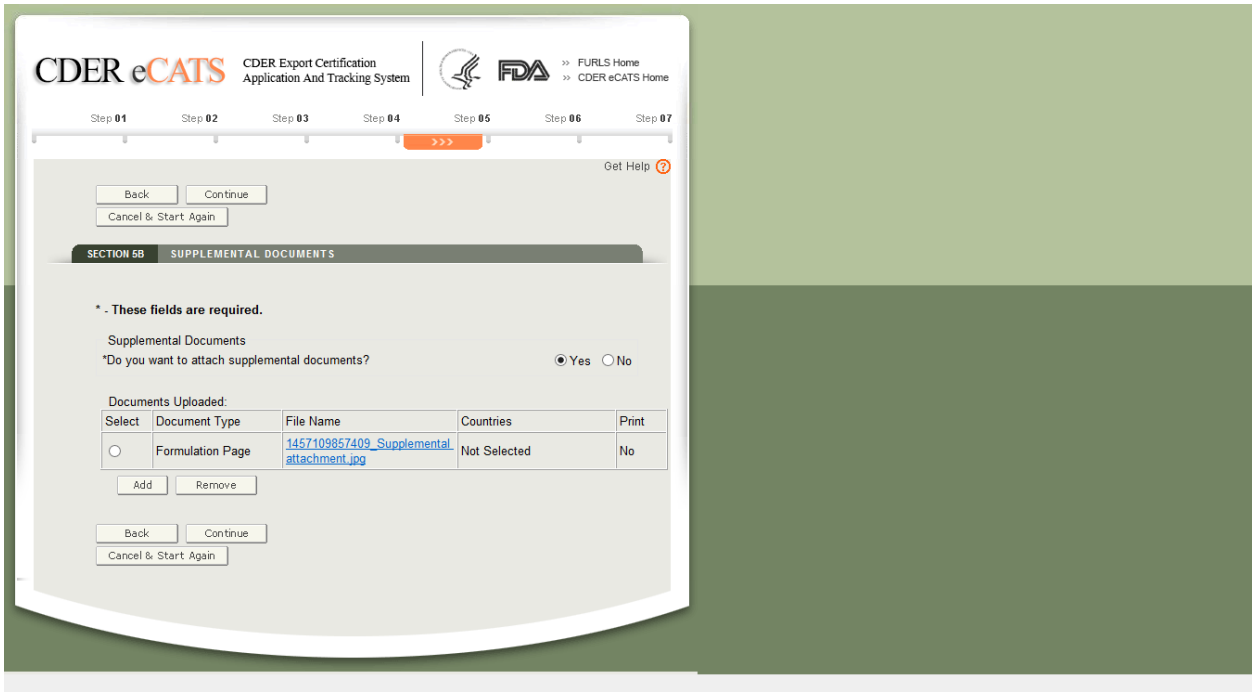
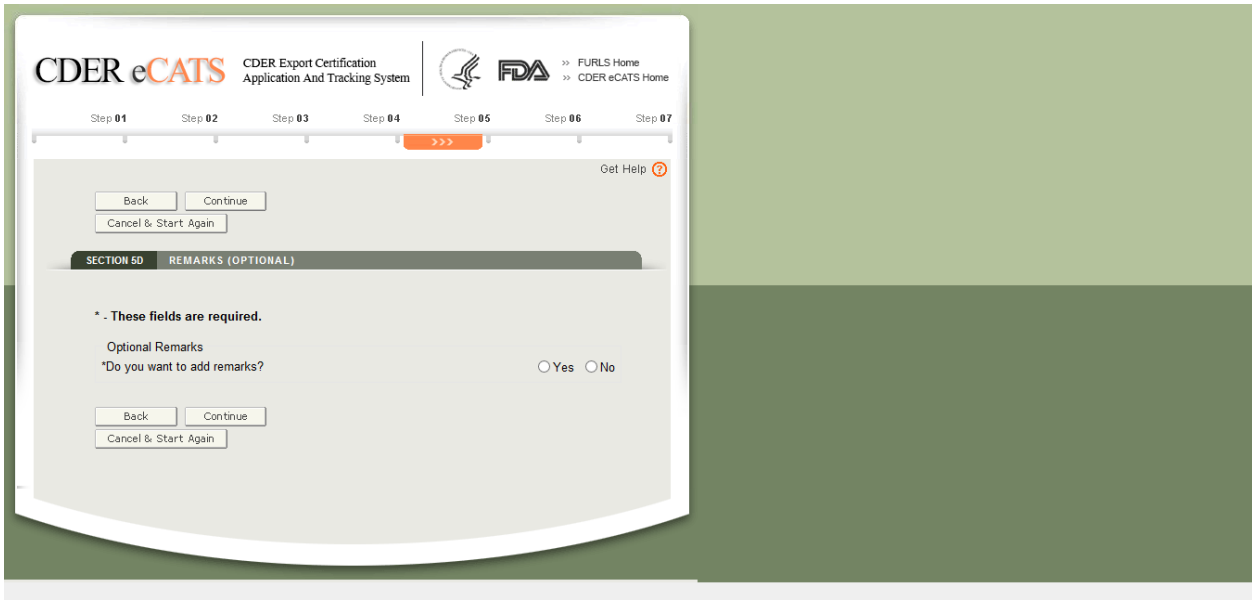
NOTE: All attached documents for this page cannot exceed 50 MB.
Allowed file types are *.png, *.jpeg, *.jpg, *.gif, *.bmp, *.dif, *.jfif, *.tif, *.tiff, and *.pdf.
The file size cannot exceed 50MB.
Documents Uploaded:
Label Type
File Name
File Size (KB)
Package or Container Label
1457109279967_package 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
Back
Continue
Cancel & Start Again

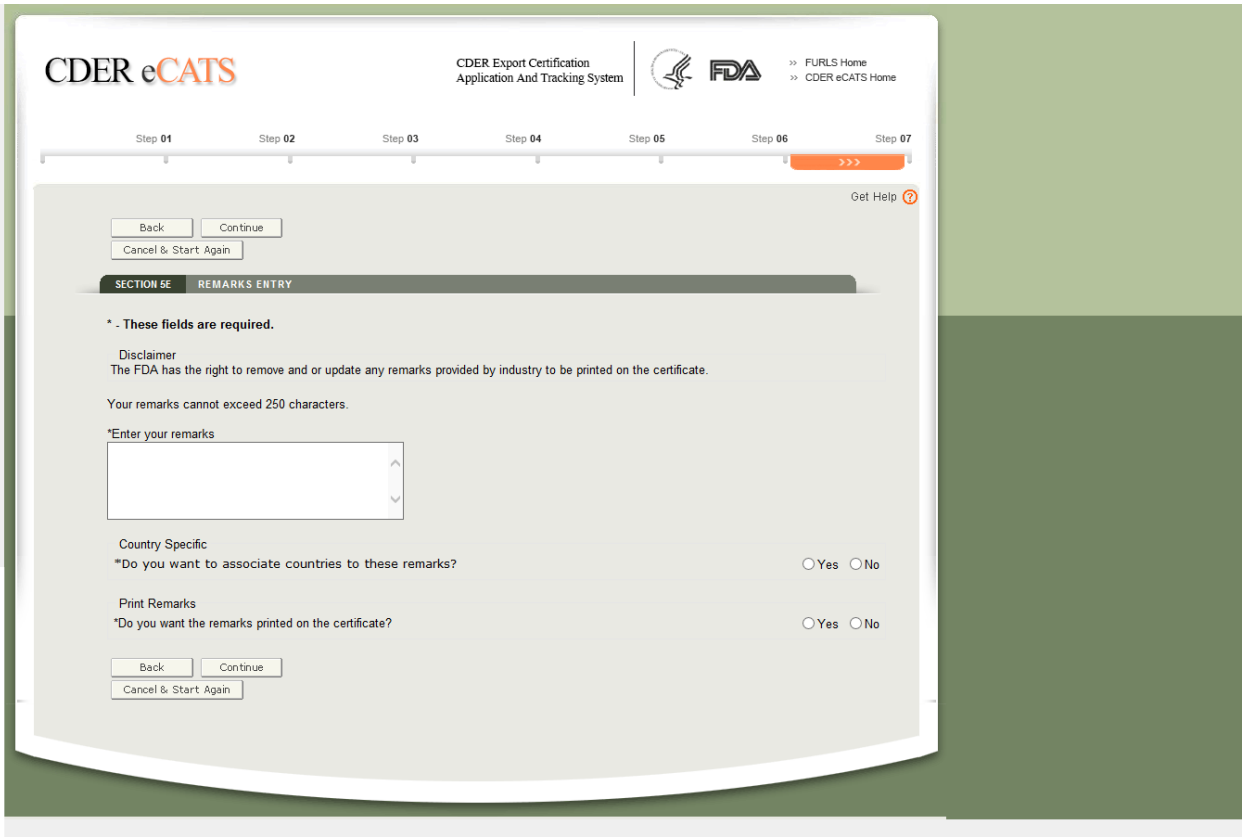

Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
Get Help
Back
Continue
Cancel & Start Again
SECTION 5C
SUPPLEMENTAL DOCUMENT DETAILS
* - These fields are required.
Please ensure that each label attachment is legible, in color and fits within an 8½ x 11 inch paper to expedite the application process.
NOTE: All attached documents for this page cannot exceed 50 MB.
Allowed file types are *.png, *.jpeg, *.jpg, *.gif, *.bmp, *.dif, *.jfif, *.tif, *.tiff, and *.pdf.
The file size cannot exceed 50MB.
*Attachment Type
--Please Select--
Formulation Page
Other
t:
Browse...
Upload
Back
Continue
Cancel & Start Again

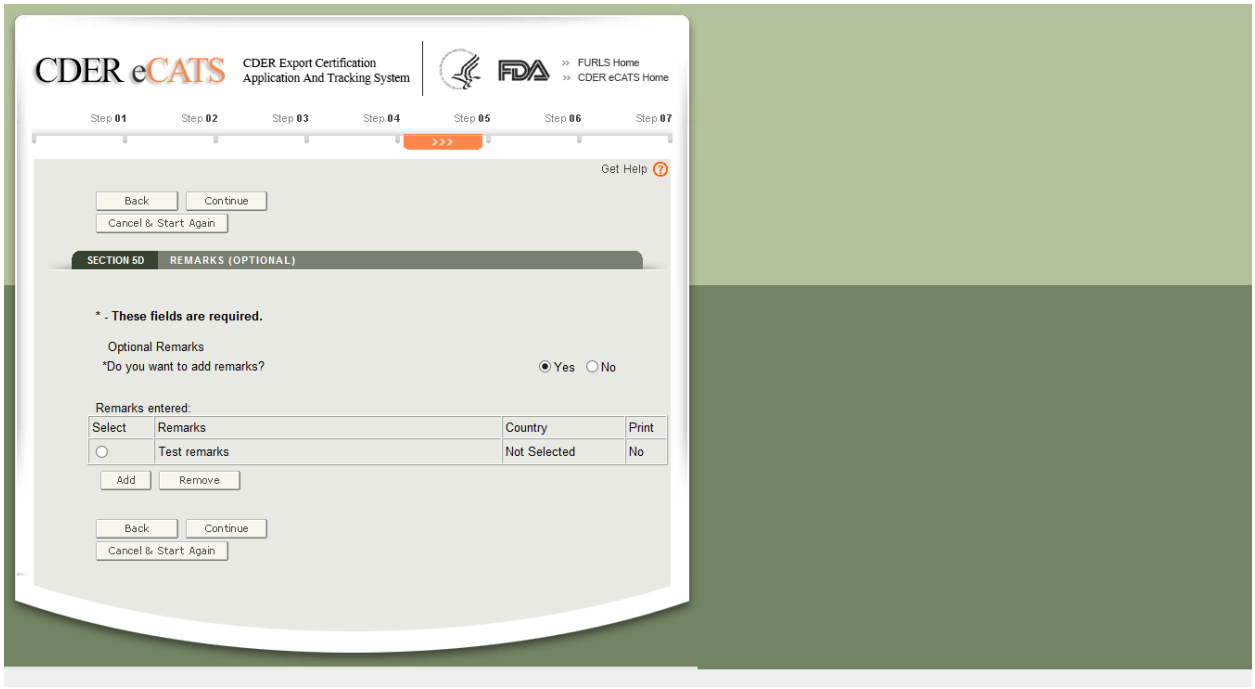

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
Get Help
Back
Continue
Cancel & Start Again
SECTION 5B
SUPPLEMENTAL DOCUMENTS
* - These fields are required.
Supplemental Documents
*Do you want to attach supplemental documents?
Yes
No
Back
Continue
Cancel & Start Again

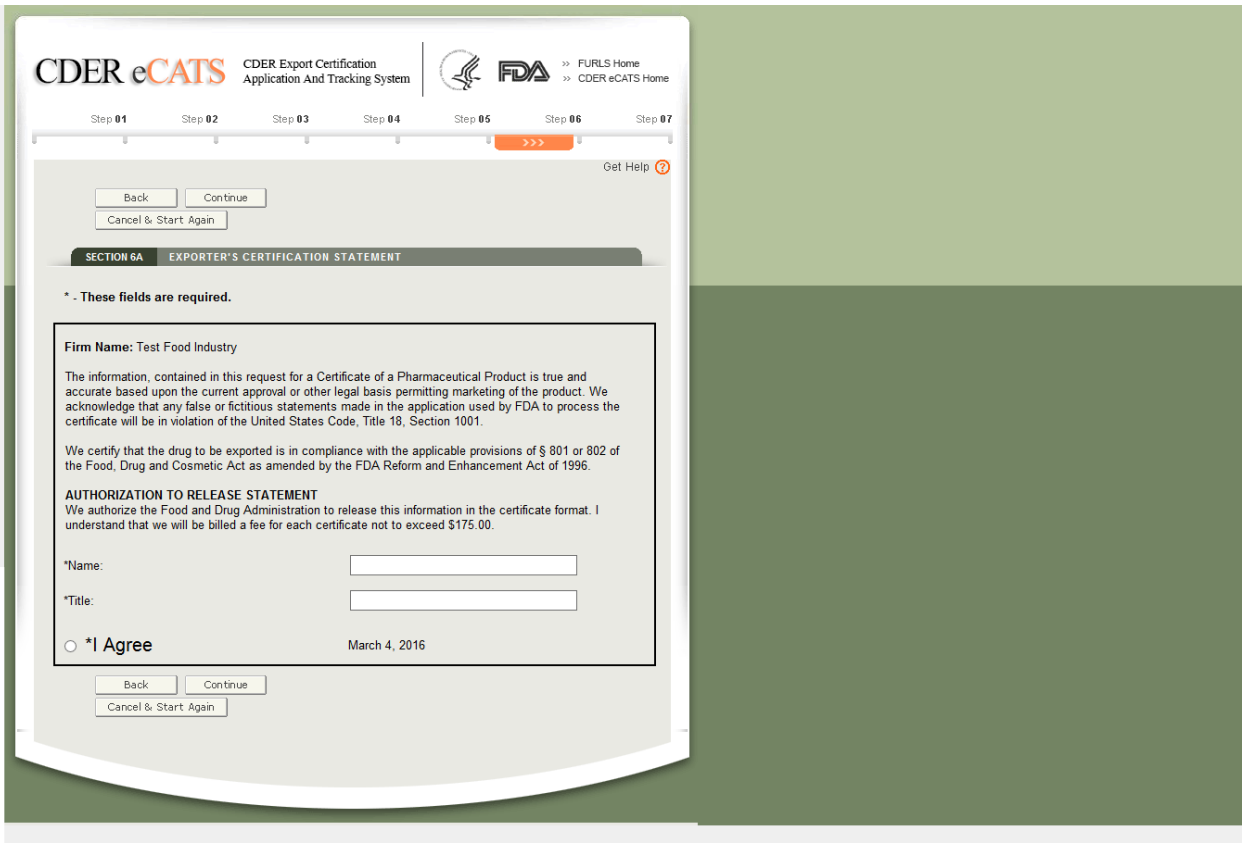

CDER eCATS
CDER Export Certification
Application And Tracking System
FDA
>> FURLS Home
>> CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
SECTION 5C
SUPPLEMENTAL DOCUMENT DETAILS
* - These fields are required.
Please ensure that 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, *.jfif, *.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
Back
Continue
Cancel & Start Again

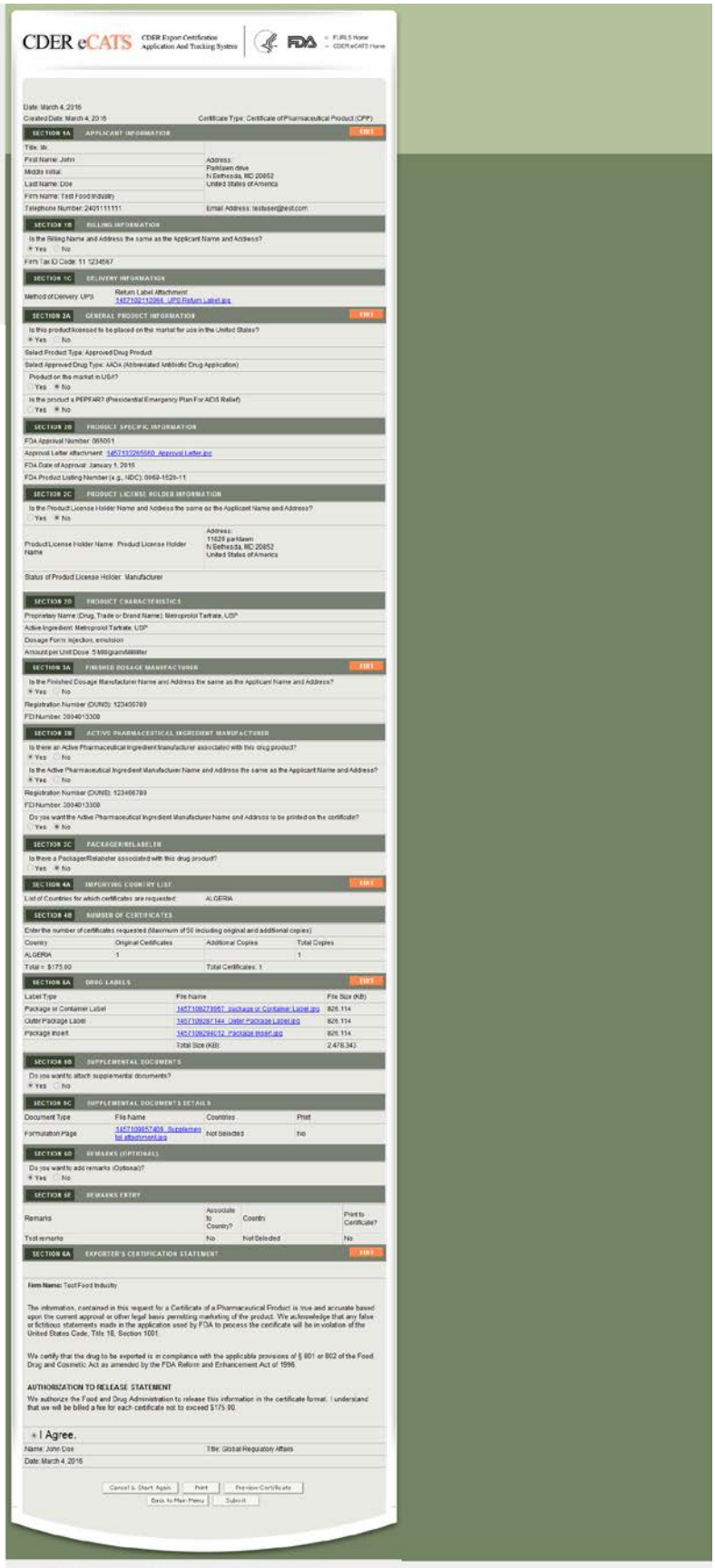

CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07
Get Help
Back
Continue
Cancel & Start Again
SECTION 5B SUPPLEMENTAL DOCUMENTS
* - These fields are required.
Supplemental Documents
*Do you want to attach supplemental documents?
Yes
No
Documents Uploaded:
Select
Document Type
File Name
Countries
Print
Formulation Page
1457109857409_Supplemental attachment.jpg
Not Selected
No
Add
Remove
Back
Continue
Cancel & Start Again


CDER eCATS
CDER Export Certification
Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
Get Help
Back
Continue
Cancel & Start Again
SECTION 5D
REMARKS (OPTIONAL)
* - These fields are required.
Optional Remarks
*Do you want to add remarks?
Yes
No
Back
Continue
Cancel & Start Again


CDER eCATS
CDER Export Certification
Application And Tracking System
FDA
FURLS Home
CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
Get Help
Back
Continue
Cancel & Start Again
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
Back
Continue
Cancel & Start Again


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
Get Help
Back
Continue
Cancel & Start Again
SECTION 5D
REMARKS (OPTIONAL)
* - These fields are required.
Optional Remarks
*Do you want to add remarks?
Yes
No
Remarks entered:
Select
Remarks
Country
Print
Test remarks
Not Selected
No
Add
Remove
Back
Continue
Cancel & Start Again


CDER eCATS
CDER Export Certification Application And Tracking System
FDA
» FURLS Home
» CDER eCATS Home
Step 01
Step 02
Step 03
Step 04
Step 05
Step 06
Step 07
>>>
Get Help
Back
Continue
Cancel & Start Again
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
Back
Continue
Cancel & Start Again



CDER eCATS CDER Export Certification Application And Tracking System

FDA

Date: March 4, 2016

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

SECTION 1A APPLICANT INFORMATION EDIT

Title: Mr.

First Name: John

Middle Initial:

Last Name: Doe

Firm Name: Test Food Industry

Telephone Number: 2401111111

Address:
Parklawn drive
N Bethesda, MD 20852
United States of America

Email Address: testuser@test.com

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:
1457102112064_UPS Return Label.jpg

SECTION 2A GENERAL PRODUCT INFORMATION EDIT

Is this product licensed to be placed on the market for use in the United States?
Yes No

Select Product Type: Approved Drug Product

Select Approved Drug Type: AADA (Abbreviated Antibiotic Drug Application)

Product on the market in USA?
Yes No

Is the product a PEPFAR? (Presidential Emergency Plan For AIDS Relief)
Yes No

SECTION 2B PRODUCT SPECIFIC INFORMATION

FDA Approval Number: 065051

Approval Letter Attachment: 1457113265560_Approval Letter.jpg

FDA Date of Approval: January 1, 2016

FDA Product Listing Number (e.g., NDC): 0069-1626-11

SECTION 2C PRODUCT LICENSE HOLDER INFORMATION

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

Product License Holder Name: Product License Holder Name

Address:
11629 parklawn
N Bethesda, MD 20852
United States of America

Status of Product License Holder: Manufacturer

SECTION 2D PRODUCT CHARACTERISTICS

Proprietary Name (Drug, Trade or Brand Name): Metroprolol Tartrate, USP

Active Ingredient: Metroprolol Tartrate, USP

Dosage Form: injection, emulsion

Amount per Unit Dose: 5 Milligram/Milliliter

SECTION 3A FINISHED DOSAGE MANUFACTURER EDIT

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

Registration Number (DUNS): 123456789

FEI Number: 3004013308

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

FEI Number: 3004013308

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

SECTION 3C PACKAGER/RELABELER

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

SECTION 4A IMPORTING COUNTRY LIST EDIT

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 = $175.00 Total Certificates: 1

SECTION 5A DRUG LABELS EDIT

Label Type	File Name	File Size (KB)
Package or Container Label	1457109273667_Package or Container Label.jpg	826.114
Outer Package Label	1457109287164_Outer Package Label.jpg	826.114
Package Insert	1457109296612_Package Insert.jpg	826.114
	Total Size (KB):	2,478.343

SECTION 6B SUPPLEMENTAL DOCUMENTS

Do you want to attach supplemental documents?
Yes No

SECTION 6C SUPPLEMENTAL DOCUMENTS DETAILS

Document Type	File Name	Countries	Print
Formulation Page	1457109657409_Supplemental attachment.jpg	Not Selected	No

SECTION 6D REMARKS (OPTIONAL)

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

SECTION 6E REMARKS ENTRY

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

SECTION 6A EXPORTER'S CERTIFICATION STATEMENT EDIT

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

Cancel & Start Again | Print | Preview Certificate | Back to Main Menu | Submit