OTC Drug Flow

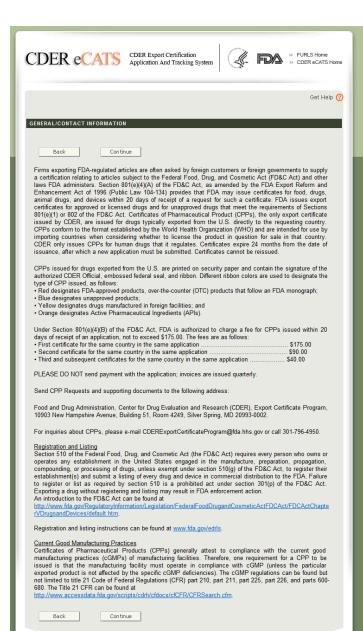








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Certificate to a Pharmaceutical Product (CPP)

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.

- 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; 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; The product is manufactured according to the requirements of its FDA approval; 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 inverse of the 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 Export Certification Application And Tracking System



 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.

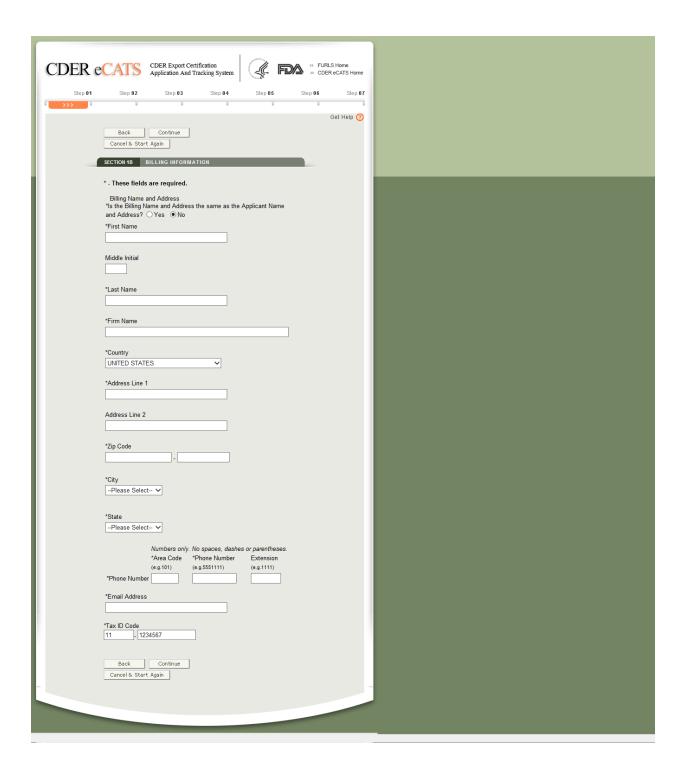
*Address Validation Decision

Return to Step 1 and make changes

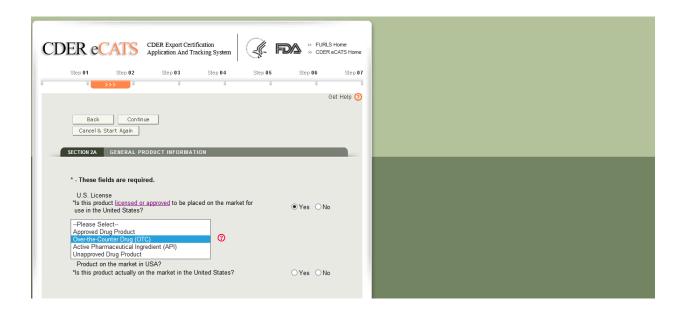
© Continue to use the existing address

Continue











CDER Export Certification Application And Tracking System



>> FURLS Home

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 🗙



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

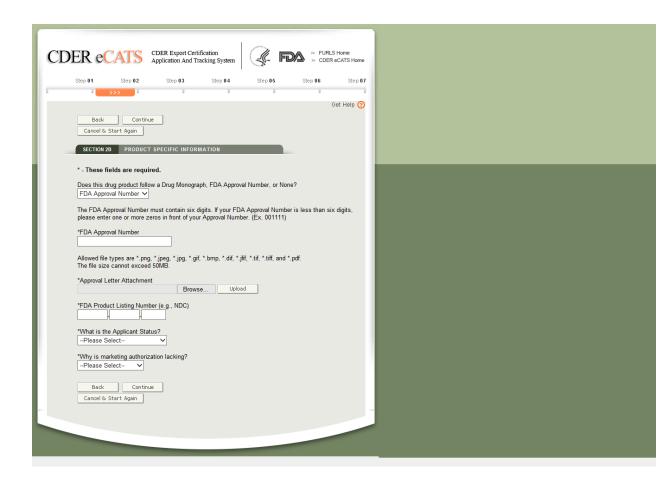
Active Pharmaceutical Ingredients (API)

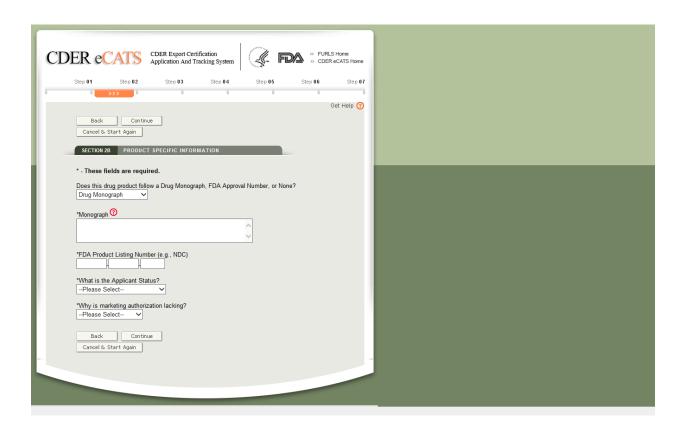
An active pharmaceutical ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

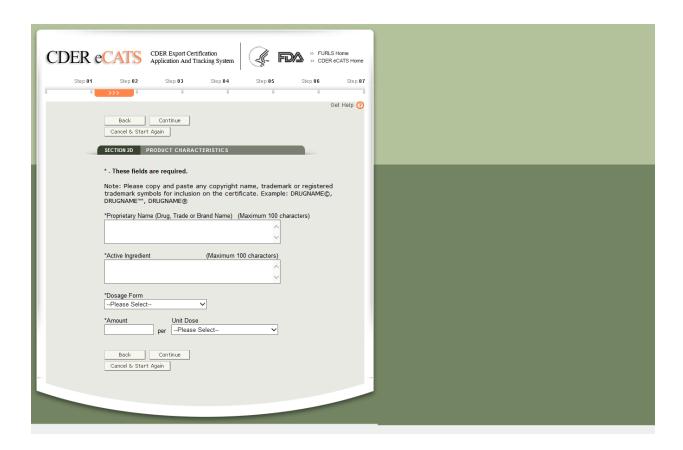
Unapproved New Drugs

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.

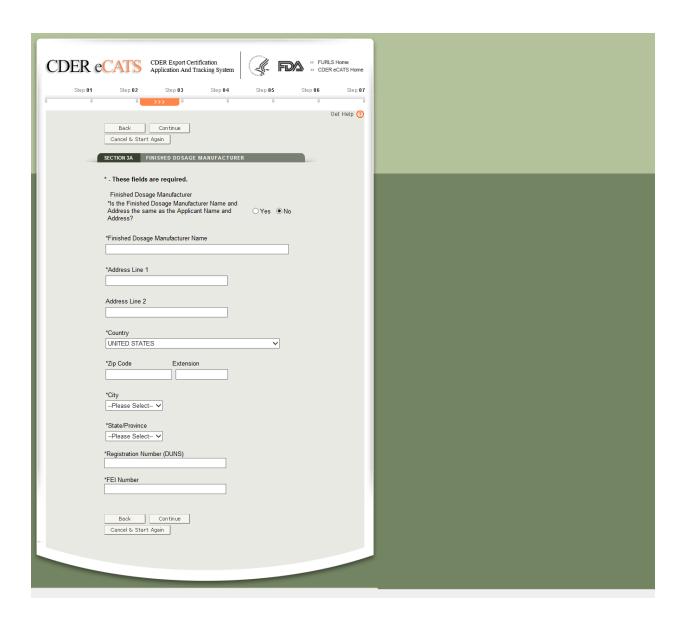




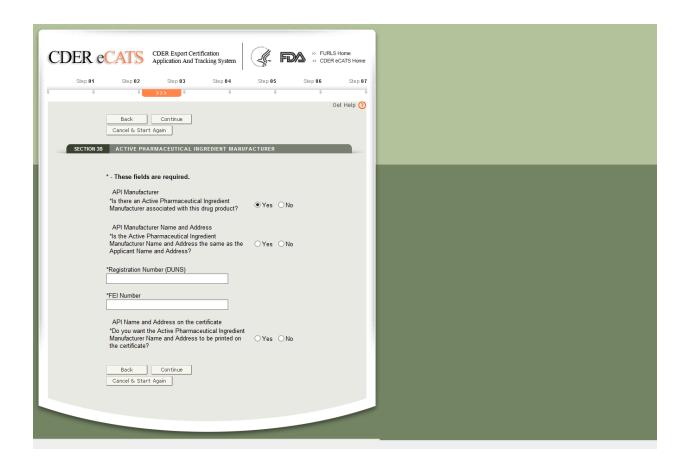






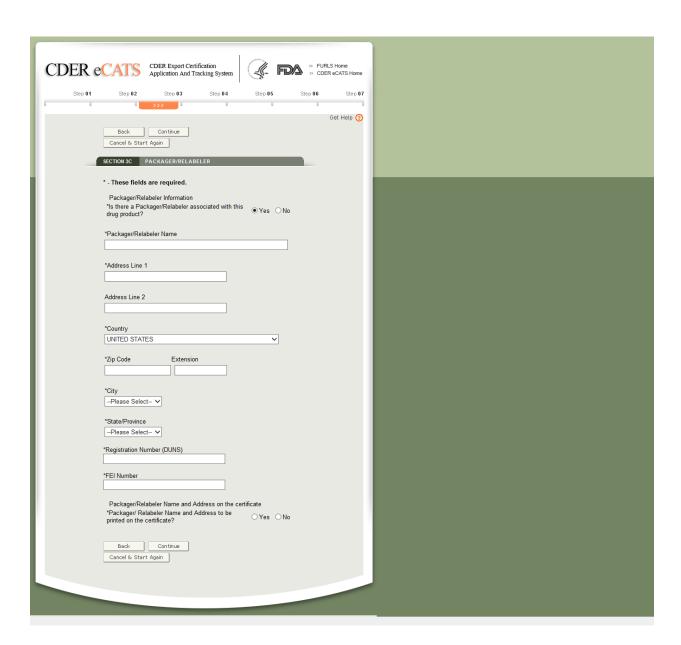


















Fee Calculation

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.



