

# Human Drug Export Certificates

Companies exporting drugs from the United States are often asked by their customers or foreign governments to supply an export “certificate” for products regulated by the U.S. Food and Drug Administration. These certificates help provide assurance that exported products can be marketed in the United States or comply with specific U.S. regulations, such as manufacturing requirements.

FDA issues certificates of pharmaceutical product (CPP). CPPs provide information about the drug’s U.S. marketing status and the manufacturer’s compliance with quality manufacturing requirements, known as current good manufacturing practices (CGMPs).

FDA issues CPPs for drugs that are approved or licensed by FDA to be marketed in the United States and for over-the-counter drugs that follow an FDA monograph. FDA also issues export certificates for unapproved drugs that meet requirements of federal law. CPPs expire after two years and a new application must be submitted once it expires.

Examples of when FDA will not issue a CPP include:

- FDA has initiated an enforcement action, such as a seizure or injunction
- The manufacturing facility is not registered with FDA
- The drug is not listed with FDA
- The manufacturing facility is not in compliance with CGMPs

## How to Apply for a CPP

CPP applications may be submitted using the online electronic platform, CDER Export Certification Application and Tracking System (CDEReCATS) or via paper using Form FDA 3613f, which can be found on FDA.gov.

Users must have an FDA Unified Registration and Listing Systems (FURLS) account ID and password to access CDEReCATS. See [www.access.fda.gov/oa](http://www.access.fda.gov/oa) to set up a FURLS account.

FDA is authorized to charge a fee for CPPs issued within 20 days of receipt of an application. See FDA’s website for more information about the fees.

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## CGMP Declarations for Human Drugs Exported from the United States

FDA issues letters, called CGMP declarations, to foreign regulators to convey the CGMP compliance status of manufacturing facilities located in the United States.

The status is based on FDA's most recent inspection. These letters help streamline other regulatory authorities' need to re-inspect facilities in the United States.

Foreign regulators can also find the CGMP status of an establishment by checking the inspection classification database on [www.fda.gov](http://www.fda.gov).

A CGMP declaration should only be requested if a foreign regulator does not accept a valid CPP and wants assurance of CGMP status for a U.S.-based manufacturing facility. A manufacturer may request a CGMP declaration using FDA's online application process, CDEReCATS, under the following conditions:

- The manufacturing facility is physically located in the United States;

- The manufacturer is requesting the CGMP declaration for its own site (parent and affiliate companies may not request a declaration);
- The manufacturer has previously obtained a CPP or can provide a CPP number in which it is included (the CPP must be valid and unexpired);
- The manufacturer's most recent FDA inspection was acceptable; and
- The establishment has been included in a marketing application submitted to a foreign regulator.

FDA sends the letter to the foreign regulator within 30 days of receipt of the request.

There is no fee associated with CGMP declarations.



Contact [CDERExportCertificateProgram@fda.hhs.gov](mailto:CDERExportCertificateProgram@fda.hhs.gov) with export certificate questions. See [www.fda.gov](http://www.fda.gov) for more information about exporting human drugs.