



July 16, 2015

Dear Export Certificate Applicant:

I am writing to inform you about a procedural change we will be implementing at the Center for Drug Evaluation and Research (CDER) in the United States Food and Drug Administration (FDA). Beginning August 3, 2015, the "Pilot Certificate of Pharmaceutical Product (CPP)" program will become a formal program, and the name will be changed to "Foreign Exported CPP."

CDER's Export Certificate Program currently issues Pilot 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. We implemented the program to accommodate industry's request to provide foreign importing countries with an FDA-issued CPP for FDA-approved products, even though the product is not manufactured and exported from the United States.

As has been the case with Pilot CPPs, 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 consistent with past practice.

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.
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 business.

For more information about CDER's Export Certificate Program, please email

CDERExportCertificateProgram@fda.hhs.gov or visit

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm>.

We appreciate your help in disseminating this information, and we thank you in advance for your cooperation.

Sincerely,

Karen C. Corallo, Director
Division of Imports, Exports, and Recalls