



July 16, 2015

Dear Export Certificate Applicant:

I am writing to inform you about a procedural change. The Center for Drug Evaluation and Research (CDER) of the United States Food and Drug Administration (FDA) will introduce a new ribbon color for Certificates of Pharmaceutical Products (CPPs) issued for Active Pharmaceutical Ingredients (APIs). Beginning August 3, 2015, we will use orange ribbons when issuing CPPs for exported API.

For all CDER export certificates, we attach a colored ribbon that represents the type of export certificate issued. Red ribbons are used for products that are FDA-approved or that follow an over-the-counter (OTC) drug monograph. Yellow ribbons are used for drugs that are foreign manufactured and blue ribbons for unapproved drugs. Currently, CPPs for APIs are issued with a red ribbon; however, because APIs are not approved by FDA, this may create a misimpression that FDA has approved the API or that the API follows a drug monograph. Using an orange ribbon to indicate that the exported product is an API will remove any potential for misunderstanding.

Please share this procedural change with others within your firm with an interest in this issue, as well as the foreign governmental entities with which you do business.

For more information about CDER export certificate program, send an email to CDERExportCertificateProgram@fda.hhs.gov or visit <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm>.

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

Sincerely,

A handwritten signature in black ink that reads "Karen C. Corallo".

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