DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993-0002

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 form for applying for Certificates of Pharmaceutical Products (CPPs). The new form is named "Request for Certificate of a Pharmaceutical Product for CDER Products" (FDA Form 3613f) and will be available in August 2015.

Currently when applying for CDER CPPs, FDA Form 3613b is used. FDA Form 3613b is also used by the Center for Biological Evaluation and Research (CBER) and the Center for Veterinary Medicine (CVM) to request CPPs for products regulated by those centers. FDA form 3613f will be exclusive to CDER, and we will no longer accept FDA Form 3613b. The new form will provide better guidance and instruction when applying for CPPs for human drugs regulated by CDER.

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,

Karen C. Corallo

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