DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

April 12, 2016

Dear Export Certificate Applicant:

We are happy to announce that the United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) Export Certificate office will introduce a new online application process for Certificates of Pharmaceutical Product (CPPs). It is called CDEReCATS – Export Certification Application and Tracking System. We expect to make CDEReCATS available to you starting May 2, 2016.

CDEReCATS will provide you an alternative to the current paper application FORM FDA 3613f. The benefits of CDEReCATS include the potential for reduced CPP processing time, guided step-by-step instructions, real-time validation of data, and email notification of status updates. You can request CPPs for human drugs regulated by CDER under approved marketing applications (New Drug Applications (NDA), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs)), over-the-counter (OTC) drug products (but not dietary supplements or cosmetics), Active Pharmaceutical Ingredients (APIs), and Unapproved Drugs.

Once available, you may access CDEReCATS from the FDA Industry Systems/FDA Unified Registration and Listing Systems (FURLS). Please note that you must have a FURLS account ID and password to access CDEReCATS. To set up a FURLS account, please go to FDA Industry Systems/FDA Unified Registration and Listing System (FURLS) at the following link: https://www.access.fda.gov/oaa.

CDER's Export Certificate office will provide live webinar training on how to use CDEReCATS to apply for specific types of CPPs as set forth below. We will send additional information regarding the webinars as the training dates approach, so please watch for that.

CDEReCATS Webinar/Training Schedule			
Training Session	Certificate Type	Date	Time (EST)
1	Approved Drug Foreign Exported	April 25, 2016	12:00pm - 1:30pm
2	Over-the-Counter (OTC)	April 25, 2016	2:00 pm- 3:30 pm
3	Active Pharmaceutical Ingredient (API)	April 27, 2016	12:00 pm- 1:30 pm
4	Unapproved Drug	April 27, 2016	2:00 pm- 3:30 pm

For more information about CDER's Export Certificate Program, please visit our website at:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm
or email: CDERExportCertificateProgram@fda.hhs.gov

We encourage you to use CDEReCATS and to share this information with those in your organization who are involved in applying for CPPs. Thank you very much for your interest and participation.

Sincerely,

Karen C. Corallo

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