Feb. 24, 2014

Dear Medical Device Establishments:

Today, the FDA's Center for Devices and Radiological Health (CDRH) announced a series of enhancements to the Internet-based system for submitting and processing export document requests. The CDRH Export Certification and Tracking System (CECATS) allows industry to submit export document requests electronically as a voluntary alternative to paper submissions.

CDRH values feedback and, in response to comments received from users, has made a number of adjustments to CECATS that will now enable you to:

- Modify applications that are submitted, as long as the certificate is not under review;
- Modify all sections of the application, if it is returned by the FDA for additional information;
- Upload UPS or Fed EX return mailing labels;
- Utilize multiple sub-headers options provided on CECATS;
- Clone Certificates of Exportability requested under Sections 801 and 802 of the Food, Drug, and Cosmetic Act;
- Sort the "Clone-able" applications in the "Enter New Application Option" screen from the main menu; and
- Upload additional items such as an Establishment Inspection Report (EIR), close out letters, and port of entry documents.

Currently, CECATS is available for:

- Certificates to Foreign Governments, which account for 95 percent of all export certificate requests submitted to CDRH; and
- Certificates of Exportability related to Sections 801(e)(1) and 802.

CECATS automates many of the steps that exporters and CDRH perform when submitting and processing export document requests. The advantages to exporters include:

- Reduction in certificate processing time;
- Real-time validation that eliminates the need to return submissions;
- Elimination of the cost of mailing the request; and
- Real-time status updates available via the Internet.

Please see our list of frequently asked questions (FAQs) for detailed instructions on accessing this system. In addition to the FAQs, online training sessions on CECATS will be held via Adobe Connect from 1:30 p.m. to 3:00 p.m. (EST) on February 25th and March 25th. We encourage participants to test their connection prior to the webinar. Please note that while you do not need to pre-register for these

sessions, participants will not be able to enter the meeting until the host has logged in on the day of the event.

CDRH looks forward to continuing to improve the processing of all export document requests, with a goal of providing the best service possible. If you have any questions concerning CECATS, please send an email to CDRHCECATS@fda.hhs.gov or call (301) 796-7400 (press option #3 for export-related inquiries).

Sincerely,

Leila Lawrence
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Office of Compliance
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