From: Strelnik, Brigitte
Sent: Friday, October 13, 2017 12:28 PM
Subject: RE: CCBFA Seminar Thursday September 21, 2017 2:00 p.m. to 4:00 p.m. Q&A additional questions

Hello,

Thank you for your inquiry. You are more than welcome to send any future questions to me and I would be happy to assist, but please send them to FDAImportsInquiry@fda.hhs.gov as well for the most expeditious response we can get you.

Under the FDA's Import for Export provisions of the Food, Drug, and Cosmetic Act, firms may import otherwise unapproved product for further processing and subsequent export. These products are exempt from approval/clearance requirements, but are not exempt from registration and listing requirements. Registration and listing and clearance/approval are two separate and independent requirements for medical devices, and the Act only exempts devices imported for export from clearance/approval.

Please also note that although some firms have previously imported devices for export without registration and listing information, the exemption for import for export devices was eliminated in the final rule that was published in August 2012 (Federal Register Vol 77, No 149 Dept of Health and Human Services FDA 21 CFR part 807 Docket No FDA-2009-N-01141 RIN 0910-AF88). The final rule states that foreign establishments that manufacture import for export devices are required to register and list the devices with FDA. In addition, this information is required to be able to transmit the entry in ACE (see FDA Supplemental Guide).

The foreign establishment is required to register, list and pay the annual registration user fee. They are also required to identify a U.S. Agent. The U.S. establishment is also required to register, list, and pay the annual registration user fee. Please see this page on Who Must Register and List.

For general Import for Export guidelines and procedures, please see Chapter 9-17 of the FDA's Regulatory Procedures Manual.

If you have any further questions on this, feel free to let us know.

Sincerely,

FDA Imports Inquiry Team

and
Brigitte K. H. Strelnik

Consumer Safety Officer

Import Program Development Branch
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Sent: Tuesday, October 03, 2017 12:14 PM
Subject: CCBFA Seminar Thursday September 21, 2017 2:00 p.m. to 4:00 p.m. Q&A additional questions

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Hello CCBFA,

During the September 21, 2017 FDA outreach meeting the presenters had stated that they would be providing supporting documentation for the questions that there asked, such as the LST being mandatory for IFE shipments. Could you please let us know if these documents have been received?