



GLOBAL LIFE SCIENCES: MEDICAL DEVICE UPDATE

Medical Device Practice

We offer a broad range of services specifically suited to the needs of manufacturers, importers and distributors of medical devices. We have defended scores of product liability cases involving a wide variety of implantable as well as institutionally-based medical devices. We regularly advise clients with respect to labeling issues and regulatory compliance under the FDA's medical device regulations while remaining sensitive to business concerns in this exciting and frequently challenging sector of the healthcare industry.

For further information on the Medical Device Practice, please contact:

Raymond A. Bonner	Coleen Klasmeier
+1.202.736.8679	+1.202.736.8132
rbonner@sidley.com	cklasmeier@sidley.com

Sidley Global Life Sciences Practice

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For further information on the Global Life Sciences Practice, please contact:

Scott Bass
 +1.202.736.8684 | +1.212.839.5613
 sbass@sidley.com

FDA Proposes New Requirements for Medical Device Imports

The Food and Drug Administration (FDA) recently **proposed changes** to certain medical device import requirements that would impact both non-U.S. medical device manufacturers and their U.S. importers.¹ The importation of medical devices into the United States is subject to a complex regulatory regime administered by FDA and U.S. Customs and Border Protection. Medical devices that do not meet regulatory requirements may be detained upon entry, which can result in significant business disruption. Comments on FDA's proposed changes to the medical device import regime are due by June 24, 2010.

Foreign Establishments Must Identify "Importers," Facilitators and Devices

Under the proposed rule, any establishment outside of the United States engaged in the manufacture, preparation, propagation, compounding or processing of a device that is imported or offered for import into the United States (*i.e.*, a "foreign establishment") must identify each of its known "importers" and each "person who imports or offers for import" the foreign establishment's devices into the United States. Among other information, the foreign establishment must provide a list of the specific medical devices that each "importer" receives.

FDA has proposed broad definitions for the terms "importer" and "person who imports or offers for import." An "importer" would be defined as an owner, consignee or recipient of a medical device that is imported into the United States. Such persons or entities would not be limited to the initial owners, consignees or recipients of the imported medical devices, although the term would not include the consumer or patient who ultimately purchases, receives or is the end-user of a device, unless the foreign establishment ships a device directly to the consumer or patient. The definition of a "person who imports or offers for import" would also be expansive, including agents, customs brokers, and other entities used by foreign establishments to facilitate imports into the United States. Carriers would be excluded from this definition.

¹ See *Implementation of Device Registration and Listing Requirements Enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Medical Device User Fee and Modernization Act of 2002, and Title II of the Food and Drug Administration Amendments Act of 2007*, 75 Fed. Reg. 14510 (Mar. 26, 2010)

FTZ and Re-export Exemptions Eliminated

The proposed rule would revoke two exemptions from the registration and listing requirements applicable to foreign establishments. Currently, a foreign establishment whose medical devices enter a foreign trade zone (FTZ) in the United States and are reexported from the FTZ without entering U.S. commerce need not register or list its devices with FDA. Similarly, a foreign establishment whose devices are imported into the United States for further processing and then exported without having been placed on the U.S. market (so-called “import for export”) is also exempt from registration and listing requirements. FDA has proposed eliminating these exemptions, citing perceived congressional intent in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) to require foreign establishments to provide more information about imported products.

Foreign Contract Manufacturers Must Register and List

The proposed rule would also extend foreign establishment registration and listing requirements to foreign contract manufacturers. Although FDA’s current regulations (21 C.F.R. §§ 807.20(a)(2) and (c)(1)) and prevailing formal interpretation (66 Fed. Reg. at 59151–52) exempt contract manufacturers, including foreign contract manufacturers, from registration and listing requirements (consistent with statutory requirements), FDA’s recent informal practice has been to require registration and listing by contract manufacturers who distribute devices on behalf of the devices’ specifications developers. This informal

practice has engendered confusion on the part of foreign contract manufacturers and their U.S.-based business partners.

The proposed rule eliminates this confusion by definitively extending registration and listing requirements to all contract manufacturers (domestic and foreign). The proposed rule also requires registration and listing by contract sterilizers (including foreign contract sterilizers). Thus, the administrative burden and costs associated with the importation into the United States of products from ex-U.S. sources can be expected to increase if the proposed rule is adopted.

Registration Failure If Information Incomplete

The proposed rule further makes clear that a foreign establishment would not be considered registered until all information required by the rule had been submitted to FDA, including the identification of “importers” and “persons who import or offer for import.” Under existing regulations, a medical device must be listed with FDA by a registered foreign establishment before it can be legally imported into the United States and entered into U.S. commerce (with limited exceptions).

Public Comments Sought

Non-U.S. medical device manufacturers and their U.S. importers may wish to submit comments seeking to limit the definition of “importers” and “persons who import or offer for import,” restore the availability of the FTZ and re-export registration and listing exemptions, and otherwise clarify the rules governing the importation of products from ex-U.S. sources, particularly from foreign contract manufacturers.

Sidley’s renowned International Trade team has extensive experience with Customs topics such as these. For more information on this issue or other Customs issues, please contact Lisa Crosby (+1.202.736.8754, lcrosby@sidley.com) and Dick Belanger (+1.202.736.8335, rbelanger@sidley.com).

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BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG LONDON LOS ANGELES NEW YORK SAN FRANCISCO SHANGHAI SINGAPORE SYDNEY TOKYO WASHINGTON, D.C.
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