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Client Alert

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FDA Publishes Frequently Asked Questions Concerning the New Medical Device Registration and Listing Requirements

President Obama signed the FDA Safety and Innovation Act (FDASIA) on July 9, 2012, which requires certain changes to the registration and listing of medical devices that will take place on October 1, 2012. FDASIA includes the Medical Device User Fee Amendments of 2012 (MDUFA III) as well as other medical device provisions. Ultimately MDUFA III represents an agreement and commitment between the U.S. medical device industry and the FDA to increase the efficiency of regulatory processes in order to reduce the time it takes to bring safe and effective medical devices to the U.S. market. The new registration and listing changes are also part of the publication of the revised 21 C.F.R Part 807 on August 2, 2012.

Starting in the Government's Fiscal Year (FY) 2013, which begins on October 1, 2012, all registered medical device establishments are required to pay the annual registration fee, regardless of establishment type or activities conducted. Moreover, certain establishments must comply with additional registration and listing requirements.

The principal changes to the registration and listing requirements are:

- All proprietary names under which a device is marketed must be reported, at a minimum, when a device is first listed and during the annual update of registration and listing information.
- Combination products (products comprising a device and a biological product or a drug) must be identified as a combination product and the type of combination product (e.g., convenience kit, prefilled drug delivery device) and must be selected from the list displayed in the FDA Unified Registration and Listing System (FURLS).
- All contract manufacturers and sterilizers of finished devices must register and list regardless of whether they put the device into commercial distribution or return the device to the manufacturer or specification developer.
- Initial importers must identify the manufacturers of the devices they are importing.

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- Foreign establishments that are exporting devices or offering devices for export to the U.S. must identify all known U.S. importers of their devices.

- A device must be listed by the manufacturer, specification developer, single-use reprocessor, remanufacturer, or repacker/relabeler before a foreign exporter, contract manufacturer, or contract sterilizer can list it.

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- Establishments that only handle complaints and were previously registered as manufacturers or specification developers should change their establishment type to "Complaint File Establishment" as required by 21 C.F.R. § 820.198.

- Establishments located in foreign trade zones must now register and list, as well as identify themselves being located in a foreign trade zone.

- All establishments that are required to register must now pay the annual registration user fee as required by FDASIA. The Secretary of the Department of Health and Human Services may grant a waiver or reduction to the fee only if it is determined to be in the best interest of public health. The total of waivers granted cannot exceed 2% of total fee revenue amounts established for the year.

On September 12, 2012, FDA released a document entitled "Frequently Asked Questions about the New Device Registration and Listing Requirements." Click here for a copy. The list of FAQs is provided to assist medical device establishments in understanding and complying with the new requirements and responsibilities for registration and listing. The FAQ addresses such topics as updating registration and listing information, proprietary names, inclusion of model numbers, combination products, foreign establishments, exporters, importers, and contract manufacturers and sterilizers.