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CHANGES TO MEDICAL DEVICE ESTABLISHMENT REGISTRATION, USER FEE, AND LISTING REQUIREMENTS

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As a result of new FDA legislation and the publication of revised federal regulations,[1] starting in Fiscal Year 2013, which begins on October 1, 2012, all medical device establishments are required to pay an annual user fee, in addition to registering and listing their medical devices with the FDA, unless exempted by the regulations. The annual user fee, for Fiscal Year 2013, for each establishment is $2,575.00.[2]

Most domestic medical device distributors, as before these changes go into effect, will *not* be required to register, list, and/or pay the fee because domestic distributors are exempt from the requirements, and the new regulations do not affect this exemption.[3]

If, however, your business manufactures, relabels or repackages medical devices, including assembling kits, you are subject to the regulations and must now pay the annual user fee, as well as registering, and list your products with the FDA.

The federal regulations define those entities that are considered "medical device establishments" as "engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use . . . ." 21 CFR 807.20(a).

The regulations, at 21 CFR 807.3(t) as revised, define "wholesale distributors" as "any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user." 21 CFR 807.20(c) as revised, in turn,

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[1] The FDA Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012. This law includes the Medical Device User Fee Amendments of 2012 (MDUFA III). MDUFA III takes effect on October 1, 2012 and will sunset in five years on October 1, 2017. For more information about user fees and MDUFA III see http://www.fda.gov/MedicalDevices/DeviceRegulationsandGuidance/Overview/MDUFAIII/default.htm . On August 2, 2012, FDA published the revised version of Title 21 of the Code of Federal Regulations (CFR), Part 807, Establishment Registration and Device Listing Regulations. *See* https://www.federalregister.gov/articles/2012/08/02/2012-18764/implementation-of-device-registration-and-listing-requirements-enacted-in-the-public-health-security

[2] http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/registrationandlisting/default.htm

[3] *See* 21 CFR 807.3(t), as revised, at prior version 21 CFR 807.3(s) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=807 ; and revised 21 CFR 807.20(c) at https://www.federalregister.gov/articles/2012/08/02/2012-18764/implementation-of-device-registration-and-listing-requirements-enacted-in-the-public-health-security .

states that "[r]egistration and listing requirements shall not pertain to any person who acts as a wholesale distributor, as defined in § 807.3(t), and who does not manufacture, repackage, process, or relabel a device." Guidance published by the FDA prior to the issuance of the new regulations also states that "domestic distributors" are not required to register, list, or pay the annual user fee.[4]

But for those businesses who private label medical devices or who otherwise repackage medical devices, including assembling kits, these entities are required to register with the FDA, list the medical devices, and pay the user fee.[5] The regulations define a "relabeler" or "repackager" as follows:

> Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer[.]

21 CFR 807.3(d)(1).[6] Material published by the FDA additionally indicates that a "kit assembler" is required to register, list, and pay the user fee and states that a "repackager" is one that "packages finished devices from bulk or repackages devices made by a manufacturer into a different containers (excluding shipping containers)."[7]

If your entity is required to register, list, and pay the fee, these actions are done electronically by using the FDA's Unified Registration and Listing System (FURLS)/ Device Registration and Listing Module (DRLM).[8] Once registered, all medical device establishments are required to identify all proprietary names for each device listed. Such names may be marked confidential to prevent publication on the FDA website if disclosure would identify confidential business relationship(s). Establishments are also required to identify combination products and the type of combination product (for example, device/drug, device/biologic), as well as information relating to, among other required information, the assigned FDA number for the approved application, whether the device, as labeled, is intended for use by the general public, and the name, registration number, and establishment type of every domestic or foreign device establishment under

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[4] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm

[5] *See* http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm314844.htm .

[6] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=807.3

[7] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm

[8] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm

joint ownership and control of the owner or operator at which the device is manufactured, repackaged, or relabeled.[9]

We will work to keep you informed about regulatory changes and developments and their impact on your business.

[9] *See* http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm314844.htm ; http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807&showFR=1&subpartNode=21:8.0.1.1.5.2