U.S. FOOD & DRUG ADMINISTRATION

September 6, 2016

Dear Device Labelers:

The Unique Device Identification rule (the UDI Rule) (78 FR 58786, September 24, 2013) establishes a system to adequately identify medical devices through their distribution and use via the supply chain to point of use with patients. The UDI Rule, which is being implemented according to an established set of compliance dates, sets forth requirements under 21 CFR 801.20 for the device label to bear a unique device identifier (UDI label requirements) and under 21 CFR 830 subpart E for submission of data to the Global Unique Device Identification Database (GUDID submission requirements).

The purpose of this letter is to inform labelers that FDA has extended the compliance date for UDI label and GUDID submission requirements to September 24, 2018, for certain class II devices as explained below. In addition, the agency is clarifying that for device constituents of certain combination products described below the compliance date for UDI label and GUDID submission requirements is September 24, 2018.

Compliance date extended for UDI label and data submission requirements to September 24, 2018, for certain class II devices

1. Collections of two or more different devices packaged together in which the devices in the package are not individually labeled.

On January 4, 2016, the FDA issued a draft guidance document entitled "Unique Device Identification: Convenience Kits: Draft Guidance for Industry and Food and Drug Administration Staff[1] in which the agency proposes an interpretation of the term "convenience kit" for purposes of applying the exception under 21 CFR 801.30(a)(11). To allow FDA the ability to finalize this draft guidance document and the interpretation of what constitutes a convenience kit, the Agency is extending the compliance date for UDI label and GUDID submission requirements for collections of two or more different class II (or class II and class I) devices packaged together in which each device in the package is not individually labeled with a UDI to September 24, 2018. This extension does not apply to collections of devices that include one or more devices that are implantable, life-sustaining or life-supporting. Some labelers may have already implemented the UDI label requirements for these devices. In such cases, this extension would apply only to the GUDID submission requirement.

2. Repackaged single-use devices

21 CFR 801.30(a)(3) provides that individual single-use devices, other than implants, all of a single version or model, are not required to bear a UDI provided they are distributed together in a single device package, intended to be stored in that device package until removed for use, and not intended for individual commercial distribution. The UDI label and GUDID submission requirements' compliance dates for repackagers[2] of class II single-use devices that

[1] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM479242.pdf

[2] A repackager packages finished devices from bulk or repackages devices made by a manufacturer into different containers (excluding shipping containers)
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm

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are not individually labeled with a UDI is extended to September 24, 2018. This extension does not apply to implantable, life-supporting or life sustaining devices.

Compliance date for device constituents of certain 21 CFR 3.2(e)(2) and 21 CFR 3.2(e)(3) combination products assigned to CDER or CBER for premarket review and regulation is September 24, 2018

For device constituents, other than devices that are implantable, life-sustaining or life-supporting, of 21 CFR 3.2(e)(2)) (commonly referred to as "co-packaged") and 21 CFR 3.2(e)(3) (commonly referred to as "cross-labeled") combination products assigned to Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) for premarket review and regulation, the compliance date for UDI label and GUDID submission requirements is September 24, 2018.

Sincerely,
/s/
Thomas P. Gross, MD, MPH
Director
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
U.S. Food and Drug Administration