

June 2, 2017

Dear Device Labelers:

The FDA intends to extend the [compliance dates for the unique device identification system \(UDI system\)](#) requirements for medical devices that generally present a lower risk to patients (certain class I and unclassified devices), such as manual surgical instruments and mechanical wheelchairs.

The FDA and industry have already implemented requirements for higher-risk medical devices (class III; implantable, life-supporting or life-sustaining (I/LS/LS); and class II devices), including implants and other devices that support and sustain patients' lives, such as artificial joints, heart valves and automated external defibrillators (AEDs). A significant number of device labels now display UDIs, and our UDI database (Global Unique Device Identification Database – GUDID) is already a large repository of device identification information. As of May 1, 2017, more than 4,000 device labelers had submitted 1.4 million records to GUDID.

With successes come challenges, and implementing UDI is no exception. For example, after fully considering the time needed to meet UDI requirements, many labelers asked FDA for extensions to comply. In addition, we identified complex policy and technical issues that need resolution, such as [how UDI applies to products such as medical procedure trays that contain implantable devices and instruments](#). Providing accurate and timely support to labelers has also been challenging, due to the sheer number and wide diversity of devices.

At the same time, we realize that a truly successful UDI system of national device identification depends on UDI being integrated into electronic health information throughout our health care system, including in the supply chain, registries, and electronic health records. To fully reap the public health [benefits](#) and a return on investment of a UDI system, high-quality UDI data must be available in standardized ways so that the health care community can and will use it with confidence.

For these reasons, we plan to engage with industry and other stakeholders to address existing challenges and optimize the quality and utility of the data for higher-risk medical devices already in the system before adding lower-risk medical devices. Taking the time to do this now will help ensure the transition from development of the UDI system to widespread use and sustainability.

UDI compliance date for class I and unclassified devices

In order to extend the compliance dates for lower-risk medical devices, the FDA plans to issue a guidance document to provide an enforcement discretion policy for labeling, GUDID data submission, standard date formatting, and direct mark requirements for class I and unclassified devices as indicated in Figure 1 below. This enforcement discretion policy would not apply to class I or unclassified implantable, life-

supporting or life-sustaining devices¹ because labelers of these devices must already be in compliance with UDI requirements.

| Type of Device | Label (21 CFR 801.20), GUDID Submission (21 CFR Part 830, subpart E), and Standard Date Format (21 CFR 801.18) Requirements | Direct Mark (21 CFR 801.45) Requirements |
|------------------------------|---|--|
| Class 1 devices ² | September 24, 2020 | September 24, 2022 |
| Unclassified devices | September 24, 2020 | September 24, 2022 |

Figure 1

¹ For implantable, life-supporting or life-sustaining devices of all classes, the compliance date for all UDI requirements and the standard date format requirement (21 CFR 801.18) was September 24, 2015.

² Class I CGMP-exempt devices are excepted from UDI requirements. 21 CFR 801.30(a)(2)

Background

On September 24, 2013, the FDA published a final rule establishing a UDI system designed to adequately identify devices through distribution and use. 78 FR 58786 (the [UDI Rule](#)). 21 CFR 801.20 requires a device to bear a unique device identifier (UDI) on its label and packages unless an exception or alternative applies. 21 CFR Part 830.300 requires data pertaining to the key characteristics of each device required to bear a UDI on its label and packages be submitted to the GUDID. 21 CFR 801.45 requires devices that must bear UDIs on their labels that are intended to be used more than once and reprocessed between uses to be directly marked with a UDI. In addition, 21 CFR 801.18 requires certain dates on device labels to be in a standard format.

For additional information, please contact the [FDA UDI Help Desk](#).

Sincerely yours,

/s/

Thomas P. Gross, MD, MPH

Director

Office of Surveillance and Biometrics

Center for Devices and Radiological Health

U.S. Food and Drug Administration