A Medical Device Company's Guide to the New Unique Device Identification (UDI) System

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On September 24, 2013, the Food and Drug Administration (FDA) issued a Final Rule regarding a new way companies must label and classify devices called the unique device identifier (UDI) system. The new rule requires each device's label and package to include a UDI unless an exception applies.[1] The Final Rule is accompanied by a draft guidance further explaining the new system's database entitled the "Global Unique Device Identification Database (GUDID)," where UDI information will be submitted and maintained, allowing information about the device to be accessed.[2]

Background

The Food and Drug Administration Amendments Act (FDAAA) of 2007 and the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 added a new section to the Federal Food, Drug, and Cosmetic Act, which requires FDA to establish a UDI system for devices and an implementation timeframe for certain devices.[3] The agency released the Proposed Rule on the UDI system on July 12, 2012, and subsequently published an amendment modifying the implementation timeframe on November 19, 2012.[4] The Final Rule is motivated by an effort to provide for more rapid identification of devices with adverse events and development of solutions to reported problems, increase the accuracy of adverse events reporting, and reduce medical errors resulting from misidentification of devices or confusion about their uses.[5]

Must I Comply with the UDI System Final Rule?

Every device's label and package must bear a UDI, unless an exception or alternative applies.[6] The following devices' label and packages are not required to bear a UDI:

- Devices or device accessories suitable for use labeled prior to the compliance dates as explained later in this article;[7]
- Class I devices that bear a Universal Product Code (UPC) or that FDA has exempted from good manufacturing practice (GMP) requirements, except for certain recordkeeping requirements;[8]
- Individual, single-use devices distributed together in a package and that are intended to be stored in the package until removed for use and which are not intended for individual

1 Unique Device Identification System Final Rule, 78 Fed. Reg. 58,786 (Sept. 24, 2013) (to be codified at 21 C.F.R. pts. 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830), available at: http://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23059.pdf.

2 Global Unique Device Identification Database Draft Guidance for Industry Availability Notice, 78 Fed. Reg. 58,545 (Sept. 24, 2013), available at: http://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23058.pdf; Food and Drug Administration, Draft Guidance: Global Unique Device Identification Database (Sept. 24, 2013), available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery.

3 Global Unique Device Identification Database Draft Guidance for Industry Availability Notice, 78 Fed. Reg. 58,545 (Sept. 24, 2013).

4 Unique Device Identification System Proposed Rule, 77 Fed. Reg. 40,736 (July 10, 2012), available at: http://www.gpo.gov/fdsys/pkg/FR-2012-07-10/pdf/2012-16621.pdf; 77 Fed. Reg. 69,393 (Nov. 19, 2012), available at:

5 78 Fed. Reg. 58,786 (Sept. 24, 2013).

6 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.20).

7 78 Fed. Reg. 58,817, 19 (Sept. 24, 2013) (to be codified at 21 C.F.R. §§ 801.3, 801.30(a)(1)); see page 4.

8 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. §§ 801.30(a)(2), 801.40(d)).

commercial distribution, as long as the package bears the UDI;[9]
- Devices packaged within the immediate container of a combination product or a convenience kit (i.e., two different devices packaged together for the user's convenience), as long as the convenience kit bears a UDI or the combination product bears a UDI or National Drug Code (NDC) number;[10]
- Devices used "solely for research, teaching or chemical analysis, and not intended for any clinical use;"[11]
- Custom devices;[12]
- Investigational devices;[13]
- Veterinary devices;[14]
- Devices intended to be exported from the United States;[15]
- Devices held by the Strategic National stockpile and granted an exception or alternative;[16]
- Devices for which FDA has established or recognized certain performance standards and provided an exception;[17] and
- Combinations products that bear an NDC number and its constituent devices if the components are combined or mixed and produced;[18]

Other exceptions or alternatives may apply if FDA initiates and grants an exception or alternative if it is "in the best interest of the public health;"[19] or, the labeler submits a written request and FDA determines "an exception is appropriate because the [UDI labeling requirement is] . . . not technologically feasible, or that an alternative would provide for more accurate, precise, or rapid device identification" than the UDI labeling requirement, "or would better ensure the safety or effectiveness of the device that would be subject to the alternative."[20] Nevertheless, even if a device is not required to bear a UDI, a firm may label the device with a UDI.[21]

How Must I Comply with the New UDI Rule?

If an exception or alternative does not apply to the device, a UDI must be issued by FDA or an organization accredited by FDA to issue a UDI, and presented on the label.[22] The UDI must include a "device identifier," a fixed set of numbers or characters that identifies the specific device's version or model and the device's labeler, and which is reassigned with every new version, model, or package.[23] The UDI must also include a "production identifier," a set of numbers or characters that identifies the following additional information, if included on the device's label: the lot or batch number, the serial number, the date the device was manufactured, the expiration date, and the distinct identification code required for a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device.[24] However, class I devices subject to the UDI rule are not required to include a "production identifier."[25]

Devices must also bear the UDI in a permanent marking form on the device itself if the device is intended to be used more than once and reprocessed before each use.[26] The UDI may be the same or different as the UDI on the device's

9 78 Fed. Reg. 58,817, 19 (Sept. 24, 2013) (to be codified at 21 C.F.R. §§ 801.3, 801.30(a)(3)). Implantable devices may not be exempt from UDI labeling requirements under this exception. Id.
10 78 Fed. Reg. 58,817, 19 (Sept. 24, 2013) (to be codified at 21 C.F.R. §§ 801.3, 801.30(a)(11),(b))).
11 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.30(a)(4)).
12 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.30(a)(5)). Custom devices are devices that, among other things, are intended for use by an individual patient named in the order of a physician or dentist and are to be made in a specific form for that patient, or are intended to meet the special needs of the physician or dentist in the course of professional practice. 21 C.F.R. § 812.3(b)).
13 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.30(a)(6)).
14 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.30(a)(7)).
15 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.30(a)(8)).
16 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.30(a)(9); 21 C.F.R. § 801.128(f)(2)).
17 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.30(a)(10)).
18 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.30(b)).
19 78 Fed. Reg. 58,818 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.55(d))).
20 78 Fed. Reg. 58,818 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.55(c)).
21 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.35(a).
22 78 Fed. Reg. 58,819, 25-26 (Sept. 24, 2013) (to be codified at 21 C.F.R. §§ 801.20((1), 830.20.)
23 78 Fed. Reg. 58,818, 25, 26 (Sept. 24, 2013) (to be codified at 21 C.F.R. §§ 801.3((1), 801.40(b), 830.3, 830.30(c), 830.50).
24 78 Fed. Reg. 58,819, 25, 26 (Sept. 24, 2013) (to be codified at 21 C.F.R. §§ 801.40(b), 830.3, 830.30(c)); see 1271.290(c).
25 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.30(d)).
26 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.45(a)).

label, as it may be used to distinguish the unpacked device from a packaged one.[27] This additional UDI on the device itself is not required if the marking would "interfere with the safety or effectiveness of the device," the marking is not "technologically feasible," the device is single-use and will undergo additional processing for the purpose of an additional single use, or the device has been marked previously, but the labeler must document the basis for this exception in the design history file that must be kept.[28] In the Proposed Rule, implantable devices were required to bear this type of marking.[29]

According to the Final Rule, once the label is required to bear the UDI, the label may no longer bear the National Health-Related Item Code (NHRIC) or NDC number assigned to the device. [30] Even if the device's label is not required to bear a UDI, the device's label or package may no longer bear these numbers as of September 24, 2018.[31]

Among other requirements, the UDI must be included in various reports, e.g., annual reports submitted by user facilities, postmarket surveillance plans, adverse event reports and records and reports of corrections and removals submitted and maintained by manufacturer and importers.[32]

Date Formatting

Under the new system, if a device's label includes a date intended to be brought to the attention of the device user, e.g., the expiration date or date of manufacture, the date must be formatted as "YYYY-MM-DD," i.e., the four digit year, followed by the two digit month, followed by the two digit day, which is the International Organization for Standardization standard 8601.[33] For instance, if the date is January 2, 2014, the date must be presented as "2014-01-02."[34] Certain products are exempt from this requirement, such as a combination product that bears a National Drug Code (NDC) number.[35] AdvaMed was "puzzled" by this requirement, noting that expiration date testing does not include the day of the month.[36]

Global Unique Device Identification Database

Labelers of devices that must bear UDIs are required to submit information to the Global Unique Device Identification Database (GUDID), a public online database that will serve as a repository of information to facilitate the identification of devices, but will not contain patient information.[37] If the labeler is required to submit information, the following must be submitted by the date the label must bear a UDI:

- The labeler, and the phone number or email of the labeler's point of contact concerning the device's identification;
- The agency(s) that assigns UDIs used by the labeler; and
- Information concerning each device's version or model, e.g., the device identifier, the device's brand name, and the FDA listing number assigned to the device.

The database must be updated if this information changes.[38] Labelers that are required to submit information to the GUDID must first request a GUDID account.[39] The GUDID draft guidance provides a step by step procedure for submission.

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27 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.45(b)).
28 78 Fed. Reg. 58,819 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.45(d),(e)); see 21 C.F.R. § 820.30(j)).
29 77 Fed. Reg. 40,772 (July 10, 2012).
30 78 Fed. Reg. 58,820 (Sept. 24, 2013), (to be codified at 21 C.F.R. § 801.57(a), (b)).
31 Id.
32 78 Fed. Reg. 58,820-23 (Sept. 24, 2013), (to be codified at 21 C.F.R. §§ 803.33(iv), 803.42(c)(6), 803.52(c)(6), 806.10(c)(5), 822.9(a)(4)).
33 78 Fed. Reg. 58,818 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.18(a)); see International Organization for Standardization, Date and Time Format- ISO 8601, available at: http://www.iso.org/iso/home/standards/iso8601.htm.
34 78 Fed. Reg. 58,818 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.18(a)).
35 Id.
36 Press Release, AdvaMed, AdvaMed Statement on Final Unique Device Identification Rule (Sept. 20, 2013), available at: http://advamed.org/news/65/advamed-statement-on-final-unique-device-identification-rule.
37 78 Fed. Reg. 58,786, 817 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 801.3); Guidance at 5; 78 Fed. Reg. 58,826 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 830.300).
38 78 Fed. Reg. 58,827 (Sept. 24, 2013) (to be codified at 21 C.F.R. § 830.330).
39 Guidance at 6; Companies can request a GUDID account at the following website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/default.htm.

When Must I Comply?

Companies must ensure that device labels bear the correct date format and UDI, and that this information is submitted to the GUDID after the labeler puts the device in commercial distribution by September 24th of:[40]

- 2014 for class III devices or devices licensed under the Public Health Service Act, though, in line with industry recommendations, FDA may grant a 1-year extension in response to a written request if it "determines that the extension would be in the best interest of the public health;"[41]
- 2015 for "implantable, life-supporting or life-sustaining devices;"
- 2016 for class II devices;
- 2018 for class I devices or devices that are not classified into class I, II, or II.

If a device fits within several of the above categories, it must comply with the UDI labeling requirement by the earliest applicable date.[42] Devices that must be directly marked with a UDI, must comply with this requirement two years after they must comply with the above requirements, (e.g., September 24th, 2016 for class III medical devices) unless the device is a "life-supporting or life-sustaining," in which case it must comply by September 24, 2015.

Companies must comply with other provisions of the rule by December 23, 2013, though a few provisions are effective October 24, 2013.[43]

Industry Response

Although as of the date of this publication, much of the device industry has yet to offer comments on the Final Rule and draft guidance,[44] AdvaMed stated that it "commends FDA for addressing many of the concerns industry raised in the proposed rule."[45] The Medical Device Manufacturers Association (MDMA) also stated that "it appears that FDA addressed a number of issues raised by stakeholders."[46]

In a Press Release, the agency stated that it intends to "phase in the UDI system, focusing first on high-risk medical devices."[47] Comments on the draft guidance are due November 25, 2013.[48]

It is imperative that companies implement the UDI system correctly, as implementing a UDI system will likely be costly, time-consuming, and require significant efforts.

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40 78 Fed. Reg. 58,815 (Sept. 24, 2013).
41 Press Release, AdvaMed, AdvaMed Statement on Final Unique Device Identification Rule (Sept. 20, 2013), available at: http://advamed.org/news/65/advamed-statement-on-final-unique-device-identification-rule.
42 78 Fed. Reg. 58,815 (Sept. 24, 2013).
43 Id. The provisions effective October 24, 2013 are: 21 C.F.R. § 801.55 (Request for an exception from or alternative to a unique device identifier requirement); 21 C.F.R. § 830.10 (Incorporation by reference); 21 C.F.R. §§ 830.100, 830.110, 830.120, and 830.130 (Provisions regarding FDA accreditation of issuing agencies). Id.
44 See Docket FDA-2011-N-0090-0274: Unique Device Identification System, available at: http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0090-0274; Docket FDA-2013-D-0636: Global Unique Device Identification Database (GUDID); Draft Guidance for Industry; Availability, available at: http://www.regulations.gov/#!docketDetail;D=FDA-2013-D-0636 and http://www.regulations.gov/#!documentDetail;D=FDA-2013-D-0636-0002.
45 Press Release, AdvaMed, AdvaMed Statement on Final Unique Device Identification Rule (Sept. 20, 2013), available at: http://advamed.org/news/65/advamed-statement-on-final-unique-device-identification-rule.
46 Press Release, Medical Device Manufacturers Association (MDMA), MDMA Statement on FDA's Final Unique Device Identification Rule (Sept. 20, 2013), available at: http://www.medicaldevices.org/node/1568.
47 Press Release, Food and Drug Administration, FDA Finalizes New System to Identify Medical Devices (Sept. 20, 2013), available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369276.htm.
48 Global Unique Device Identification Database Draft Guidance for Industry Availability Notice, 78 Fed. Reg. 58,545 (Sept. 24, 2013).

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