



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1853]

Unique Device Identification System: Form and Content of the Unique Device Identifier; Draft Guidance for Industry and Food and Drug Administration Staff; Availability and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry and FDA staff entitled "Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)." When finalized, this draft document will define the expected content and forms of the unique device identifier (UDI), to assist both labelers and FDA-accredited issuing agencies better ensure the UDIs developed under systems for the issuance of UDIs are in compliance with the unique device identification system rule (UDI Rule). This draft guidance is not the final version of the guidance nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-1853 for "Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Alternatively, you may submit written requests for a single copy of the draft guidance to the Office of Communications, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3303, Silver Spring, MD 20993-0002, 301-796-5995, GUDIDSupport@fda.hhs.gov. For questions about this document regarding CBER-regulated

devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

SUPPLEMENTARY INFORMATION:

I. Background

The UDI Rule, establishing the unique device identification system, was published on September 24, 2013 (78 FR 58786). The main objective of the UDI system is to adequately identify devices through distribution and use. Among other requirements, the UDI Rule requires the label and device packages of every medical device distributed in the United States to bear a UDI, unless an exception or alternative applies (21 CFR 801.20).

The UDI Rule is intended to create a standardized identification system for medical devices used in the United States that makes it possible to rapidly and definitively identify a device and some key attributes that affect its safe and effective use. The UDI Rule specifies that the labeler, as defined under § 801.3 (21 CFR 801.3), is responsible for complying with the UDI labeling (21 CFR part 801, subpart B) and Global Unique Device Identification Database (GUDID) submission (21 CFR part 830, subpart E) requirements. The UDI Rule also requires UDIs to be issued under a system operated by an FDA-accredited issuing agency (21 CFR 830.20(a)). Each labeler, therefore, must work with one or more FDA-accredited issuing agencies to develop UDIs for devices that are required to bear a UDI. In order for there to be an effective identification system, it is essential that the FDA-accredited issuing agencies develop and operate systems for the assignment of UDIs that allow labelers using these systems to be in compliance with UDI labeling requirements.

In this guidance, when finalized, we describe the two forms of a UDI and clarify the content of the UDI, including the data delimiters that identify specific data elements within the UDI. The order of the data in a UDI and UDI carrier are discussed as well.

The UDI, as defined under § 801.3, is an identifier that adequately identifies a device through its distribution and use. A UDI is composed of: (1) A device identifier (DI), (2) typically one or more production identifiers (PIs) when included in a device label, and (3) the data delimiters for the DI and PIs included in the UDI. The regulation at § 801.40(a) (21 CFR 801.40(a)) specifies that the UDI must be presented in both easily readable plain-text and automatic identification and data capture (AIDC) technology forms on the label of the device and on each device package. For those devices required to be directly marked with a UDI under 21 CFR 801.45, the UDI may be provided through either or both forms, or any alternative technology that will provide the UDI of the device on demand. "Easily readable plain-text" means the legible interpretation of the data characters encoded in the AIDC form of the full UDI, including the data delimiters. The easily readable plain-text form of the UDI should include the DI, any PIs, and data delimiters contained in the UDI. The UDI Rule does not require the use of specific forms of AIDC or specific AIDC technologies to present the UDI, and labelers may choose to use more than one type of AIDC technology form. The AIDC form of the UDI must be in a format that can be read by a bar code scanner or some other AIDC technology. If a labeler chooses a bar code form of AIDC, we expect that the bar code form of the UDI will be tested for print quality.

We interpret §§ 801.3 and 801.40 as specifying that a UDI is composed solely of a single DI and one or more of the five PIs listed in §§ 801.3 and 801.40(b), along with the data delimiters for the DI and PIs. While some of the FDA-accredited issuing agencies may allow for

non-UDI elements, such as quantity, in the UDI carrier, we do not recognize any such additional non-UDI elements as being part of the UDI. For the purposes of this draft guidance, "data delimiter" means a defined character or set of characters that identifies specific data elements within an encoded data string. The data delimiters indicate the DI value or the PI values that follow each data delimiter within the UDI, and may also indicate other non-UDI elements that may be included within the UDI carrier. Data delimiters for the DI and PIs should be included in the UDI. If non-UDI elements are included in the UDI carrier, separate data delimiters for any these non-UDI elements outside the scope of a UDI should be included in the UDI carrier. Data delimiters should be included in both the easily readable plain-text and AIDC technology forms of the UDI. The data delimiters vary based on the FDA-accredited issuing agencies, and consist of a specific set of characters used to identify the information immediately following the data delimiter.

For purposes of this draft guidance, we define "UDI carrier" as the means to convey the UDI and any non-UDI elements by using easily readable plain-text and AIDC forms. In the UDI carrier, the data represented in the UDI should precede any non-UDI elements and should be distinguishable from the UDI elements. The easily readable plain-text form of the UDI should be ordered to specify the DI first, followed by the PIs. If there are any non-UDI elements in the UDI carrier, the non-UDI elements should follow the PIs that are part of the UDI. For more information on non-UDI elements capable of being included in the UDI carrier, labelers should contact their FDA-accredited issuing agency.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current

thinking of FDA on "Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)". It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Request for Comments

FDA is seeking additional information on this issue. FDA is particularly interested in receiving information relating to the following question: Are there any additional standards, in addition to those referenced in this draft guidance, that should be used to determine the print quality of the AIDC form of the UDI?

IV. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm> or at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)" may send an email request to CDRH-Guidance@fda.hhs.gov or ocod@fda.hhs.gov, or by calling 1-800-835-4709 or 240-402-7800, to receive an electronic copy of the document. Please use the document number GUD1500035 to identify the guidance you are requesting.

V. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information described in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485, and the collections of information in 21 CFR part 830 have been approved under OMB control number 0910-0720.

Dated: July 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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