



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. FDA-2017-D-6841]

Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Availability of guidance.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance entitled "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff." This guidance revises the guidance by the same title issued November 5, 2018, and describes FDA's intention with respect to the enforcement of unique device identification (UDI) requirements for class I and unclassified devices, other than implantable, life-sustaining, or life-supporting (I/LS/LS) devices. In this revised guidance, FDA clarifies that, at this time, in light of the considerations described in the guidance, it does not intend to enforce standard date formatting, labeling, and Global Unique Device Identification Database (GUDID) data submission requirements for these devices before September 24, 2022. The guidance is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2017-D-6841 for "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 guidance document entitled "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002 or the Center for Biologics Evaluation and Research, Office of Communication, Outreach,

and Development, 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20903. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: *For Center for Devices and Radiological Health-regulated devices:* Christina Savisaar, UDI Regulatory Policy Support, 10903 New Hampshire Ave., Bldg. 32, Rm. 3255, 301-796-5995, email: GUDIDSupport@fda.hhs.gov.

For Center for Biologics Evaluation and Research-regulated devices: Stephen Ripley, Office of Communication, Outreach, and Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, or call 1-800-835-4709 or 240-402-8010.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff." On September 24, 2013, FDA published a final rule establishing a unique device identification system designed to adequately identify devices through distribution and use (the UDI Rule). Phased implementation of the regulatory requirements set forth in that final rule is based on a series of established compliance dates based primarily on device classification, which range from September 24, 2014, to September 24, 2020.

The UDI Rule requires a device to bear a UDI on its label and packages unless an exception or alternative applies (see 21 CFR 801.20), and special labeling requirements apply to stand-alone software regulated as a device (21 CFR 801.50). The UDI Rule also requires that data pertaining to the key characteristics of each device required to bear a UDI be submitted to

FDA's GUDID (21 CFR 830.300). In addition, the UDI Rule added 21 CFR 801.18, which requires certain dates on device labels to be in a standard format. For devices that: (1) must bear UDIs on their labels and (2) are intended to be used more than once and reprocessed between uses, 21 CFR 801.45 requires the devices to be directly marked with a UDI. Compliance dates for these labeling, GUDID data submission, standard date format, and direct marking requirements can be found in the preamble to the UDI Rule, 78 FR 58786 at 58815 to 58816.

This guidance describes FDA's intention with regard to enforcement of these requirements for class I and unclassified devices, other than I/LS/LS devices. This revised guidance supersedes the November 2018 guidance of the same title, "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff." In this revised guidance, FDA states that, at this time, in light of the considerations described in the guidance, it does not intend to enforce the requirements under 21 CFR 801.18, 801.20, 801.50, and 830.300 for class I and unclassified devices, other than I/LS/LS devices, prior to September 24, 2022, regardless of the date they are manufactured and labeled. The guidance explains that FDA believes it is important to continue focusing its resources on addressing UDI implementation issues and data quality for higher risk devices and, at this time, concludes that continuing its existing policy with regard to enforcement of these requirements for class I and unclassified devices, other than I/LS/LS devices, is consistent with the public health. In addition, while some editorial changes were made to improve clarity, other policies described in the November 2018 guidance remain the same in the revised guidance.

FDA considered comments received on the guidance that appeared in the *Federal Register* on November 5, 2018 (83 FR 55372) as the Agency revised the guidance.

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). FDA has determined that this guidance presents a less burdensome policy that is consistent with public health. Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking." 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.

II. Electronic Access

Persons interested in obtaining a copy of the 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 <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov> or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>. Persons unable to download an electronic copy of "Unique Device Identification: Policy Regarding Compliance Dates for

Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 17029 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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. 3501-3521). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR Part	Topic	OMB Control No.
801 subpart B and 830	Unique Device Identification	0910-0720
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073

Dated: June 25, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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