4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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, HHS.

ACTION: Notice of availability.

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 describes FDA's intention with respect to the enforcement of unique device identification requirements for class I and unclassified devices, other than implantable, life-sustaining, or life-supporting (I/LS/LS) devices. FDA 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, 2020. In addition, FDA does not intend to enforce direct mark requirements for these devices before September 24, 2022. This guidance also describes FDA's direct mark compliance policy for class III, LS/LS, and class II devices that are nonsterile, manufactured and labeled prior to their applicable direct mark compliance date, and remain in inventory, as well as for class I and unclassified devices that are nonsterile, manufactured and labeled prior to September 24, 2022, and remain in inventory.

FDA does not intend to enforce the direct mark requirements for these devices when the device's unique device identifier (UDI) can be derived from other information directly marked on the device. The guidance document 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.

- 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.gpo.gov/fdsys/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.

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. 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. 66, Rm. 3319, 301-796-5995, email: GUDIDSupport@fda.hhs.gov.

For Center of 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 unique device identifier 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 final 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 labeling, GUDID data submission, standard date format, and direct marking requirements can be found in 78 FR 58786 at 58815 to 58816.

This guidance describes FDA's intention with regard to enforcement of labeling, standard date formatting, GUDID data submission, and direct marking for class I and unclassified devices, other than I/LS/LS devices. This guidance also describes FDA's intention with regard to direct mark requirements for class III, LS/LS, and class II devices that are nonsterile, manufactured and labeled prior to their applicable direct mark compliance date, and remain in inventory, as well as FDA's intention with regard to direct mark requirements for class I and unclassified devices that are nonsterile, manufactured and labeled prior to September 24, 2022, and remain in inventory.

FDA considered comments received on the guidance that appeared in the *Federal Register* on January 16, 2018 (83 FR 2057). FDA revised the guidance as appropriate in response to the comments. This guidance supersedes the January 2018 guidance of the same name, "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff."

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2) (21 CFR 10.115(g)(2))). FDA has determined that this guidance document 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.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 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. This guidance is not subject to Executive Order 12866.

III. 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. This guidance document is also available at https://www.regulations.gov or https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. 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 to identify the guidance you are requesting.

IV. 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. 3501-3520). 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: October 31, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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