Contains Nonbinding Recommendations

Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking

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Immediately in Effect Guidance for Industry and Food and Drug Administration Staff

Document issued on July 1, 2020

This document supersedes 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, issued November 5, 2018.

For questions about this document concerning CDRH-regulated devices contact UDI Regulatory Policy Support, 301-796-5995, email: GUDIDSupport@fda.hhs.gov.

For questions about this document concerning CBER-regulated devices contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2017-D-6841. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 17029 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA's unique device identification system is designed to adequately identify devices through distribution and use.[1] Its requirements were designed to be phased in over seven years according to established compliance dates based primarily on device classification.

The compliance dates established for class I and unclassified devices, other than implantable, life-supporting, or life-sustaining (I/LS/LS) devices[2] are:

[1] The final rule establishing the unique device identification system was published September 24, 2013 (78 FR 58786).

[2] Implantable, life-supporting, or life-sustaining devices of all classes were required to comply with labeling, direct mark, and GUDID submission requirements under 21 CFR 801.20, 801.45, 801.50, and 830.300, as well as the standard date format requirement under 21 CFR 801.18 by September 24, 2015, unless an exception or alternative applied. See 78 FR at 58815.

- September 24, 2018, for the following requirements:
    - Standard date formatting (21 CFR 801.18),
    - Labeling (21 CFR 801.20, 21 CFR 801.50), and
    - Global Unique Device Identification Database (GUDID) data submission (21 CFR 830.300); and
- September 24, 2020, for direct mark requirements (21 CFR 801.45).[3]

This guidance describes FDA's intention with regard to enforcement of these requirements for class I and unclassified devices.[4]

This guidance also describes FDA's direct mark compliance policy for class III, LS/LS, and class II devices that are non-sterile, that are manufactured and labeled prior to their applicable direct mark compliance date, and that remain in inventory, as well as for class I and unclassified devices that are not LS/LS devices, that are non-sterile, that are manufactured and labeled prior to September 24, 2022, and that remain in inventory.

Throughout this guidance document, the terms "we," "us," and "our" refer to FDA staff from the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). "You" and "your" refer to the labeler, as defined in 21 CFR 801.3.

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (section 701(h)(1)(C)(i) of the FD&C Act and 21 CFR 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

On September 24, 2013, the FDA published a final rule establishing a unique device identification system designed to adequately identify devices through distribution and use (the "UDI Rule").[5] Phased implementation of the regulatory requirements set forth in that

[3] See 78 FR at 58815-58816.

[4] The compliance policies for class I and unclassified devices described in this guidance do not apply to I/LS/LS devices. Additionally, class I devices that FDA has by regulation exempted from the good manufacturing practice requirements are outside the scope of this guidance because such devices are excepted from UDI requirements (see 21 CFR 801.30(a)(2)).

[5] 78 FR 58786.

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.[6]

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. As explained in the preamble to the UDI Rule, FDA aligned the compliance date for standard date format requirements under 21 CFR 801.18 with the compliance date by which a device must bear a UDI on its label and packages under 21 CFR 801.20 to avoid the need to make changes to a device label more than once to implement the requirements in the final rule.[7] 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.[8]

Fully realizing the benefits of the unique device identification system depends on UDI being integrated into data sources throughout our healthcare system, including in the supply chain, electronic health records, and registries. This requires UDI data to be of a high quality, such that all stakeholders in the healthcare community have sufficient confidence in the accuracy and completeness of that data.

In January 2018, FDA issued a guidance document, "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices," which stated that for class I and unclassified devices, the Agency did not intend to enforce standard date formatting, UDI labeling, and GUDID data submission requirements (21 CFR 801.18, 21 CFR 801.20, 21 CFR 801.50, and 21 CFR 830.300) prior to September 24, 2020 and direct mark requirements (21 CFR 801.45) prior to September 24, 2022.[9] That guidance explained that, as FDA and industry had worked to implement the UDI requirements, the Agency had identified complex policy and technical issues that required resolution to help ensure that UDI data are high quality and are available in standardized ways. The guidance further explained that FDA had received a large number of inquiries from labelers of class II, class III, and I/LS/LS devices relating to those policy and technical issues and anticipated receiving a similarly high volume of questions from labelers of class I and unclassified devices. Therefore, the guidance stated that the Agency intended to focus its resources on addressing implementation challenges and optimizing the quality and utility of UDI data for higher-risk devices before focusing on UDI implementation issues for lower-risk devices to help ensure the transition from development of the unique device identification system to

[6] See 78 FR at 58815-58816.
[7] See 78 FR at 58795.
[8] For more information on direct mark requirements under 21 CFR 801.45, see "Unique Device Identification: Direct Marking of Devices Guidance for Industry and Food and Drug Administration Staff" published on November 17, 2017 at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-direct-marking-devices.
[9] 83 FR 2057 (Jan. 16, 2018).

widespread use and sustainability. The January 2018 guidance was superseded by a previous version of this guidance issued in November 2018, which retained the original compliance policy and also clarified FDA's policy on direct marking requirements for certain devices.[10]

Since January 2018, FDA has continued to work with labelers on implementation of UDI requirements and has identified additional policy and technical issues to resolve in order to help ensure the quality and utility of UDI data. We also continue to receive many inquiries from labelers related to these issues and believe it is important to continue focusing our resources on addressing implementation issues and data quality for higher risk devices. Accordingly, at this time, we conclude that continuing our existing policy with regard to enforcement of requirements under 21 CFR 801.18, 801.20, 801.50, and 830.300 for certain class I and unclassified devices for an additional period of time, as described in this guidance, is consistent with the public health. In addition, for those labelers that have not already implemented UDI requirements for class I and unclassified devices, preparing to implement UDI requirements while addressing the challenges related to Coronavirus Disease 2019 (COVID-19) could be very difficult and could divert resources from COVID-19 response efforts. To the extent this policy helps labelers remain focused on public health needs related to COVID-19, we believe the policy is further consistent with the public health.

Additionally, one remaining challenge for labelers is meeting the UDI direct mark requirements for certain finished devices that are manufactured and labeled before the labeler has implemented direct marking and that remain in inventory. The cost of remediating existing devices in inventory to add a direct mark may be substantial, as it can entail different design changes and design validations than those made in order to add a required UDI direct mark to future lots of the device.

The compliance policy described in this guidance for certain devices in inventory that do not comply with the direct mark requirements is intended to facilitate use of those devices while still realizing some UDI-related benefits to patient safety. The lower burden of the approach outlined in this guidance also helps reduce the risk that industry will choose to avoid the cost of remediation by discarding inventory, potentially creating device shortages and negatively impacting patients and providers. Weighing the considerations at this time, we conclude that this direct mark compliance policy for certain inventory devices appropriately serves the public health.

III. Policy On Standard Date Formatting, UDI Labeling, and GUDID Data Submission Requirements for Class I and Unclassified Devices

At this time, in light of the considerations above, FDA does not intend to enforce standard date formatting, UDI labeling, and GUDID data submission requirements under 21 CFR

[10] 83 FR 55372 (Nov. 5, 2018).

801.18, 21 CFR 801.20, 21 CFR 801.50, and 21 CFR 830.300 for class I and unclassified devices, other than I/LS/LS devices,[11] before September 24, 2022.

We note that, pursuant to 21 CFR 801.30(a)(1), a finished device manufactured and labeled prior to the compliance date established by FDA for 21 CFR 801.20 regarding that device is excepted from the requirement to bear a UDI for a period of three years after that compliance date. The compliance dates established in the preamble of the UDI Rule have not changed. Finished class I and unclassified devices, other than I/LS/LS devices, manufactured and labeled prior to September 24, 2018, are excepted from UDI labeling and GUDID data submission requirements for a period of three years after the established compliance date or until September 24, 2021, (see 21 CFR 801.30(a)(1)). However, FDA 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.

IV. Policy for Direct Mark of Certain Devices

A. Class III, LS/LS, and Class II Non-Sterile Devices Manufactured and Labeled Prior to the Established Direct Mark Compliance Date That Remain in Inventory

The policy in this Section IV.A. of this guidance applies only to finished class III, LS/LS, and class II devices that are non-sterile, that were manufactured and labeled prior to their established direct mark compliance date, and that remain in inventory.[12] In general, the direct mark compliance date for class III devices is September 24, 2016; for LS/LS devices is September 24, 2015; and for class II devices is September 24, 2018.[13] However, pursuant to 21 CFR 801.30(a)(1), finished devices manufactured and labeled prior to the applicable compliance date established by FDA for 21 CFR 801.20 are not required to comply with UDI requirements, including direct mark requirements under 21 CFR 801.45, until three years after that labeling compliance date.[14] This provision was intended to reduce burden associated with the UDI Rule for inventories of finished devices that were manufactured and labeled prior to the applicable compliance date.[15]

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[11] Section 519(f) of the FD&C Act requires implementation of FDA's unique device identification system regulations for I/LS/LS devices within two years of finalizing those regulations. For class I and unclassified I/LS/LS devices, the compliance date established by the FDA is September 24, 2015. See 78 FR at 58815-58816.

[12] For other categories of devices subject to direct marking under 21 CFR 801.45, please see the table in Figure 2 on our website at https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-exceptions-alternatives-and-time-extensions for additional information that may be applicable.

[13] See 78 FR at 58815-58816.

[14] This exception has expired for class III, LS/LS, and class II devices.

[15] See 78 FR at 58798.

For the class III, LS/LS, and class II devices described above, including device constituents of a copackaged combination product or kit, FDA does not intend to enforce UDI direct mark requirements under 21 CFR 801.45 when the device's UDI can be derived from other information directly marked on the device.

In determining whether a device's UDI can be derived from other information directly marked on the device, FDA intends to consider whether the labeler has developed and made available a method for constructing the UDI from other information directly marked on the device (such as catalog number, lot number, serial number) such that the UDI is readily available at the point of use and has documented or referenced that method in the Device Master Record. FDA also intends to develop a new field(s) in GUDID to capture that a device is subject to such a method for constructing the UDI. We recommend that labelers use the new field(s) to document, when applicable, that their devices are subject to such a method when the field becomes available.

B. Class I and Unclassified Devices

The direct mark compliance date for class I and unclassified devices, except for LS/LS devices,[16] is September 24, 2020.[17] At this time, in light of the considerations above, FDA does not intend to enforce UDI direct mark requirements under 21 CFR 801.45 for those devices before September 24, 2022. This policy applies to sterile and non-sterile devices and includes device constituents of a copackaged combination product or kit.

In addition, after September 24, 2022, FDA does not intend to enforce UDI direct mark requirements under 21 CFR 801.45 for finished class I and unclassified devices, including class I and unclassified device constituents of a copackaged combination product or kit, that are not LS/LS, that are non-sterile, that were manufactured and labeled prior to September 24, 2022, and that remain in inventory, when the device's UDI can be derived from other information directly marked on the device. In determining whether a device's UDI can be derived from other information directly marked on the device, FDA intends to consider whether the labeler has developed and made available a method for constructing the UDI from other information directly marked on the device (such as catalog number, lot number, serial number) such that the UDI is readily available at the point of use and has documented or referenced that method in the Device Master Record. As noted above, FDA intends to develop a new field(s) in GUDID to capture that a device is subject to such a method for constructing the UDI. We recommend that labelers use the new field(s) to document, when applicable, that their devices are subject to such a method when the field becomes available.

[16] Section 519(f) of the FD&C Act requires implementation of FDA's unique device identification system regulations for I/LS/LS devices within two years of finalizing those regulations. For class I and unclassified LS/LS devices, the direct mark compliance date established by the FDA is September 24, 2015. See 78 FR at 58815-58816.

[17] See 78 FR at 58815-58816.