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Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices

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

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

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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

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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Table of Contents

I. Introduction 1
II. Background 2
III. Compliance Dates for Class I and Unclassified Devices 4

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 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 though distribution and use.[1] The unique device identification system requirements are being 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:

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).

[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. See 78 FR at 58815.

This guidance describes FDA's intention with regard to enforcement of these requirements for class I and unclassified devices. As described in further detail below, FDA does not intend to enforce standard date formatting, labeling, and GUDID data submission requirements under 21 CFR 801.18, 21 CFR 801.20, 21 CFR 801.50, and 21 CFR 830.300 for these devices before September 24, 2020. In addition, FDA does not intend to enforce direct mark requirements under 21 CFR 801.45 for these devices before September 24, 2022. The policy described in this guidance does not apply to I/LS/LS devices. This policy also does not apply to class I devices that FDA has by regulation exempted from the good manufacturing practice requirements because such devices are excepted from UDI requirements (see 21 CFR 801.30(a)(2)).

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. Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

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").[3] 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.[4]

The UDI Rule requires a device to bear a unique device identifier (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

[3] 78 FR 58786.
[4] See 78 FR at 58815-58816.

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. The compliance date for labeling, GUDID data submission, and standard date format requirements for class I and unclassified devices, other than I/LS/LS devices, is September 24, 2018. 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.[5]

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. The compliance date for UDI direct mark requirements for class I and unclassified devices, other than I/LS/LS devices, is September 24, 2020.

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.

For class II, class III, and I/LS/LS devices, the compliance dates established for most UDI requirements have already passed. As FDA and industry have worked to implement these requirements, the agency has identified complex policy and technical issues that require resolution to help ensure that UDI data are high quality and are available in standardized ways. FDA 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. Based on experience with UDI implementation to date, FDA anticipates receiving a similarly high volume of questions from labelers of class I and unclassified devices as compliance dates applicable to those devices approach.

To fully reap the public health benefits and a return on investment of the unique device identification system, the Agency intends to focus its resources on addressing existing 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. Undertaking this endeavor now will help ensure the transition from development of the unique device identification system to widespread use and sustainability.

[5] See 78 FR at 58795.

III. Compliance Dates for Class I and Unclassified Devices

A. Class I and Unclassified Devices Manufactured and Labeled on or After September 24, 2018

As summarized in Table 1 below, FDA does not intend to enforce standard date formatting, UDI labeling, and GUDID data submission requirements under 21 CFR 801.18, 21 CFR 801.20, 21 CFR 801.50, and 21 CFR 830.300 for class I and unclassified devices before September 24, 2020. FDA also does not intend to enforce direct mark requirements under 21 CFR 801.45 for these devices before September 24, 2022.

This policy does not apply to class I or unclassified I/LS/LS devices because the compliance dates established by the FDA for those devices have already passed.[6]

B. Finished Class I and Unclassified Devices Manufactured and Labeled Before September 24, 2018

In addition, 21 CFR 801.30(a)(1) provides that a finished device manufactured and labeled prior to the compliance date established by the 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. This provision is 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.[7]

GUDID data submission requirements and direct mark requirements are tied to the requirement under 21 CFR 801.20 that a device bear a UDI on its label. (See 21 CFR 801.45(a); 21 CFR 830.300(a); 21 CFR 830.330(a).) Therefore, if the exception in 21 CFR 801.30(a)(1) applies, a device is excepted from labeling requirements under 21 CFR 801.20 and 21 CFR 801.50, as well as from GUDID data submission and direct mark requirements, for a period of three years after the established 21 CFR 801.20 compliance date for that device.

While FDA does not intend to enforce the requirements under 21 CFR 801.18, 801.20, 801.45, 801.50 and 830.300 for class I and unclassified devices, other than I/LS/LS devices, prior to the dates described above in Section III.A, the compliance dates established in the preamble of the UDI Rule have not changed. This means 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

[6] 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.

[7] See 78 FR at 58798.

three years after the established compliance date or until September 24, 2021. (See 21 CFR 801.30(a)(1).) Although not covered by 21 CFR 801.30(a)(1), we also do not intend to enforce standard date format requirements under 21 CFR 801.18 during that same three-year period for finished class I and unclassified devices, other than I/LS/LS devices, manufactured and labeled before September 24, 2018.

Pursuant to 21 CFR 801.30(a)(1), finished class I and unclassified devices, other than I/LS/LS devices, manufactured and labeled prior to September 24, 2018, would also be excepted from direct marking requirements until September 24, 2021. However, with the exception of I/LS/LS devices, we do not intend to enforce direct mark requirements before September 24, 2022, for class I and unclassified devices (including those manufactured and labeled prior to September 24, 2018). We believe this policy regarding direct mark compliance dates is appropriate because it is not in the best interest of the public health for labelers of class I and unclassified devices to prioritize remediating devices in inventory to meet direct mark requirements prior to addressing direct marking, and its impact on the safety and effectiveness, for devices manufactured following labelers' full implementation of UDI.

Table 1

Type of Device	**FDA does not intend to enforce UDI labeling (21 CFR 801.20 & 801.50), GUDID Data Submission (21 CFR 830.300), and Standard Date Format (21 CFR 801.18) requirements before:**	**FDA does not intend to enforce Direct Mark requirements (21 CFR 801.45) before:**
Class 1 and unclassified devices manufactured and labeled on or after September 24, 2018	September 24, 2020	September 24, 2022
Finished class 1 and unclassified devices manufactured and labeled before September 24, 2018	September 24, 2021[8]	September 24, 2022

[8] As explained above, and consistent with 21 CFR 801.30(a)(1), finished class I and unclassified devices manufactured and labeled before September 24, 2018, are excepted from the UDI labeling and GUDID submission requirements by regulation until September 24, 2021.