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Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices

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Guidance for Industry and Food and Drug Administration Staff

Document issued on July 25, 2022

This document supersedes 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, issued July 1, 2020.

For questions about this document regarding CDRH-regulated devices, contact the FDA UDI Help Desk, 301-796-5995, email: 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, or by email at ocod@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION

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

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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 (UDI 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:

- September 24, 2018, for the following requirements:
  - Standard date formatting (21 CFR 801.18),
  - Labeling (21 CFR 801.20, 21 CFR 801.50), and

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

[2] Section 519(f) of the Federal Food, Drug, and Cosmetic Act requires implementation of FDA's UDI system regulations for I/LS/LS devices within two years of finalizing those regulations. I/LS/LS devices 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 58815-58816.

  - 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 policies with regard to enforcement of these requirements for class I and unclassified devices,[4] including the Agency's compliance policy regarding GUDID submission requirements under 21 CFR 830.300 for certain class I devices considered consumer health products. In addition, the guidance describes how a labeler of a class I device can determine whether its device is within the scope of that compliance policy.

This guidance also reiterates 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.

A portion of this guidance describing a 75-day extension of an existing FDA compliance policy 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) 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)). FDA has determined that this approach presents a less burdensome policy that is consistent with public health. Although the portion of this guidance describing that policy is being implemented immediately, the guidance remains subject to comment in accordance with the Agency's good guidance practices. The remainder of the updates to this guidance are being implemented following the opportunity for public comment on FDA's draft guidance, Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices, issued October 14, 2021.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, 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.

[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 (21 CFR 801.30(a)(2)).

II. Background

On September 24, 2013, the FDA published a final rule establishing a UDI system designed to adequately identify devices through distribution and use (the "UDI Rule").[5] 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.[6]

The UDI Rule requires a device to bear a unique device identifier (UDI) on its label and packages unless an exception or alternative applies (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). GUDID provides a repository of device safety information for FDA. Most of the information submitted to GUDID is also available to the public through AccessGUDID.[7] AccessGUDID enables healthcare providers and patients to obtain useful safety information on specific device models, such as sterility requirements and MRI compatibility information.

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.[8] 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.[9]

The UDI system seeks to improve the identification of medical devices by making it possible to rapidly and definitively identify a device and certain key attributes related to a device's safe and effective use. Fully realizing the benefits of the UDI system depends on UDIs 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 the initial version of this guidance document, "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices,"[10]

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[5] 78 FR 58786.
[6] See 78 FR at 58815-58816.
[7] Available at: https://accessgudid.nlm.nih.gov/
[8] See 78 FR at 58795.
[9] For more information on direct mark requirements under 21 CFR 801.45, see "Unique Device Identification: Direct Marking of Devices" (Direct Mark Guidance), available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique- device-identification-direct-marking-devices.
[10] 83 FR 2057 (Jan. 16, 2018). This previous version of the guidance stated that for class I and unclassified devices, the Agency did not intend to enforce standard date formatting, UDI labeling, and GUDID data submission

which was superseded in November 2018 by the guidance, "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking,"[11] and then subsequently superseded in July 2020 by the guidance with the same title (hereafter referred to as "2020 UDI Compliance Policy Guidance").[12] Throughout that time, FDA has been working with labelers on implementing UDI requirements and addressing policy and technical issues. The prior versions of this guidance reflected our belief that it was important to continue focusing our resources on addressing UDI implementation issues and data quality for higher risk devices. In addition, as described in the 2020 UDI Compliance Policy Guidance, to the extent the policy articulated in that guidance helped labelers remain focused on public health needs related to Coronavirus Disease 2019 (COVID-19), we believe it was further consistent with the public health.

As UDI implementation has progressed, FDA has gained further insight into the public health benefits and potential burdens of UDI requirements for class I devices, which generally pose the lowest risk. Many 510(k)-exempt class I devices are sold directly to consumers over-the-counter in brick-and-mortar and/or online stores. For purposes of this guidance, we refer to these devices, when they do not fall within one or more of the categories identified in section III.B.2, as "consumer health products." These class I devices are also typically labeled with a Universal Product Code (UPC),[13] which is a barcode primarily used for scanning items at the point of sale. The UPC is used to identify products to a very granular level—such as where in stores the product is displayed, and whether the product has temporary promotional packaging—and the UPC for the same version or model of a device can change frequently.

With respect to class I devices that are consumer health products, FDA believes that the entry of UDI data into GUDID, especially given the frequent changes to the UPCs serving as the UDIs for these devices, is burdensome to stakeholders. Further, FDA considered the public health benefit of GUDID submission for consumer health products and the risks to public health if GUDID submission is not provided for these devices. After reviewing available postmarket information, such as medical device reports and recall data for class I devices, FDA has a better understanding of the devices and device characteristics for which GUDID information is particularly useful in evaluating and improving device safety throughout a product lifecycle, as well as those for which GUDID information may be less important in this regard. Based on this analysis, at this time, FDA does not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for consumer health products.

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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.

[11] 83 FR 55372 (Nov. 5, 2018). This previous version of the guidance retained the original compliance policy and clarified FDA's policy on direct marking requirements for certain non-sterile devices in inventory.

[12] 85 FR 39477 (Jul. 1, 2020). This previous version of the guidance stated that FDA did 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, other than I/LS/LS devices, before September 24, 2022.

[13] For class I devices, the UDI Rule provides that the UPC may serve as the UDI (21 CFR 801.40(d)). As with the production identifier exception for class I devices (21 CFR 801.30(d)), this option for a UPC was provided after weighing the public health benefit against the burden on industry with respect to these lower risk devices.

Class I devices that FDA does **not** consider to be consumer health products may pose greater risks to public health. These devices are typically used in healthcare settings and are often subject to additional regulatory controls, such as the requirement to submit premarket notification, restrictions under section 520(e) of the FD&C Act, and other requirements. For these devices, FDA has determined that submission of UDI data into GUDID is particularly important to help enable FDA and other stakeholders to evaluate and improve device safety throughout the product lifecycle.[14] Submission of UDI data into GUDID for these devices may also help reduce medical errors and simplify the integration of device use information into data systems.[15] These devices are discussed further in section III.B.2.

Section III.B.2 and section III.C also explain that we intend to extend our existing compliance policy regarding GUDID submission requirements for class I and unclassified devices, other than I/LS/LS devices, regardless of whether they are consumer health products, for an additional 75 calendar days. In the 2020 UDI Compliance Policy Guidance, FDA stated that we did not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for class I and unclassified devices, other than I/LS/LS devices, before September 24, 2022.[16] We recognize, however, that the new policy regarding consumer health products, described in section III.B of this guidance, is being finalized close to that date and that some labelers may have been waiting for the publication of this guidance before planning for GUDID submission. In light of these considerations, at this time, we do not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for class I and unclassified devices, other than I/LS/LS devices, before December 8, 2022. We believe this brief extension of the policy may help facilitate submission of high quality UDI data to GUDID and is consistent with the public health. The other policies and related dates in this guidance remain the same and have not changed since the publication of the 2020 UDI Compliance Policy Guidance. FDA's UDI webpage[17] contains additional information about UDI compliance dates and other dates related to UDI compliance policies.

Additionally, as explained in prior versions of this guidance, 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 has been challenging for labelers. 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 section IV of 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

[14] GUDID data may be used to facilitate recalls and medical device reporting, in analysis of premarket approval application (PMA) annual reports, and for other FDA processes.
[15] The preamble to the UDI Rule discusses the potential benefits of GUDID submission in more detail (see 78 FR 58786).
[16] See 85 FR 39477 (Jul. 1, 2020).
[17] Available at: https://www.fda.gov/udi

negatively impacting patients and providers. At this time, we have concluded 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 Submission Requirements for Class I and Unclassified Devices

A. Compliance Policy for Standard Date Formatting and UDI Labeling Requirements for Class I and Unclassified Devices

As previously stated in the 2020 UDI Compliance Policy Guidance, FDA does not intend to enforce standard date formatting and UDI labeling requirements under 21 CFR 801.18, 21 CFR 801.20, and 21 CFR 801.50 for class I and unclassified devices, other than I/LS/LS devices,[18] before September 24, 2022.[19]

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 submission requirements for a period of three years after the established compliance date or until September 24, 2021 (21 CFR 801.30(a)(1)). However, FDA does not intend to enforce the requirements under 21 CFR 801.18, 801.20, and 801.50 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.

B. Compliance Policy for GUDID Submission Requirements for Class I Devices

1. Class I Devices Considered Consumer Health Products

At this time, FDA does not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for class I devices considered consumer health products that are required to bear a UDI on their labels and device packages. For purposes of this guidance, "consumer health products" means 510(k)-exempt class I devices that are sold directly to consumers over-the-counter in brick-and-mortar and/or online stores and that do not fall within one or more of the categories

[18] See footnote 2.

[19] This policy for standard date formatting and UDI labeling requirements under 21 CFR 801.18, 21 CFR 801.20, and 21 CFR 801.50 for class I and unclassified devices, other than I/LS/LS devices, remains the same as the policy in the 2020 UDI Compliance Policy Guidance. See 85 FR 39477 (Jul. 1, 2020).

identified in section III.B.2. In addition to being sold directly to consumers, some consumer health products may be sold to or used in professional healthcare facilities.[20] Consumer health products are typically labeled with a UPC, which may serve as the UDI for class I devices (21 CFR 801.40(d)).[21]

If a labeler has questions regarding whether their device is considered a consumer health product that is within the scope of this compliance policy, the labeler may contact the FDA at GUDIDSupport@fda.hhs.gov.

2. Class I Devices Not Considered Consumer Health Products by FDA

FDA has determined that class I devices that we do not consider consumer health products may pose greater risks to public health and, based on FDA's analysis, GUDID data is particularly important to monitoring the safety of these devices. These potentially higher risk devices are typically used exclusively in professional healthcare facilities and are often subject to additional regulatory controls.

Class I devices that fall into one or more of the categories described below are not considered consumer health products for purposes of this guidance and, therefore, do not fall within the compliance policy described in section III.B.1 of this guidance. However, FDA does not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for class I devices, other than I/LS/LS devices,[22] regardless of whether they fall within that compliance policy, before December 8, 2022 (an additional 75 calendar days).[23]

a. Class I Reserved Devices

The majority of class I devices are exempt from the 510(k) premarket notification process. However, "any class I device that is intended for a use which is of substantial importance in preventing impairment of human health… or … that presents a potential unreasonable risk of illness or injury" is not exempt from the 510(k) notification process. FD&C Act section 510(l)(1). These devices are typically referred to as "Class I Reserved Devices." More

[20] "Professional healthcare facility" is defined as any environment where personnel with medical training are continually available to oversee or administer the use of medical devices. This includes, but is not limited to, hospitals, long-term care facilities, nursing homes, emergency medical services, clinics, physicians' offices, and outpatient treatment facilities; or a clinical laboratory. For more information, see the following guidance: "Design Considerations for Devices Intended for Home Use", available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-devices-intended-home-use.

[21] Class I devices that bear UPCs on their labels and device packages are deemed to meet all UDI labeling requirements of 21 CFR 801, subpart B (21 CFR 801.40(d)), and the UPC will serve as the UDI required by 21 CFR 801.20. These devices are not required to bear a UDI, in addition to a UPC, but may elect to do so.

[22] See footnote 2.

[23] In the 2020 UDI Compliance Policy Guidance, we stated that we do not intend to enforce the GUDID data submission requirements under 21 CFR 830.300 for class I devices, other than I/LS/LS devices, before September 24, 2022. See 85 FR 39477 (Jul. 1, 2020).

information about devices considered to be Class I Reserved Devices can be found on FDA's website.[24]

b. Restricted Devices

Under section 520(e) of the FD&C Act, FDA may by regulation require that a device be restricted to sale, distribution, or use only upon written or oral authorization by a practitioner licensed by law to administer or use such device (i.e., prescription use) or such other conditions as may be prescribed in such regulation. For example, regulations restricting the sale, distribution, and use of in vitro diagnostic devices are located in 21 CFR part 809, subpart C.

c. Implantable Devices

"Implantable device" is defined at 21 CFR 801.3 as "a device that is intended to be placed in a surgically or naturally formed cavity of the human body" and "is regarded as an implantable device . . . only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner of Food and Drugs determines otherwise in order to protect human health."

d. Life-Supporting or Life-Sustaining Devices

"Life-supporting or life-sustaining device" is defined at 21 CFR 860.3 as a device that is "essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life." FDA recommends evaluating the characteristics of the device and looking to the device's intended use to determine whether a particular device is life-supporting or life-sustaining.

e. Certain Devices Distributed to Professional Healthcare Facilities and Intended for Use by Healthcare Professionals Only

The compliance policy described in section III.B.1 does not apply to devices that are distributed to professional healthcare facilities, are intended for use by healthcare professionals only, and are: (1) reusable or reprocessed,[25] including those that are non-sterile and sterilized on-site before use; or (2) intended for wound care.

C. Compliance Policy for GUDID Submission Requirements for Unclassified Devices

[24] Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/3151.cfm

[25] For purposes of this guidance, consistent with FDA's Direct Mark Guidance, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-direct-marking-devices, we consider a device to be reusable if it is "intended to be used more than once," meaning that it is intended for repeated uses on or by different patients. If the device is intended to be used more than once on or by the same patient, and not on or by multiple patients, it is not considered reusable for purposes of this guidance. Also consistent with the Direct Mark Guidance, we consider a device intended to be reprocessed if it is intended to undergo high-level disinfection and/or sterilization before each use or between uses.

An unclassified device is a pre-amendments device type[26] for which a classification regulation has not been promulgated. Unclassified devices generally require submission of a 510(k) premarket notification. FDA has issued compliance policies related to certain unclassified devices.[27] FDA does not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for unclassified devices, other than I/LS/LS devices,[28] before December 8, 2022 (an additional 75 calendar days).[29]

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.[30] 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.[31] 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.[32] 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.[33]

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.

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[26] A pre-amendments device type is one that was in commercial distribution before May 28, 1976, the date the Medical Device Amendments were signed into law.

[27] See the following guidance: "Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements", available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/intent-exempt-certain-unclassified-medical-devices-premarket-notification-requirements

[28] See footnote 2.

[29] In the 2020 UDI Compliance Policy Guidance, we stated that we do not intend to enforce the GUDID data submission requirements under 21 CFR 830.300 for unclassified devices, other than I/LS/LS devices, before September 24, 2022. See 85 FR 39477 (Jul. 1, 2020).

[30] For other categories of devices subject to direct marking under 21 CFR 801.45, please see 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.

[31] See 78 FR at 58815-58816.

[32] This exception has expired for all devices.

[33] See 78 FR at 58798.

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 DMR. 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,[34] is September 24, 2020.[35] As previously stated in the 2020 UDI Compliance Policy Guidance, FDA does not intend to enforce UDI direct mark requirements under 21 CFR 801.45 for those devices before September 24, 2022.[36] 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 DMR. 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.

[34] See footnote 2.
[35] See 78 FR at 58815-58816.
[36] This policy for UDI direct mark requirements under 21 CFR 801.45 for class I and unclassified devices, other than LS/LS devices, remains the same as the policy in the 2020 UDI Compliance Policy Guidance. See 85 FR 39477 (Jul. 1, 2020).