GS1 HEALTHCARE US

U.S. FDA Unique Device Identification (UDI) Rule
Frequently Asked Questions (FAQs)

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GS1 US

THE GLOBAL LANGUAGE
OF BUSINESS

CONTENTS

ABOUT GS1

GS1® is a neutral, not-for-profit, global organization that develops and maintains the most widely-used supply chain standards system in the world. GS1 Standards improve the efficiency, safety, and visibility of supply chains across multiple sectors. With local Member Organizations in over 110 countries, GS1 engages with communities of trading partners, industry organizations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 Standards.

ABOUT GS1 US

GS1 US, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code (UNSPSC).

ABOUT GS1 HEALTHCARE

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers & distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US in the United States.

ABOUT GS1 HEALTHCARE US®

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

DOCUMENT PURPOSE

This document is for informational purposes only and is not intended to provide legal advice. Legal interpretations and questions regarding specific business application for regulatory compliance should be directed to company legal and regulatory compliance departments.

This document includes a section which presents questions that GS1/GS1 US submitted to the FDA UDI Help Desk. The answers in that section are the FDA UDI Help Desk responses to those questions, which were all accompanied by the following disclaimer:

> **This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my current best judgment but does not constitute an advisory opinion, may not represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. Staff prepared this communication in response to a specific set of facts submitted in a specific inquiry. You should not extrapolate this response to different or broader circumstances. This communication is intended for the exclusive use of the recipient. It may contain information that is protected, privileged, or confidential, and it should not be modified. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you have received this communication in error, please immediately delete all copies from the saved sources and notify the FDA UDI help desk by direct reply to this email immediately.**

Please read below for a list of the most commonly asked questions about the U.S. FDA Unique Device Identification (UDI) Rule issued on September 24, 2014. (The final rule can be found at https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system.)

GENERAL QUESTIONS ABOUT THE U.S. FDA UDI RULE

1. GENERAL

1.1. What is UDI?

A UDI is a unique numeric or alphanumeric identification code assigned to medical devices by the labeler (e.g., manufacturer) of the device. A UDI typically includes two segments: a "device identifier" (DI) and a "production identifier" (PI).

1.2. What is DI?

DI stands for Device Identifier. A UDI includes two segments: a "device identifier" (DI) and a "production identifier" (PI). The DI segment of the UDI is always required. In the GS1 world, the DI is a GTIN.

1.3. What is PI?

PI stands for Production Identifier. There are five types of information that constitute PI under the rule: (1) expiration date, (2) batch or lot number, (3) serial number, (4) manufacturing date, and (5) distinct identification code [i.e., donor identifier for human cell tissue products (HCT/P)]. Under the rule, the PI segment of the UDI is only required if PI appears anywhere on the device label or package (e.g., if expiration date appears somewhere on the label, then the PI Expiration Date must be included in the UDI for that device). Conversely, if no PIs appear on the label or package, then the UDI would only be a DI.

1.4. Who does the U.S. FDA UDI Rule apply to?

The requirements of the U.S. FDA UDI Rule apply to "labelers" of medical devices. The labeler of each device is responsible for meeting labeling and Global UDI Database (GUDID) data submission requirements (as well as the direct marking and date format requirements where applicable).

1.5. What is a labeler?

The rule defines a "labeler" as:

> *(1) Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and*
>
> *(2) Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.*

According to the rule, labelers include manufacturers, reprocessors, specification developers, repackagers and relabelers that cause a label to be applied to a medical device.

1.6. Does the U.S. FDA UDI Rule apply to hospitals?

The U.S. FDA UDI Rule applies to "labelers" of medical devices. If a hospital acts as a "labeler" within the definition of the U.S. FDA UDI Rule, then the hospital has to comply with the rule. Consult with your compliance team for more information about your hospital and activities. Nonetheless, hospitals will have to be prepared to work with these new identifiers as well as leverage the new GUDID (database) content for recalls and more.

1.7. Does the U.S. FDA UDI Rule apply to unclassified devices? If so, what is the compliance timeline?

Unclassified devices are included in the U.S. FDA UDI Rule. The compliance dates for devices not classified as Class 1, Class 2 or Cass 3 are provided below:

DEVICES NOT CLASSIFIED AS CLASS 1, CLASS 2 OR CLASS 3	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2018** *(5 years after publication date)*
	Direct Marking Requirements	**September 24, 2020** *(7 years after publication date)*

1.8. I am a foreign medical device manufacturer. Does the U.S. FDA UDI Rule apply to me?

The U.S. FDA UDI Rule applies to medical devices sold in the USA. Medical device manufacturers, foreign or domestic, must comply with the rule for any medical device to be sold in the USA. Consult with your regulatory compliance team for guidance specific to your company and products.

1.9. Does the U.S. FDA UDI Rule require UDI information in Electronic Health Records (EHRs)?

The U.S. FDA UDI Rule itself does not include any references to EHRs.

1.10. Is it true that the U.S. FDA UDI Rule sunsets NDC/NHRIC codes for medical devices?

Yes. The U.S. FDA UDI Rule terminates the use of NHRICs and NDCs for medical devices *on the date a device must be labeled with a UDI*. (The NDC/NHRIC for any device that is not required to bear a UDI will be rescinded no later than September 24, 2018.) Therefore, on the date that your device must be labeled with a UDI, you may no longer continue to label it with an NHRIC number. However, in the interim, you may label your device with both a UDI and an NHRIC. In the GUDID, we suggest that you enter the UDI as the primary DI and the NHRIC as the secondary DI, and then remove the secondary DI (i.e., the NHRIC code) by the applicable compliance date.

1.11. What's going to happen to my Labeler Code?

The rule permits continued use of an FDA-issued NDC/NHRIC Labeler Code under an FDA–accredited system for the issuance of UDIs provided that (1) such use is permitted by the issuing agency that administers the system, and (2) the labeler submits a request for continued use of the Labeler Code. The FDA must receive the request no later than September 24, 2014. Consult with your regulatory compliance team for additional information and guidance.

1.12. What about global regulations and regulators?

FDA stated that they worked to align with international standards and approaches wherever possible. However, GS1 US is not an expert on foreign regulations. For more information, consult GS1 Global Office website for information about global regulations (www.gs1.org). In addition, visit the International Medical Device Regulators Forum (IMDRF) web site (www.imdrf.org) to see the guidance documentation on this subject, and consult with your regulatory compliance team for more specific information.

1.13. How can I contact the FDA for more information?

The FDA provides an FDA UDI Help Desk and a variety of resources to assist users:

- FDA UDI Website is key resource – www.fda.gov/UDI
- For Regulatory and GUDID Questions: click on UDI Help Desk link
- To Receive Notifications from FDA: click on Unique Device Identification: Get e-mail updates
- Look for Schedule of Planned (and Notification of Unplanned) Downtimes
- FDA Electronic Submissions Gateway (ESG) questions (HL7 SPL submission)
  - Policy questions – esgprep@fda.hhs.gov
  - Technical questions – esgreg@gnsi.com

2. UDI NUMBER

2.1. Did the U.S. FDA UDI Rule mandate specific PIs?

No. The U.S. FDA UDI Rule does not require any specific PI(s). It simply requires that *whatever PI(s) appear on the device label or package* must also be included in the UDI. (If there are no PI(s) on the device label or package, then PIs will not be expected as a part of that UDI.)

2.2. What PI(s) should I use on our device packages and labels?

There are a variety of reasons manufacturers put PIs on device labels and packages (e.g., to support their own product tracking strategies; to comply with other regulatory requirements; etc.). The U.S. FDA UDI Rule does not require any specific PIs. It simply requires that *whatever PI(s) appear on the device label or package* (for whatever reason) must also be included in the UDI. Consult with your regulatory compliance and/or quality teams to decide what PI(s) (if any) should be used on your device(s).

2.3. What if there are several PIs on our device labels? Which do I need to include in the UDI?

The U.S. FDA UDI Rule requires that all PIs that appear on a device label or package must be included in the UDI for that device (e.g., if a device label includes expiration date and batch/lot number, then the UDI for that device must include PI segments for both expiration date and batch/lot number).

2.4. Is UDI required on every level of packaging?

Yes, UDI should be on every level of packaging, except for the logistics unit.

2.5. I have a UPN. Is that the same as UDI?

Not exactly. The UPN is a term coined by the DOD in the early 1990s and refers to either a GS1 GTIN or a HIBCC LIC. A UDI includes two segments: a “device identifier” (DI) and a “production identifier” (PI). The GTIN (“UPN”) can serve as the DI. The other UDI segment, “PI”, is required if PIs appear anywhere on the device label or package. So if your device label or package includes PI(s), then the UDI for that device requires not only a GTIN (“UPN”) but also GS1 Application Identifier(s) to represent the PI(s).

2.6. Can I use U.P.C. numbers as my UDIs?

For Class 1 devices -- yes. The U.P.C. number will serve as the UDI. Nonetheless, the U.P.C./UDI must still be registered in the GUDID with the required data attributes. (For other classes, it will depend on whether the device contains additional PI on the label or package. Consult with your regulatory compliance team for additional information and guidance.)

2.7. Where do I get UDIs for my products from?

You will be assigning your own UDIs under systems operated by FDA-accredited ‘‘issuing agencies.’’ GS1 is an FDA-accredited UDI Issuing Agency, and you can use GS1 Standards for your UDIs (i.e., GTINs).

2.8. Do individual single-use devices (SUDs) packaged together need a UDI?

The U.S. FDA UDI Rule requires that the package containing the individual SUDs must bear a UDI, but that the individual SUDs in that package do not (as long as they are of a single version/model and not intended for individual sale). For example, a box of bandages must have a UDI, but the individual bandages contained within do not. (NOTE: The exception for individual SUDs is not available for any implantable device.) Consult with your regulatory compliance team for additional information and guidance.

2.9. Do repackaged products require a UDI?

Yes. The U.S. FDA UDI Rule speaks to “labelers,” and the definition of “labeler” includes "any person who causes the label of a device to be *replaced or modified with the intent that the device will be introduced into commercial distribution*." Consult with your regulatory compliance team for additional information and guidance.

2.10. Do repackaged products have the original manufacturer UDI or the repackager UDI?

It will have the repackager UDI. According to the rule, a relabeled device needs to be distinguishable from the version/model that bears the original label and repackagers are responsible for their own labeling. Therefore, the rule states that repackagers are not permitted to use the UDI assigned by the original labeler.

3. LABELING

3.1. Did the U.S. FDA UDI Rule mandate specific barcodes or AIDC methods?

No. The U.S. FDA UDI Rule did not require a specific barcode or AIDC technology. The rule only requires that the UDI be presented on the label or package in both human-readable format and an AIDC format.

3.2. Can RFID tags be used to comply with UDI?

The rule does not require or prohibit any specific AIDC technology.

3.3. Will my U.P.C. barcode satisfy UDI labeling requirements?

For Class 1 devices -- yes. Pursuant to the rule, Class 1 devices marked with a U.P.C. barcode on the label are considered to have met the UDI labeling requirements. (The U.P.C. number will serve as the UDI – which must still be registered in the GUDID with the required data attributes.) For other classes, it will depend on whether the device contains additional PI(s) on the label or package. Consult with your regulatory compliance team for additional information and guidance.

3.4. Do the components or constituent parts of kits/combination products need a UDI?

The general rule is that only the packaged kit/combination product needs a UDI on its label, and that the individual devices contained within do not. However, there are special rules for kits/combination products that are "properly marked with NDCs" (i.e., because they contain a pharmaceutical). Consult with your compliance team for guidance specific to your products.

3.5. Can we encode additional information in a GS1 barcode that is being used for UDI?

The U.S. FDA UDI Rule does not prohibit encoding additional information on the UDI data carrier. GS1 US believes that the best practice is to encode the required AIs first along with the required HRI.

4. STANDARDIZED DATE FORMAT

4.1. What is the standardized date format in the U.S. FDA UDI Rule?

The U.S. FDA UDI Rule adopted the standard YYYY-MM-DD as the standardized format for dates on device labels.

4.2. Is the UDI standardized date format the same as the ISO standard?

Yes – and no. The U.S. FDA UDI Rule adopted YYYY-MM-DD, which is an ISO standard. However, the ISO standard also includes abbreviated date formats (like YYYY-MM), which the U.S. FDA UDI Rule does not allow. Only the full ISO format is acceptable pursuant to the U.S. FDA UDI Rule. In addition, the rule requires the dashes between the date segments, whereas the dashes are optional under the ISO rule.

4.3. What if we don't specify the day in our expiration dates (or production dates)?

The U.S. FDA UDI Rule requires that a day be specified in dates. Consult with your regulatory compliance and quality teams to develop a strategy for specifying the day.

4.4. When does the new date standard go into effect?

Dates on labels will have to be in the new format *no later than the date on which the label of the device must bear a UDI*. Consult the compliance schedule (see question 7.1) for the timelines, and your regulatory compliance team for additional information and guidance.

5. DIRECT MARKING

5.1. Do all devices need to be directly marked with their UDI?

No. The rule only requires direct marking for *re-usable medical devices that need to be reprocessed before reuse*.

5.2. Do implantables need to be directly marked with their UDI?

No. The rule states that implantables do not need to be directly marked with their UDI.

5.3. When do direct marking requirements go into effect?

Direct marking requirements go into effect two years after the UDI labeling requirement goes into effect for a device [except for devices falling within the "Implantable, Life-Sustaining, and Life-Supporting" category for which the direct marking requirements (if any) go into effect simultaneously with the UDI labeling requirement for those devices (i.e., September 24, 2015)]. Consult the compliance schedule (see question 7.1) for the timelines, and your regulatory compliance team for additional information and guidance.

6. FDA GLOBAL UDI DATABASE (GUDID)

6.1. Who is responsible for submitting UDIs to the GUDID?

Labelers will need to publish and maintain the UDI and the required data attributes to the GUDID. '

6.2. What needs to be submitted to the GUDID?

Labelers will need to submit the UDI for each device along with a standard set of basic identifying data attributes to the GUDID.

6.3. What methods are available for reporting UDIs and the associated data to the GUDID?

The draft GUDID guidance provides for publishing/reporting via HL7s Structured Product Language (SPL) or via a direct point of entry website. The draft guidance also enables labelers to designate "third party submitters" authorized to submit data to the GUDID on the labeler's behalf (e.g., GDSN-certified data pools focused on healthcare such as 1WorldSync, FSEnet, and GHX Health ConneXion).

6.4. Will the GUDID record PI information (such as specific serial numbers and lots) for every item?

No. The GUDID only includes yes/no fields to indicate which PI(s) are included on the device. The actual values for the PI(s) are not recorded in the GUDID. In other words, the GUDID records which PI(s), if any, appear on the label of the device, but does not record any PI values.

6.5. When do I have to submit our UDIs and data to the GUDID?

UDIs and the associated data must be submitted to the GUDID on the same date that the UDI labeling requirements for the device go into effect. Consult the compliance schedule (see question 7.1) for the timelines, and your regulatory compliance team for additional information and guidance.

7. COMPLIANCE SCHEDULE

7.1. What are the compliance dates for UDI?

The rule provides a compliance schedule based on post-market risk class. For each class, there is one compliance date that applies to the labeling requirements, data submission to the GUDID, and the standardized date format requirement, and another compliance date 2 years later for the direct marking requirements. The compliance dates for each risk class/group are provided in the table below.

UDI COMPLIANCE DATES		
CLASS 1	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2018** *(5 years after publication date)*
	Direct Marking Requirements	**September 24, 2020** *(7 years after publication date)*
CLASS 2	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2016** *(3 years after publication date)*
	Direct Marking Requirements	**September 24, 2018** *(5 years after publication date)*
CLASS 3	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2014** *(1 year after publication date)*
	Direct Marking Requirements	**September 24, 2016** *(3 years after publication date)*
DEVICES LICENSED UNDER THE PUBLIC HEALTH SERVICE ACT	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2014** *(1 year after publication date)*
	Direct Marking Requirements	**September 24, 2016** *(3 years after publication date)*
IMPLANTABLE, LIFE-SUPPORTING OR LIFE-SUSTAINING DEVICES	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2015** *(2 years after publication date)*
	Direct Marking Requirements	**September 24, 2015** *(2 years after publication date)*
DEVICES NOT CLASSIFIED AS CLASS 1, CLASS 2 OR CLASS 3	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2018** *(5 years after publication date)*
	Direct Marking Requirements	**September 24, 2020** *(7 years after publication date)*

7.2. What about existing inventories? Do manufacturers have to remark them?

Generally, no. There are two exceptions for existing inventories:

- A device that is in commercial distribution prior to the applicable compliance date does not have to comply with the final rule.
- Devices that are manufactured and labeled before their compliance date have an exception from the rule. (However, this exception expires 3 years after the compliance date for that device.)

Consult with your regulatory compliance team for additional information and guidance.

QUESTIONS ABOUT UDI & GS1 STANDARDS

8. GENERAL

8.1. Can I use GS1 Standards for UDI?

Yes. GS1 Standards have been recognized as a permissible format for UDI.

8.2. Is GS1 US an issuing agency?

Yes. GS1 Global has been accredited by the FDA as a UDI Issuing Agency (which covers all of the local GS1 member organizations such as GS1 US).

8.3. What is difference in brand owner versus labeler?

In the context of the U.S. FDA UDI Rule and GS1, these terms are interchangeable. *Brand owner* is a GS1 term and *Labeler* is the FDA term.

8.4. What tools does GS1 US offer?

GS1 US has a dedicated web page of specific UDI resources (like at UDI Quick Start Guide, UDI Poster, etc.) that can found at http://www.gs1us.org/hcudi An implementation guide with detailed information for how to use GS1 Standards for UDI will be released soon and published on that web page as well. In addition, GS1 US offers on demand and live webinars, and a variety of impactful materials such as the Healthcare GTIN Allocation Rules and case studies, all available on the GS1 US web site. GS1 US also offers an online system called Data Driver to create GTINs and print barcodes.

8.5. What does it cost to be a member of GS1 US?

Consult the application pricing model on our website (http://www.gs1us.org/get-started/im-new-to-gs1-us) for information about pricing for a GS1 Company Prefix, Partner Connections, and/or belonging to the GS1 Healthcare US Initiative.

9. IDENTIFIERS

9.1. I have U.P.C.s on my products. How do get I GTINs?

You already have them. The identification numbers encoded in your U.P.C.'s are GTINs. They are 12-digit GTINs known as GTIN-12s.

9.2. Do I need to request continued use of my Labeler Code if my GS1 Company Prefix embeds it?

Yes. If you want to continue using a GS1 Company Prefix that embeds your NHRIC Labeler Code, then you need to request continued use of that NHRIC Labeler Code from the FDA.

10. DATA CARRIERS

10.1. What is the best barcode to use?

Individual organizations must select the data carrier(s) that is best for them considering the constraints of the application, including the type of device, size, use, and scanning environment. In the global healthcare industry, there is a movement toward the use GS1-128 and GS1 DataMatrix as a best practice. Nonetheless, other GS1 barcodes, including GS1 DataBar and Composite, are still available for use and perfectly correct for use now and in the future. GS1 Healthcare US will soon be releasing an implementation guide for using GS1 Standards for UDI, and it includes detailed information and instructions for each of the various barcode options.

10.2. What is difference between an ISO 128 and GS1-128?

The ISO 128 is like a "generic" standard. The GS1-128 is specifically designed to accept GS1 data structures (e.g., GTIN; batch/lot number; expiration date; etc). Encoding GS1 data structures in an ISO 128 is not compliant with the GS1 General Specification and will fail verification.

10.3. Will the GS1 DataMatrix be too small to scan?

The GS1 Data Matrix can be scanned using a camera or imager scanner (not a linear barcode scanner). It will be able to be read successfully if the GS1 General Specifications are followed.

10.4. Do I have to include UDI data under the barcode even if it appears elsewhere on the label (e.g., expiration date)?

Information printed below or beside a barcode is referred to as Human Readable Interpretation (HRI). (The U.S. FDA UDI Rule was silent with regard to this information.) In general, the GS1 System requires printing HRI for all of the information encoded within the barcode. However, this may not always be possible due to many factors such as the type of item being marked, intended use of the item, available space, etc. If it is not possible to print all of the HRI, Figure 4.12.1 – 1 in the GS1 General Specifications provides guidance to help you determine the most appropriate course of action. GS1 US believes that the best practice is to encode the required AIs first along with the required HRI.

11. DATA SYNCHRONIZATION

11.1. Will GS1 US feed the GUDID for my company if I use Data Driver?

No. Data Driver is a tool/utility that a small-to-medium manufacturer might choose to use to generate GTINs and print barcodes.

11.2. Will I be able to use the GDSN to submit my UDIs and associated data to the GUDID?

Yes, based on our preliminary review of the draft GUDID Guidance. Although more specific information will likely be provided by your GDSN-certified Data Pool once the guidance is finalized, the expected process is:

- The labeler would designate their GDSN-certified Data Pool as a "third-party submitter" authorized to submit data to the GUDID on the labeler's behalf.
- Then, the labeler would register their UDI product data with the data pool and instruct them to submit the product data on their behalf to the GUDID.
- The Data Pool would then convert the GDSN message to the FDA-required HL7 Structured Product Labeling (SPL) format, and register the data with the FDA GUDID.

QUESTIONS SUBMITTED TO THE FDA UDI HELP DESK BY GS1/GS1 US

This section presents questions that GS1/GS1 US submitted to the FDA UDI Help Desk. The answers in this section are the FDA's responses to those questions. Every FDA UDI Help Desk response was accompanied by the following disclaimer:

> **This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my current best judgment but does not constitute an advisory opinion, may not represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. Staff prepared this communication in response to a specific set of facts submitted in a specific inquiry. You should not extrapolate this response to different or broader circumstances. This communication is intended for the exclusive use of the recipient. It may contain information that is protected, privileged, or confidential, and it should not be modified. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you have received this communication in error, please immediately delete all copies from the saved sources and notify the FDA UDI help desk by direct reply to this email immediately.**

12. ADDRESS FOR REQUESTING RETENTION OF NHRIC LABELER CODE

12.1. Please provide the FDA email or the FDA mail address to request retention of NHRIC labeler codes as per the FDA UDI rule of September 24, 2013.

A labeler who wishes to continue to use a NHRIC number on the label of a medical device may submit a help desk case through the UDI website at www.fda.gov/UDI. An FDA UDI Help Desk analyst will then respond to that help desk case with the information that needs to be submitted in the NHRIC request. All requested information should be sent to the FDA by directly replying to the email from the FDA UDI Help Desk analyst. The NHRIC requests must be submitted no later than September 24, 2014. Please see the attached form* for instructions for requesting continued use of an assigned NHRIC labeler code.

** The form is provided in Appendix A.*

13. DATABASE OF UDI HELP DESK QUESTIONS AND RESPONSES

13.1. Will the FDA publish all of the questions to the UDI Help Desk and responses? And if so, how soon?

The FDA UDI Help Desk intends to create publicly available Frequently Asked Questions. However, there is no indication when this will be available.

14. DEVICES WITHOUT UDI MARKINGS TODAY

14.1. I'm a distributor. I've seen devices without (UDI) markings. What should we do?

The requirements of the final rule apply to medical devices put in commercial distribution after the applicable compliance date. The first compliance date, by which class III devices and devices licensed under the PHS Act must bear a UDI, is September 24, 2014. Therefore, there are no devices in the United States that currently require a UDI on the device label.

15. HUMAN READABLE INFORMATION UNDER THE AIDC

15.1. Must the UDI information encoded in the AIDC be displayed under the AIDC (barcode) even though similar information appears on the product label itself, e.g. expiry date?

The UDI must be presented in two forms: easily readable plain-text and automatic identification and data capture (AIDC) technology. Therefore, simply having the lot number and expiration date, for example, on the device label will not suffice as this information is not presented as the UDI. The UDI, in the correct format, must be on the device label as required under 21 CFR 801.40. Please see Appendix C in the GUDID guidance document available at www.fda.gov/udi.

16. US FDA UDI DATE FORMAT AND GS1 APPLICATION IDENTIFIERS

16.1. What impact does the US FDA requirement for the use of an all numeric "YYYY-MM-DD" date format in UDI have on the format or use of the GS1 date-related AIDC technology Application Identifiers [e.g., AI(11) Production Date, AI(17) Expiration Date, etc.]?

There is no impact on the use of GS1 date-related AIDC technology Application Identifiers [e.g., AI(11) Production Date, AI(17) Expiration Date, etc.].

Background & Rationale:

1. The US FDA UDI regulation of 24 September 2013 selected a date format to be placed on the label "consistent with international standards and the requirements of the European Union and other nations."

2. The US FDA UDI final rule provides that all "dates on medical device labels intended to be brought to the attention of the user" must be presented as a fixed length, eight (8) digit, all numeric field composed of 4 digits for the year (YYYY), two digits for the month (MM) and two digits for the day (DD) or "YYYY-MM-DD". For example for the "October 15, 2013" would be represented "2013-10-15". The dashes (or "hyphens") between the digits are mandatory as noted in the FDA final rule.

3. The US FDA has further instructed that a day must be part of this format and cannot be blank or zero filled. (See section 801.18)

4. In the recorded & noted discussion concerning date formats, the FDA stated (as is found in Federal Register /Vol. 78, No. 185 /Tuesday, September 24, 2013 /Rules and Regulations 58797): "Thus the specified use of YYYY-MM-DD for "dates on medical device labels intended to be brought to the attention of the user" does not affect the format or use of those dates when represented in AIDC technology."

17. GUIDANCE RE: NHRIC AS THE SECONDARY DI IN THE GUDID

17.1. The FDA response to my question included an attachment. The attachment stated that: "In the GUDID, we suggest that you enter the UDI (from an accredited issuing agency) as the Primary DI and the NHRIC as the Secondary DI – and by the applicable compliance date, remove the Secondary DI (i.e., the NHRIC code)." However, the FDA GUDID Draft Guidance to Industry states, "Cannot edit or delete [Name of secondary DI issuing agency] after the grace period" (Appendix B, pages 34/35). There appears to be contradictory guidance in these two documents. Please clarify which is correct.

Please note that the GUDID draft guidance is a draft. Changes are currently being made in the GUDID and changes will be made in the future. Stay tuned for updates in the business rules of GUDID.

18. FDA UDI AND GUDID TIMEFRAMES FOR TRANSFERRED PRODUCTS

18.1. Manufacturer A is transferring several class 3 products to another Manufacturer (B). Is Manufacturer A under obligation to load the GUDID with these products during or before the transfer? Does the FDA have a timeframe for Manufacturer B remarking and entering into the GUDID?

Under 21 CFR 830.330, the labeler of a device shall submit to FDA an update to the information required by 21 CFR 830.310 whenever the information changes. The updated information must be submitted no later than the date a device is first labeled with the changed information. If the information does not appear on the label of a device, the updated information must be submitted within 10 business days of the change.

LIST OF ACRONYMS FROM THE U.S. FDA UDI RULE

AIDC	automatic identification and data capture
CMS	Center for Medicare & Medicaid Services
DI	Device Identifier
DM	direct marking
EDI	electronic data interchange
EHR	electronic health record
EMR	electronic medical record
FDA	Food & Drug Administration
FDAAA	Food and Drug Administration Amendments Act
GAO	Government Accountability Office
GDSN	Global Data Synchronization Network
GHTF	Global Harmonization Task Force
GLN	Global Location Number
GMDN	Global Medical Device Nomenclature
GTIN	Global Trade Item Number
GUDID	Global Unique Device Identification Database
HIE	health information exchange
HIT	health information technology
HL7	Health Level Seven
LOINC	Logical Observation Identifiers Names and Codes
MO	Member Organization
MU	meaningful use
NDC	National Drug Code

NHRIC	National Health Related Items Code
ONC	Office of the National Coordinator for Health Information Technology
PHR	personal health record
PI	production information or production identifier
RFID	radio frequency identification
SPL	Structured Product Labeling
UDI	Unique Device Identification
UNSPSC	United Nations Standard Products and Services Code

APPENDIX A: FDA CORRESPONDENCE RE: REQUESTS FOR RETENTION OF LABELER CODE

The following form was forwarded by the FDA UDI Help Desk in response to a question about the process for requesting retention of NHRIC/NDC Labeler Codes (Question 12.1 above):

Instructions for requesting continued use of an assigned National Health-Related Item Code (NHRIC) labeler code

Each request for continued use of an assigned National Health-Related Item Code (NHRIC) labeler code must be submitted no later than 1 year after date of publication of the Unique Device Identification System Final Rule in Federal Register, September 24, 2013, 78 FR 58785.

Your request must contain:

- Your name, mailing address, email address, and phone number, if you are the labeler currently using the labeler code.
- The owner/operator account identification you used to submit your registration and listing information to FDA's Unified Registration and Listing System (FURLS).
- The FDA labeler code that you want to continue using.

For all devices, send your request:

- By DIRECT REPLY to this email

Please note: On the date that your device must be labeled with a UDI, you may no longer continue to label it with a NHRIC number. However, in the interim, you may label your device with both a UDI and NHRIC. In the GUDID, we suggest that you enter the UDI (from an accredited issuing agency) as the primary DI and the NHRIC as the secondary DI – and by the applicable compliance date, remove the secondary DI (i.e., the NHRIC code).

However, you may continue to use a NHRIC labeler code in accredited issuing agency system as long as you have registered that NHRIC labeler code with FDA. This registration must take place by September 24, 2014.

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