Food and Drug Administration; Unique Device Identification System

[Docket No. FDA-2011-N-0090]

Summary of Proposed Rule

Introduction

On July 10, 2012, the Food and Drug Administration (FDA) published a proposed rule establishing a unique device identification (UDI) system for medical devices, as required by section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA). More specifically, the proposed rule would require the label and package of medical devices to bear a UDI and would provide for alternative placement or an exception for a particular device or type of device. In addition, this proposed rule would require certain devices to be directly marked with a UDI, with exceptions. Medical device records through the required recordkeeping and reporting systems would need to be modified to include the UDI. Further, under the proposed rule, the FDA would establish the Global Unique Device Identification Database (GUDID), a public database containing information about devices labeled with a UDI (the GUDID would not include patient information). The proposed rule would require labelers of medical devices to submit information concerning each device to the GUDID. The proposed rule would also establish the accreditation requirements for agencies that may operate a system for the issuance of UDIs and the conditions for when FDA might act as an issuing agency.

The proposed rule would also require dates on medical device labels (such as expiration dates) to conform to a standard format.

The 120-day comment period will end on November 7, 2012 (the day after Election Day). A separate 60-day comment period on the information collection burdens associated with the proposed rule will end on September 10, 2012. [Editor’s Note: The recently enacted FDA Safety and Innovation Act, P.L. 112-144, requires publication of a final rule within 6 months after the comment period closes.]

The preamble of the proposed rule discusses the various provisions and also then later poses 35 specific questions regarding these matters. These questions are listed at the end of this summary (with some editorial adjustments). A review of the questions may help stakeholders in preparing their comments on the proposed rule.

Background

FDA states that requiring adequate identification of medical devices through distribution and use would serve the following public health objectives:
1. Reduce medical errors by providing rapid and continuous Internet access to a single, authoritative source of information, the GUDID, to facilitate the unambiguous identification of medical devices used in the United States;
2. Simplify the integration of device use information into data systems, including patient records, particularly electronic patient records;
3. Provide for more rapid identification of medical devices with adverse events;
4. Provide for more rapid development of solutions to reported problems;
5. Provide for more rapid, more efficient resolution of device recalls;
6. Allow for better-focused and more effective FDA safety communication;
7. Provide an easily-accessible source of definitive device identification information; and
8. Provide additional benefits, such as use by other Federal agencies for a wide variety of purposes, allowing providers to electronically capture and record important information concerning the use of a device on a patient, facilitating detection of counterfeit products, improving device traceability, improving postmarket surveillance, and supporting global public health initiatives, including more efficient and effective cross-border identification of devices, adverse event reporting and postmarket surveillance.

FDA acknowledges that the full benefits of UDI depend on the adoption of information technology systems by hospitals and other healthcare facilities (including the use of scanners) and on statistical methodologies to interpret the data aggregated using the UDI. FDA further notes that UDI users must be able to store UDI information in various administrative, clinical and payment information systems, including electronic health records (EHRs). However, FDA emphasizes that the proposed rules does not require hospitals and other healthcare facilities to adopt specific IT technology or take actions to capture UDI information in various information systems.

The proposed rule lists the following as the principles that guided its development:

- The UDI system should generally include all classes of devices, with appropriate exceptions.
- The UDI system should be based on existing, broadly-accepted standards.
- The UDI system should recognize that the private sector has already implemented device identification systems, and, where possible, the rule should not require significant alteration of those systems (FDA specifically refers to the international not-for-profit association known as “GS1,” which operates a system that uses a Global Trade Identification Number (GTIN) to identify a device and also operates the Universal Product Code (UPC) system, and the Health Industry Business Communications Council (HIBCC), which operates a system that encodes an identifier in a Health Industry Bar Code (HIBC) to identify a device).
- Burdens should be minimized.
- The UDI system should be open to technological advancements (especially new forms of automatic identification and data capture (AIDC) technology).
- The UDI system should be designed to integrate smoothly with other FDA systems, such as registration and listing, postmarket surveillance, and adverse event reporting.
- Requirements should be phased in over several years to ensure smooth and effective implementation.
- The UDI system should foster innovation by, and competition among, issuing agencies.
- There will be effective FDA oversight of issuing agencies.
- The UDI system should provide for appropriate regulatory flexibility, including exceptions and alternatives.
- Safeguards should be provided to protect small businesses.
- The establishment of a publicly accessible GUDID database is a critical component of an effective UDI system (the UDI is simply a numerical or alphanumerical code and would not itself communicate any information directly concerning a device).

FDA reviews the various steps it has taken to consult with the healthcare community and industry regarding the UDI and related matters prior to issuance of the proposed rule. These included meeting with various stakeholders in 2005, commissioning a report from Eastern Research Group, Inc. (ERG), concerning the benefits, costs, and issues with developing and implementing a UDI System, requesting comments through publication of a notice in the August 11, 2006 Federal Register, a public meeting held on October 25, 2006, and a public workshop held on February 12, 2009, for which stakeholders were asked to submit comments (these comments may be viewed at http://www.regulations.gov by searching for “FDA-2008-N-0661”).

**Description of the Proposed Rule**

**A. UDI Labeling Requirements**

1. **Definitions**

FDA proposes new definitions for a number of terms and relies on existing definition for others. Key terms include the following:

- **Combination product**: a product involving at least one device and at least one drug or biological product.
- **Convenience kit**: when two or more different types of medical devices are packaged together for the convenience of the user.
- **Device package**: a package that contains a fixed quantity of devices (a change to the quantity of devices in a package is one of the changes that results in a new version or model).
- **Implantable device**: a device that is intended to be placed in a surgically or naturally formed cavity of the human body but only if it is intended to remain
implanted continuously for a period of 30 days or more, unless the FDA Commissioner determines otherwise in order to protect human health.

- **Labeler:** any person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label (FDA notes that the labeler would, in most instances, be the device manufacturer, but that the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler).

- **Shipping container:** a package, container, or pallet that is used for the shipment or transportation of devices from one point to another and whose contents may vary from one shipment to another (the proposed rule would not require a UDI on any shipping container).

- **Unique device identifier:** an identifier that adequately identifies a device through its distribution and use, which may be composed of: (1) a **device identifier** (a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device); and (2) a **production identifier** (a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device: (i) the lot or batch within which a device was manufactured; (ii) the serial number of a specified device; (iii) the expiration date of a specific device; and (iv) the date a specific device was manufactured). FDA notes that this regulation does not itself require any production identifier to appear on a device label, but acknowledges that other unnamed FDA regulations and conditions of approval might; production identifiers would not be required in the case of class I devices.

- **Version or model:** a device package containing one or more devices that have identical specifications, performance, size, and composition, within specified limits.

2. Effective Dates

Table 7 of the proposed rule lists the proposed implementation timetable. In brief, the proposed rule would impose UDI labeling requirements and related GUDID information submission requirements for class III, II and I devices beginning 1, 3, and 5 years, respectively, following publication of the final rule. [Editor’s note: The recently enacted FDA Safety and Innovation Act will reportedly require adjustments to this proposed timetable; in particular, the Act requires adoption of a UDI requirement within 2 years of the publication of a final rule for all implantable and “life-sustaining” devices, including any class II devices in these categories.]

FDA notes that a UDI would be required to appear on an individual device package, on a box of five packages, and on a carton of ten boxes of 5 device packages, because both the box and the carton would be considered device packages. FDA adds that if there were no UDI on the outer packaging (that is, a
box or carton), the container would need to be opened to access it, “which could facilitate tampering and contribute to the very problems that the UDI system is designed to remedy.”

3. Combination Products and Convenience Kits

A combination product whose primary mode of action is that of a device would be subject to UDI labeling requirements. On the other hand, if the FDA has determined that the primary mode of action of a combination product is not that of a device, it would not require a UDI on the label or package of the combination product (FDA expects such a product would to be identified by a National Drug Code (NDC)). In addition, each device constituent part of a combination product would need to have its own UDI regardless of whether the combination product itself is subject to UDI labeling unless such constituent part is “physically, chemically, or otherwise combined with other constituents of the combination product in such a way that it is not possible for the device constituent part to be used except as part of the use of the combination product”; FDA gives as an example of the latter a drug-eluting stent).

FDA also proposes to require a UDI on the label and device package of each convenience kit, as well as a distinct UDI for each device in a convenience kit, unless an included device is intended for a single use (e.g., an adhesive bandage).

If the proposed rule requires that the UDI of an included device be directly marked on the device, that requirement would need to be met (see below for further discussion of direct marking).

4. Exceptions and Alternatives

Under the proposed rule, a labeler that chooses for business or other reasons to voluntarily comply with any provision from which the labeler is excepted may do so. The proposed rule (§801.30) provides a large number of exceptions to the UDI and related GUDID information submission requirements as follows:

- For devices, other than prescription devices, that are sold at retail establishments, such as drug stores, and the exception applies even when such devices are sold directly to a hospital or other health care facility (FDA gives as examples automatic external defibrillators, insulin syringes, glucometers, tampons, thermometers, toothbrushes, and bandages, and notes further that for those labelers that choose to submit data to the GUDID on a voluntary basis for such excepted devices, a UPC may serve as a UDI). **FDA requests comments on the extent to which devices sold in retail establishments should be subject to the requirements of the proposed rule.**
- Any class I device that FDA has by regulation exempted from the good manufacturing practice (GMP) requirements of part 820, the Quality Systems
Regulation (if such regulation requires that a class I device remain subject to §820.180, with respect to general requirements concerning records, or §820.198, with respect to complaint files, that device would nevertheless qualify for this exception). FDA gives as examples of such class I devices tuning fork (product code GWX), elastic bandage (product code FQM), examination gown (product code FME), bedpan (product code FOB), and manual toothbrush (product code EFW), and adds that it has provided a list of the devices that at present would be eligible for this exception, “List of class I devices, by product code, that FDA has by regulation exempted from the GMP requirements of 21 CFR part 820, Quality Systems Regulation,” FDA, April 2012,” which is reference 9 in the proposed rule.

- For individual class I, single-use devices, all of a single version or model, that are distributed together in a single package, whose uses are generally known to the persons by whom they are intended to be used, and which are not intended or promoted for individual sale (FDA gives a box of examination gloves or a box of adhesive bandages as examples; the device package, that is, the box, would still need to bear a UDI on its label, but not the individual gloves or bandages). Labelers of class II devices that would qualify for this exception but for their classification may request an exception or alternative (this request process is discussed below).
- For a device used solely for research, teaching, or chemical analysis, and is not intended for any clinical use.
- For a custom device or a device made to meet the unique needs of a patient or physician;
- For an investigational device within the meaning of 21 CFR part 812.
- For a veterinary medical device not intended for use in the diagnosis of disease or other conditions in man, in the cure, mitigation, treatment, or prevention of disease in man, or intended to affect the structure or any function of the body of man.
- For a device intended for export from the United States.
- For a device held by the Strategic National Stockpile and granted an exception or alternative under §801.128(f)(2) (for background on the Strategic National Stockpile, see FDA’s Interim Final Rule concerning Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile, 72 FR 73601, December 28, 2007).
- For a device for which FDA has established a standard pursuant to section 514(b) of the Federal Food, Drug, and Cosmetic Act (FD&C) Act and has provided therein an exception from the UDI requirement, or for which FDA has recognized all or part of a standard pursuant to section 514(c) of the FD&C Act and has included such an exception within the scope of that recognition.
- For a device constituent part of a combination product, provided that such constituent part is physically, chemically, or otherwise combined with other constituents of the combination product in such a way that it is not possible

* The preamble mischaracterizes this as reference 10 (Ref 10) but it is obviously reference 9.
for the device constituent part to be used except as part of the use of the combination product.

- For a device that is packaged in a convenience kit, provided that the device is intended for single use.
- For shipping containers, because they often contain different, unrelated devices, and sometimes other items as well.
- For class I devices, for which only the UDI could include only the device identifier, not any production identifier.

In addition to the preceding categorical exceptions, the proposed rule (§801.35) also authorizes additional, case-by-case, labeling exceptions and alternatives. Only a device labeler may request such an exception or alternative, although the FDA may provide an exception or alternative on its own initiative. A request for an exception or alternative would have to:

- Identify the device that would be subject to the exception or alternative;
- Identify the UDI labeling requirements that are the subject of the request for an exception or alternative;
- If requesting an exception, explain why the UDI labeling requirements are not technologically feasible;
- If requesting an alternative, describe it and explain how it would provide for more accurate, precise, or rapid device identification than the standard requirements or how the alternative would better ensure the safety or effectiveness of the device; and
- Provide an estimate of the number of labelers and the number of devices that would be affected if FDA grants the requested exception or alternative.

FDA could also request additional information needed to clarify the scope or effects of a request. A request could be submitted to FDA as part of a premarket submission\(^1\) or through a written request at any time after a premarket submission has been filed. Such separately written requests would go to the Division of Small Manufacturers, Consumer, and International Assistance, Center for Devices and Radiological Health, Bldg. 66, rm. 4621, 10903 New Hampshire Ave., Silver Spring, MD 20993. FDA could impose conditions as part of any approved exception or alternative, and the agency proposes to provide information about any such exception or alternative on its Internet site. Also, if necessary to facilitate or implement an approved alternative, FDA may, at its discretion, act as an issuing agency.

A device exempt from UDI requirements could nonetheless be labeled with a UDI. And if a labeler voluntarily includes a UDI on the device label, the labeler may also voluntarily provide information concerning the device to the GUDID.

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\(^1\) FDA defines "premarket submission" to mean a premarket approval application; a product development protocol; a premarket report; a humanitarian device exemption application; a biologics license application; a supplement; a premarket notification submission; or a new drug application for a transitional device.
5. UDI Requirements

A required UDI must appear on a device label and on a device package in an easily-readable, plain-text format (FDA does not propose to specify a particular font or point size for the UDI in this proposed rule but notes that the UDI would be subject to existing requirements that govern medical device labels). The UDI would also have to be provided on device labels and device packages through AIDC technology, which could be a bar code, radiofrequency identification (RFID), near-field communications (NFC), or any other technology (present or future) that serves the same objectives.

FDA assumes that most labelers would choose a bar code, which FDA says may be formatted in any way that meets the technical requirements of the bar coding system that is employed. If the AIDC technology is not visible on the device label or package, the labeler would have to include a symbol on the label or package. This symbol may be a symbol endorsed in an international or national standard recognized by FDA under section 514(c) of the FD&C (for example, symbols specified for differing types of RFID systems), a symbol generally recognized by the persons who typically use the device (not further explained), or the following generic symbol:

![UDI AIDC]

6. Direct Marking of Devices (§801.50)

FDA proposes that the following devices would need to be directly marked with a UDI:
- An implantable device (as defined above);
- A device that is intended to be used more than once and that is intended to be sterilized before each use; and
- Stand-alone software that is a “device” under §201(h) of the FD&C Act (FDA notes that this category excludes software that is an integrated component of a device, such as software embedded in a chip that is part of a circuit in a device).

Direct marking would have to be provided through easily-readable plain text and/or AIDC technology (or any alternative technology that will allow for identification of the device); FDA gives as examples providing the UDI of the device on demand to an external reader or sensor, or making the UDI or a barcode or other representation of the UDI discernible to an x-ray or other imaging system. If the device is stand-alone software, the direct marking would have to be provided through an easily-readable plain-text statement displayed whenever the software is started and/or an easily-readable plain-text statement
FDA seeks comments about the utility of marking stand-alone software in this manner.

In all instances of direct marking, the UDI conveyed by such direct marking may be either the UDI that appears on the label of the device, or a different UDI used to distinguish the unpackaged device from the device while it remains in packaged form. FDA proposes that the requirement for direct marking of a device would go into effect two years after the date specified for compliance with UDI label requirements for that device (that is, 3 years after publication of the final rule in the case of class III devices, for which the UDI label requirements would take effect 1 year after publication of such final rule).

FDA proposes the following 6 exceptions to the direct marking requirement:

1. Direct marking would interfere with the safe and effective use of the device.
2. Direct marking is not technologically feasible (FDA says this could include “circumstances, where for a very small firm, the capital investment in technology to allow direct part marking so exceeds [the] benefit of applying the requirement that FDA could find direct part marking to be ‘not technologically feasible’
3. The device is intended to remain implanted continuously for a period of less than 30 days, unless the FDA Commissioner determines otherwise in order to protect human health.
4. The device has been previously directly marked (FDA notes that a labeler may re-mark a previously-marked device if the labeler concludes that such re-marking would not adversely affect the safety or effectiveness of the device).
5. The device is sold at retail and bears a Universal Product Code (UPC).
6. The device is software that is not stand-alone software, but is a component of a medical device (FDA gives as examples software incorporated into devices such as infusion pumps and software integrated and used to control systems such as magnetic resonance imaging (MRI) machines).

FDA proposes that labelers who determine that their device qualifies for an exception from direct marking would have to document the basis of their decision in the design history file as required by §820.30(j) of the Quality System Regulation. Further, if a labeler determined that a device qualifies because direct marking would interfere with the safe and effective use of the device or because the labeler determines the device cannot be marked because it is not technologically feasible, the labeler would have to send a notice to the FDA providing the following information:

- Identification of the exception, or exceptions that the labeler is invoking;
- An explanation of the factors that make the exception applicable to the device; and
- The name of, and contact information for, the person who determined that the exception is applicable to the device.
FDA says it does not intend to routinely respond to such notices, but it may request additional information, review information in the relevant device history records when it conducts an establishment inspection, or take such other action as may be appropriate.

7. Use of NHRIC and NDC Codes

FDA proposes that once a device is subject to UDI requirements that it could no longer be identified with the National Health-Related Item Code (NHRIC) or National Drug Code (NDC) assigned to it.

8. Formatting of Dates on Medical Device Labels (§801.18)

FDA proposes a standard formatting for dates provided on medical device labels: Month, Day, Year, with the month shown as a three-letter abbreviation of the month, the day shown in modern Arabic numerals (with no leading zeros) and the year shown in modern Arabic numerals, using the civil calendar in use in the United States, in 4 digits (e.g., JAN 3, 2012 and SEP 30, 2012). For this requirement, FDA provides a limited exception for electronic products to which a standard is applicable under subchapter J, Radiologic Health; 21 CFR §1010.3(a)(2)(ii) specifies the date format for such products.

The standard format requirement for dates would take effect one year following publication of the final rule. **FDA seeks comments on whether the proposed date format and associated effective date are feasible and appropriate, including whether the effective date should be linked to the UDI implementation date for each class of devices.**

B. Requirements Relating to Issuing Agencies and Submission of Data to the Global Unique Device Identification Database

1. Definitions

FDA proposes to define “issuing agency” as an organization accredited by FDA to operate a system for the issuance of UDIs. The proposed rule would permit multiple issuing agencies and, under certain circumstances, FDA could act as an issuing agency.

2. Composition and Issuance of Valid UDIs

FDA further proposes that every UDI must be issued under a system operated by FDA or an FDA-accredited issuing agency, and must conform to the international standards that would be incorporated by reference, with UDIs to be composed only of characters from a single character set defined by one of the incorporated standards. These standards are:
1. International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 646.1991, Information technology—ISO 7-bit coded character set for information exchange (would limit the plain-text version of a UDI to a particular set of alpha-numeric characters);

2. ISO/IEC 15459-2:2006, Information Technology-Unique Identifiers-Part 2 Registration procedures (would require organizations wishing to become issuing agencies to apply to the Registration Authority and obtain and an Issuing Agency Code (IAC), which assures that multiple issuing agencies can create globally unique identifiers and minimizes the risk of duplicative identifiers);

3. ISO/IEC 15459-4:2008, Information technology-Unique identifiers—Part 4: Individual items (would provide the framework for the development of UDIs for serialized devices); and

4. ISO/IEC 15459-6:2007, Information technology-Unique identifiers-Part 6: Unique identifier for product groupings (would provide the framework for the development of UDIs for lot or batch controlled devices).

3. Use of UDIs

FDA proposes that labelers would be prohibited from using more than one device identifier from any particular accredited system to identify a particular version or model of a device, but if they use systems operated by two or more issuing agencies, they would be permitted to identify a device with one identifier from each system. Labelers would also be prohibited from using one device identifier to identify more than one version or model of a device. If they discontinue a particular version or model of a device, they would be prohibited from reassigning the device identifier to another device; however, if they re-introduced a discontinued device and no changes have been made that would require a new device identifier, they would be permitted to use the same device identifier that was previously used to identify the device. If a UDI issuing agency ceases to be accredited, FDA would permit affected labelers to continue to label their devices using the device identifier issued under the system operated by that issuing agency until such time as this rule requires labelers to discontinue use of a particular UDI.

A labeler would be permitted to replace one device identifier with another for a particular version or model of a device for any reason, but would be required to use a new device identifier under the following circumstances:

- The labeler makes a change that has the potential to affect the safety or effectiveness of the device.
- The labeler changes from a nonsterile package to a sterile package, or from a sterile package to a nonsterile one.
- The labeler changes the quantity of devices in a package.
- The labeler relabels a device that was previously labeled with a UDI by another labeler (such a labeler would need to keep a record showing the relationship of the prior device identifier to the new one).
4. Accrediting UDI Issuing Agencies

FDA proposes to accredit as issuing agencies only private nonprofit organizations or State agencies "in order to minimize potential conflicts of interest and to help ensure that the fees assessed are reasonable to small businesses" (FDA proposes to define "small business" to mean a medical device manufacturer with 500 or fewer employees, or a medical device relabeler or repackager with 100 or fewer employees). FDA proposes to accredit such an organization or State agency if it meets all of the following criteria:

- The system uses UDIs that meet the requirements of the proposed rule to adequately identify a device through its distribution and use.
- The system it operates conforms to the international standards incorporated by reference (listed above).
- The issuing agency makes its system available to all users according to a single set of consistent, fair, and reasonable terms and conditions.

An organization or State agency wishing to be accredited as an issuing agency would have to submit an application to FDA that includes: contact information; evidence of nonprofit status; information on the system that will be used to assign UDIs; fee schedules, if any, with an explanation of any fee waivers or reductions available to small businesses; satisfactory assurances that the applicant would comply with the requirements of this rule; and other information required by FDA to clarify the application for accreditation.

FDA proposes that the initial accreditation of an issuing agency would be for a period of 3 years, and renewed accreditation for 7 years. An issuing agency would have to inform FDA that it wishes to renew its accreditation and would have to submit a complete renewal application at least 6 months prior to expiration of its accreditation. Within 60 days of receipt of any application for accreditation, FDA will notify the applicant of any deficiencies and will request correction of those deficiencies within 60 days. If FDA does not reach a final decision on a renewal application before the expiration of an issuing agency’s accreditation, the approval will be deemed extended until FDA reaches a final decision on the application.

5. Issuing Agency Responsibilities (§830.120)

The proposed rule lists the following as responsibilities of an FDA-accredited issuing agency:

- Operating a system for assignment of UDIs that meets FDA’s requirements and the international standards incorporated by reference;
- Making information available concerning its system for the assignment of UDIs;
- Maintaining a list of labelers that use its system for the assignment of UDIs and providing FDA with a copy of the list each year;
Upon request, providing FDA with information concerning a labeler that is employing the issuing agency’s system; and

Remaining in compliance with the eligibility and accreditation criteria.

An issuing agency wishing to relinquish its accreditation would need to submit a letter stating its intent to FDA at least 9 months before the date it will relinquish its accreditation, and it would have to notify all labelers that are participating in the issuing agency’s UDI system, in a manner and time period approved by FDA, of the date that it will cease to serve as an issuing agency. In addition, FDA may suspend or revoke the accreditation of an issuing agency if it finds, after providing the issuing agency with notice and opportunity for an informal hearing, that the issuing agency has been guilty of misrepresentation in obtaining its accreditation, failed to fulfill the responsibilities of an issuing agency, or has violated or aided and abetted in the violation of any regulations promulgated pursuant to section 510(e) or 519(f) of the FD&C Act.

6. FDA as an Issuing Agency

FDA proposes to act as an issuing agency during any period where there is no accredited issuing agency, or if it determines that a significant number of small businesses would be substantially and adversely affected by the fees required by all accredited issuing agencies. If FDA acts as an issuing agency, it would not, under current law, assess a fee for its services, and any labeler (large or small) would be permitted to use FDA as its issuing agency. FDA adds that it anticipates that issuing agencies “will be sensitive to the needs of small businesses,” so that FDA will not have to act as an issuing agency.

7. GUDID Data Submission

In terms of the GUDID, FDA proposes to reject or remove submitted information under circumstances specified in §830.300(d), such as when the information concerns a device that is neither manufactured in the United States nor in interstate commerce in the United States. FDA also proposes (in §830.310) that each labeler would be required to provide minimal information about itself, allowing FDA to communicate with the labeler, as well as the following 13 types of information regarding each version or model of a device labeled with a UDI:

1. The device identifier portion of the UDI associated with the version or model.
2. When reporting a substitution of a new device identifier that will be used in lieu of a previously-reported identifier, the device identifier that was previously assigned to the device.
3. If FDA regulations require the device to bear a UDI as a permanent marking on the device itself, the device identifier portion of the UDI that appears as a permanent marking on the device or a statement that the device identifier that appears as a permanent marking on the device is...
identical to that reported as the UDI assigned to the version or model (for application to the device’s label and packaging).

4. The proprietary, trade, or brand name of the device;
5. Any version or model number or similar reference that appears on the label of the device.
6. If the device is labeled as sterile, a statement to that effect.
7. If the device is labeled as containing natural rubber latex that contacts humans, or is labeled as having packaging containing natural rubber latex that contacts humans, a statement to that effect.
8. If the device is available in more than one size, the size of the particular version or model, together with the unit of measure, as it appears on the label of the device.
9. The type(s) of production identifiers that appear on the label of the device (FDA emphasizes that it would not require the reporting of the actual production identifiers to the GUDID, noting that this approach “would be extraordinarily difficult to administer and would impose significant costs and burdens on labelers”).
10. The FDA premarket submission number of an approved or cleared device, or a statement that FDA has by regulation exempted the device from premarket notification (FDA views this information as “essential” to linking data in the GUDID with other existing FDA data sources).
11. The FDA listing number assigned to the device (this is the only data element that would not be disclosed to the public because listing numbers “serve important governmental functions (e.g., admissibility determinations for shipments of foreign-origin FDA-regulated products seeking to enter domestic commerce) that would be harmed if they were made public.”)
12. The Global Medical Device Nomenclature (GMDN) code for the device (the GMDN is a comprehensive system of generic descriptors (preferred terms) with definitions used to generically identify medical devices).
13. The number of individual devices contained in each device package.

Each labeler would have to designate an individual to serve as a point of contact with FDA on matters relating to the identification of medical devices marketed by the labeler. FDA further proposes to require electronic submission of required data except where such electronic submission is not technologically feasible for a labeler, which FDA expects will be extraordinarily rare. FDA currently anticipates providing two ways to submit data electronically: (1) as part of a structured product label (SPL) conforming to an American National Standards Institute/Health Level Seven format, which FDA anticipates would be preferred by most large labelers; and (2) data elements entered directly into the GUDID through a secure Internet site, which may be preferred by some small labelers.

‡ FDA notes that the GMDN data are not currently available to the public unless a fee is paid to the GMDN Agency but anticipates that such data will be available to the public at no cost by the time the final rule is published; if that is not the case, FDA says it will not include this requirement in the final rule.
FDA further proposes that device identification data would need to be submitted to the GUDID no later than the late the device label must bear a UDI. FDA adds that a labeler who wishes to submit information concerning a device prior to the proposed effective date may submit a request to FDA to do so, and that FDA would accommodate such requests when consistent with its ability to process the additional information in an orderly manner. Labelers would be required to update the information they reported to the GUDID whenever the information changes, and such update would have to be submitted no later than the date a device is first labeled with the changed information; if the information does not appear on the device label, the update would have to be submitted within 10 days of the change.

Labelers would not be permitted to submit any non-required device information to the GUDID except where FDA acts to permit the submission of specified additional information (termed ancillary information). FDA proposes to provide information concerning the ancillary information that it will accept through the GUDID Web site, http://www.fda.gov/udi, and warns that it may periodically change the ancillary information that it would accept (changes would be announced at least 60 days before they took effect).

Each labeler would be required to retain records linking all UDIs to the associated version or model until 3 years after the date the labeler ceases to market such version or model.

C. Conforming Amendments

FDA proposes the following conforming amendments:

- Amend Part 16, Regulatory Hearing before Food and Drug Administration, to state that an informal regulatory hearing is available when FDA acts to suspend or revoke the accreditation of an issuing agency;
- Amend §§803.32, 803.42, and 803.52 to require UDIs to be included in individual adverse event reports submitted by device user facilities (such as hospitals), importers, and manufacturers, and amend §803.33 to require a UDI, when available, to be provided with each adverse event reported in a user facility’s annual report to FDA;
- Amend §§806.10 and 806.20 to permit and encourage use of UDIs to identify devices that are the subject of reports of corrections and removals, and in records of corrections and removals that are not required to be reported to FDA;
- Amend §810.10(b)(2) to indicate that FDA will include UDIs, when known, in the “pertinent descriptive information” it provides in a cease distribution and notification order issued under FDA’s recall authority;
- Amend §814.84(b) to require each periodic report for a Class III device to include information on all device identifiers in effect at the time of the report, together with information on all device identifiers discontinued since the previous periodic report;
Amend §820.120(b), concerning the inspection of labels prior to release for storage or use, to include examination of the accuracy of the UDI within the scope of the labeling inspection, and amend §§820.184(f), 820.198(e)(3), and 820.200(d)(2) to clarify that the device history record, complaint records, and a service report, respectively, are to include any UDI or UPC that is used to identify the device;

Amend §821.25(a)(2)(i) and (a)(3)(i) to authorize a manufacturer, when adopting a tracking methodology, to use a UDI of each tracked device when the UDI is necessary to provide for effective tracking, amend §821.30(a)(2) and (b)(2) to require a distributor or final distributor, respectively, upon purchasing or otherwise acquiring any interest in a tracked device, to include the UDI among other information to be provided to the manufacturer of the device, and amend §821.30(c)(1) to require a multiple distributor to include the UDI of a device among the other information required in a written record each time the device is distributed for use by a patient; and

Amend §822.9(a)(4) to require device identifiers be included among the information required in a postmarket surveillance plan submitted to FDA.

**Analysis of Impacts**

FDA considers the proposed rule a significant regulatory action but says it is uncertain whether the proposed rule would have a significant economic impact on a substantial number of small entities.

Over 10 years, FDA estimates the costs of the proposed rule at $514 million using a 7 percent discount rate and $588.6 million using a 3 percent rate. Annualized costs over this period are estimated at $68.4 million using a 7 percent discount rate and $66.9 million using a 3 percent discount rate. Most of these costs would be incurred by domestic labelers, with other costs being incurred by issuing agencies and the FDA itself. FDA says that it lacks sufficient information to quantify the potential impact on foreign labelers, and adds that its estimates are uncertain and could be as much as 50 percent lower or 50 percent higher.

For domestic labelers, the largest components of one-time costs would include the costs to integrate the UDI into existing information systems, to install, test and validate barcode printing software and to train employees, and to purchase and install equipment needed to print and verify the UDI on labels. Other significant costs would be incurred to redesign device labels to incorporate the date format within 1 year and to allow space for the UDI barcode, and for the direct marking of certain devices. The largest annual cost components include labor, operating, and maintenance associated with equipment for printing operations, and labor related to software maintenance and training needed to maintain the UDI information system.

For issuing agencies, the 10-year and annualized costs using a 7 percent/3 percent discount rate, respectively, are estimated at $0.9 million/$1 million and
$0.1 million/$0.1 million. Similarly, the costs to the FDA to establish and maintain the GUDID are estimated at $13.7 million/$16.1 million and $1.8 million/$1.8 million, respectively.

FDA notes that the estimated costs of compliance for domestic labelers as a percentage of revenues exceed 1 percent for about 32 firms with fewer than 19 employees that label devices subject to the direct marking requirements. Also, for an estimated 8 firms with fewer than 5 employees, the burden of the proposed rule would represent about 8 percent of their average revenues. FDA adds that if direct marking of devices were not required, no firms would experience costs exceeding 1 percent of revenues.

**Information Collection Requirements**

Total estimated information collection burdens for the first year are as follows: 2,662 hours for reporting, 11,055 hours for recordkeeping, 23,790 hours for third-party disclosure (UDI), and 632,298 hours for third-party disclosure (date format). The ongoing estimated annual burdens are as follows: 7,289 hours for reporting, 302,212 hours for recordkeeping, and 270,143 hours for third-party disclosure.

A copy of the supporting statement for this information collection will be available at [http://www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain) and will be posted to the docket at [http://www.regulations.gov](http://www.regulations.gov) in docket FDA-2011-N-0090. Comments should be emailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for FDA, oira_submission@omb.eop.gov, and a copy of the comments sent to the FDA.

**Specific Questions Posed by FDA**

*FDA requests comments on the following questions:*

**Objectives of the UDI System and Potential Uses of UDIs**

1. Which of the objectives and potential uses identified for the UDI system are most important to you? Are there any important objectives or uses we have not identified or have not adequately discussed? If you consider any objective or use identified here inappropriate, unimportant, or unconvincing, please identify the objective or use and explain your views.

**Implementation of the UDI System—Effective Dates**

2. Do the proposed effective dates provide adequate time to prepare to meet the rule’s requirements? If you believe a particular effective date does not provide adequate time to prepare to meet one or more of the rule’s requirements, please identify the requirement, provide an explanation of the difficulties you foresee in meeting the requirement, and provide a
suggested effective date that would provide adequate time to prepare to meet the requirement.

3. Will the 1-year effective date (for the date standard format requirement) result in less efficient planning as compared to a later date? Taking into account the effective dates for the other requirements of the proposed rule, what should be the effective date for the formatted date requirement and why?

UDI Labeling Requirements

4. Is the requirement for a plain-text UDI clear? If you believe the requirement for a plain-text UDI would require changes to your labeling processes that are substantially different from those required for other types of labeling changes that you routinely make, please describe the changes you would have to make and provide an estimate of the cost of those changes?

5. Is the requirement for an AIDC technology clear? What type of AIDC technology do you expect to use? If you believe the requirement for AIDC would require changes to your manufacturing, labeling, or packaging processes that are substantially different from those required for other types of labeling changes that you routinely make, please describe the changes you would have to make and provide an estimate of the cost of those changes.

Combination Products

6. If a combination product’s primary mode of action is that of a device, is it appropriate to require each device constituent part of the combination product to bear its own UDI?

7. If a combination product’s primary mode of action is not that of a device, is it appropriate to require each device constituent part of the combination product to bear its own UDI?

UDI labeling of certain combination products that are not labeled with an NDC

8. Should FDA require a UDI on the label and package of every combination product that has a device constituent part, regardless of its primary mode of action, except when the primary mode of action is not that of a device, and the combination product is labeled with an NDC?
Convenience Kits

9. Is it necessary to require a UDI for each device included in a convenience kit?

10. Would it be appropriate to provide an additional exception from UDI labeling for any class I device included in a convenience kit, even if intended for more than just one single use?

11. Instead of requiring a UDI on the label of each device included in a convenience kit, would it be more appropriate to require the label of the convenience kit to identify each device included in the kit, together with the UDI of each such device (this would include the UDI of a device that does not bear a UDI because it qualifies for an exception as a device constituent part of a combination product that is physically, chemically, or otherwise combined with other constituents of the combination product in such a way that it is not possible for the device constituent part to be used except as part of the use of the combination product)?

Direct Marking

12. Is it appropriate to require direct marking for all implantable devices? Should the requirement be limited to certain types of implants? If so, how should we define which implantable devices meet that requirement?

13. Is it appropriate to require direct marking for all devices intended for more than one use that require sterilization before each use? Are there good reasons to require direct marking for all devices intended for more than one use, regardless of whether the device must be sterilized before each use?

14. The proposed rule would require direct marking of stand-alone software devices, but does not define “stand-alone software” (which FDA emphasizes does not include software that is “a component of a medical device”). Because the term “component” has been in common use for many years, FDA believes that the medical device industry has an adequate understanding of when software is stand-alone that is itself a medical device and when software is only a component of a medical device. Does the “component” distinction provide enough clarity for you to understand when software is stand-alone software that requires direct marking? If not, please suggest how FDA could define “stand-alone software” so that it would be clear when software must be directly marked.

15. Are there other types of devices that you believe would benefit from direct marking? If you were to prioritize the need for direct marking of different types of devices, what devices are most in need of direct marking to...
ensure their adequate identification through distribution and use? What attributes do these devices have in common that makes direct marking important?

**UDI Labeling Exceptions and Alternatives**

16. Are any of the categorical exceptions provided in the proposed rule inappropriate? If so, identify the exception and explain why you believe the exception is inappropriate?
17. Are there any additional categorical exceptions that you believe would be appropriate? Please explain.

18. Under one of the proposed exceptions, a class I device that FDA has exempted from our GMP requirements would not be required to bear a UDI. Is this exception appropriate? Are there any devices listed in reference 9 of the proposed rule for which this exception is not appropriate and which should be required to bear a UDI? Are there other class I devices that are exempt from GMP requirements that do not appear on the FDA list cited as reference 9 in the proposed rule?§

19. Class 1 devices are very diverse. FDA proposes to except all of these devices from the proposed requirement that their labels bear a production identifier. Many of these class I devices are also subject to other proposed exceptions. Although class I devices are generally low risk or very well understood devices, FDA notes the class includes devices that have been recalled or the subject of serious patient safety concerns. For such devices, the benefit of requiring that their labels bear device identifiers likely outweighs the cost savings of excepting such devices entirely from UDI. FDA is soliciting comments on: (1) whether additional class I devices, additional categories of class I devices, or all class I devices should be granted exceptions from device identifier requirements; and (2) whether any class I devices covered by the proposed rule should be subject to the requirement that their labels bear a production identifier.

20. Does the proposed procedure for requesting a case-by-case exception from, or alternative to, the requirement for a device to bear a unique device identifier provide a reasonable basis for accommodating requests for exceptions from, or alternatives to, the general rule for UDI labeling?

**Form of Unique Device Identifier**

21. Should FDA require the use of specific AIDC technologies or have a role in approving the use of new AIDC technologies that are used to provide a UDI, or should we leave this decision to the healthcare community and issuing agencies?

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§ Once again, the preamble mistakenly refers to reference 10 in some places.
22. We propose to permit use of a generic symbol to provide notice of the presence of AIDC technology that provides a UDI:

![UDI AIDC symbol]

Should we restrict this provision to allow use of the generic symbol only when there is no symbol endorsed in an international standard, and no symbol generally recognized by the persons who typically use the device? For example, there are recognized symbols for RFID and NFC technologies; should we require use of one of these recognized symbols when that form of AIDC technology is used?

Roles of the Issuing Agency

23. Do the proposed accreditation requirements provide sufficient opportunity for interested and qualified organizations to be accredited as an issuing agency?

24. Will the existence of multiple UDI systems confuse device user facilities or impose unreasonable costs on device user facilities?

25. Would it be preferable for FDA to accredit only one national issuing agency, through careful evaluation of the strengths and weaknesses of alternative systems, through a competitive contract or some other means? If you believe a single national issuing agency would be preferable, please explain your views and explain how FDA should make such a designation, including neutral criteria that FDA should apply when evaluating possible candidates.

26. Are there compelling reasons to permit a for-profit organization to be accredited as an issuing agency?

Data Submission Requirements and the GUDID

27. If you believe any of the information that would need to be submitted to the GUDID is not necessary to assure the adequate identification of a medical device, please identify the information you believe is unnecessary and provide an explanation of your views.

28. If you believe that additional information should be required to assure the adequate identification of a medical device, please identify the information you believe is necessary and provide an explanation of your views. Some additional attributes that have been suggested are: prescription and/or over-the-counter; MRI Compatibility Type (safe, unsafe, conditional), and if conditional, the description of the conditions; storage and handling
conditions (e.g., maximum storage temperature, needs to be refrigerated, keep out of light); country of origin, manufacturer, and/or intended sale; short and/or long descriptions; marketed for home use; labeled as hazardous; contains radioactive isotopes (radioactive element and atomic number); and has Material Safety Data Sheet (MSDS)—MSDS Hyperlink. Please provide your views on the need for each of these additional attributes. If you believe an attribute would be useful, should it be part of our mandatory reporting requirements, or should it be collected on a voluntary basis as ancillary information?

29. If you believe that it is unreasonable to tie submission of UDI data to the date the label of the device must bear a UDI, please suggest an alternative time frame and provide an explanation of why the delay in submission of information is necessary.

30. Do the two proposed approaches for data submission provide sufficient options for submitting data to the GUDID? If you are a labeler, which approach would you expect to use? If you expect to use both, please discuss the circumstances that would lead you to use one or the other approach.

31. What information would FDA need to provide in its guidance on submitting data to the GUDID? What questions would you want to see asked and answered in the guidance?

Format of Dates Provided on Medical Device Labels

32. Will a specified format for dates on medical device labels reduce confusion concerning expiration dates?

33. Which format would patients better understand, the “U.S.” format (e.g., SEP 30, 2011), or the “international” format (e.g., 30 SEP 2011)?

34. Which format would health care professionals better understand, the “U.S.” format or the “international” format?

35. Is there a strong reason to favor one format over the other?