

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830

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

RIN 0910-AG31

Unique Device Identification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish a unique device identification system to implement the requirement added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Public Law 110-85. Section 226 of FDAAA amended the FD&C Act to add new section 519(f), which directs FDA to promulgate regulations establishing a unique device identification system for medical devices. The system established by this rule would require the label of medical devices and device packages to include a unique device identifier (UDI), except where the rule provides for alternative placement of the UDI or provides an exception for a particular device or type of device such as devices sold over-the-counter and low risk devices. Each UDI would have to be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. The UDI would also be required to be directly marked on the device itself for certain categories of devices for which the labeling requirement may not be sufficient, for example, those that remain in use for an extended period

of time and devices that are likely to become separated from their labeling. The rule would require the submission of information concerning each device to a database that FDA intends to make public, to ensure that the UDI can be used to adequately identify the device through its distribution and use. The database would include information about the devices; it would not include patient information. Health care professionals and others will be able to use the UDI to rapidly and precisely identify a device and obtain important information concerning the device. The unique device identification system will help reduce medical errors, and will allow FDA, the healthcare community, and industry to more rapidly review and assess adverse event reports, identify problems relating to a particular device, and thereby allow for more rapid and effective corrective actions that focus sharply on the specific devices that are of concern. FDA consulted extensively with the medical device industry, the broader healthcare community, and other stakeholders in the development of this proposed rule and invites comment on whether the proposed approach achieves these goals while minimizing burdens to the maximum extent possible.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], (see section V, the “Information Collection Requirements” section of this document). See section VII for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0090 and/or RIN No. 0910-AG31, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 (see the “Information Collection

Requirements” section of this document) must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) at FAX: 202-395-7285, or email comments to OIRA_submission@omb.eop.gov. Please mark your comments to the attention of the FDA desk officer and reference this rule.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No., and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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SUPPLEMENTARY INFORMATION:**Executive Summary****Purpose of the Regulatory Action**

This rule is intended to substantially reduce existing obstacles to the adequate identification of medical devices used in the United States. By making it possible to rapidly and definitively identify a device and key attributes that affect its safe and effective use, the rule would reduce medical errors that result from misidentification of a device or confusion concerning its appropriate use. The identification system established under this rule would lead to more accurate reporting of adverse events by making it easier to identify the device prior to submitting a report. It would allow FDA, healthcare providers, and industry to more rapidly extract useful information from adverse event reports, pinpoint the particular device at issue and thereby gain a better understanding of the underlying problems, and take appropriate, better-focused, corrective action. The rule will also require dates on medical device labels to conform to a standard format to ensure those dates are unambiguous and clearly understood by device users.

The rule will fulfill the statutory requirement of section 519(f) of the FD&C Act (21 U.S.C. 360i(f)), which directs FDA to promulgate regulations establishing a unique device identification system for medical devices; this requirement was added to the FD&C Act by section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Public Law 110-85.

In developing the proposed rule, FDA has been partnering with industry to conduct pilot tests to identify potential issues and generate feedback on the development of a UDI system. Throughout the pilot activities, labeler organizations from the medical device industry focused on identifying and understanding potential issues that would arise for labelers in implementing UDI and provided that feedback to FDA. The proposed rule reflects this industry input and the lessons learned from these pilot activities. FDA also solicited input through public meetings; a public workshop with stakeholders from the medical device industry, hospitals, payors and other stakeholders; and, a public request for information on a series of key questions related to the development of UDIs through which FDA received extensive input from the medical device industry and the broader healthcare community. FDA solicits comments on the proposed rule from all interested stakeholders, and is particularly interested in industry comment on whether the proposed approach reflects the lessons from the pilot activities.

Under the proposed system, the health care community and the public would be able to identify a device through a UDI that will appear on the label and package of a device. The UDI will provide a key to obtain critical information from a new database, the Global Unique Device Identification Database (GUDID), which will include information important to the identification of devices. UDIs will appear in both plain-text format and a format that can be read by a bar code scanner or some other AIDC technology. Certain devices for which the labeling

requirement alone may not be sufficient would also be directly marked with a UDI, allowing accurate identification even when the device is no longer accompanied by its label or package. The types of devices that would be subject to the direct marking require are implantable devices; devices intended to be used more than once, and which are intended to be sterilized before each use; and stand-alone software. These types of devices have physical characteristics, or characteristics of use, that significantly increases the probability that the device will become separated from its label, particularly when used over an extended period of time.

By ensuring the adequate identification of medical devices through distribution and use, the rule would serve several important public health objectives--

Reduce Medical Errors. The presence of a UDI that is linked to device information in the GUDID database will facilitate rapid and accurate identification of a device, thereby removing a cause of confusion that can lead to inappropriate use of a device (e.g., confusion as to whether a device is packaged as sterile, or failure to recognize that a device is the subject of a recall or enforcement action). Using a device's UDI, you will be able to use the GUDID to positively identify the device and obtain important descriptive information, preventing confusion with any similar device which might lead to misuse of the device. Health care providers will no longer have to access multiple, inconsistent, and potentially incomplete sources in an attempt to identify a device, its key attributes, and a designated source for additional information.

Simplify the Integration of Device Use Information into Data Systems. UDIs, particularly when provided through AIDC technology, would allow rapid and accurate data acquisition, recording, and retrieval. The use of UDIs in computerized physician order entry systems will help ensure that the intended device will be used in the treatment of a patient, rather

than some similar device that may not fully meet the requirements of the health care professional who ordered the use of the device.

Provide for More Rapid Identification of Medical Devices With Adverse Events. An essential prerequisite to resolving adverse events is the timely and precise identification of the particular device or devices that may have a connection with an adverse event. The inclusion of UDIs in adverse event reports would lead to greater accuracy in reporting, by eliminating uncertainty concerning the identity of the device that is the subject of a report.

Provide for More Rapid Development of Solutions to Reported Problems. The rule also would require the inclusion of UDIs in adverse event reports that are required under part 803. This would allow manufacturers and FDA to more rapidly review, aggregate, and analyze related reports regarding a particular device, leading to more rapid isolation and identification of the underlying problems, and development of an appropriate solution to a particular concern.

Provide for More Rapid, More Efficient Resolution of Device Recalls. Delays in identifying recalled devices can result in the continued use of those devices on patients and involves an increased risk for patient harm. A device labeled with a UDI can be identified rapidly and with great precision and the UDI, particularly when combined with AIDC technology, will hasten the identification of devices that are the subject of a recall. The more rapidly a recall is implemented and completed, the more rapidly the risks presented are reduced and eliminated.

Better-Focused and More Effective FDA Safety Communication. By citing UDIs, FDA would be able to more precisely focus safety alerts, public health notifications, or other communications, eliminating confusion with similar devices and allowing more rapid responsive action. Users of similar devices that are not the subject of the safety alert would be relieved of

the uncertainty concerning whether they have been exposed to, or are affected by, a problem or risk.

Provide an Easily-Accessible Source of Definitive Device Identification Information.

While not required, inclusion of device identifiers in informational and educational materials, such as package inserts, training materials, educational materials, and other supplementary information, could provide a quick and useful means for patients and health care professionals to obtain additional information concerning a device, without having to provide that information in the document. This could allow the document to focus on its important core messages without the distraction of greater complexity, while a reader who wants those additional details could use the UDI to obtain information from the GUDID.

Additional Benefits. FDA expects the UDI system will provide additional benefits. For example, UDIs could be used to enhance management of the Strategic National Stockpile, inventory management, and the provision of high-quality medical services. UDIs will facilitate the development of more useful electronic patient records by allowing providers to electronically capture and record important information concerning the use (including implantation) of a device on a patient. UDIs could help identify similar devices in the event of a shortage, and could help detect counterfeit devices.

Standard Format for Dates Provided on a Device Label or Package. The rule would also contribute to improved identification of medical devices, and at the same time, better ensure the safe use of devices, by requiring dates on medical device labels to conform to a standard format — Month Day, Year (e.g. JAN 1, 2012) — to ensure dates are unambiguous and clearly understood by device users.

Summary of the Major Provisions of the Regulatory Action in Question

This rule would require the label of medical devices and device packages to include a UDI, except where the rule provides for alternative placement of the UDI or provides an exception for a particular device or type of device. Each UDI would have to be provided in a plain-text version and in a form that uses AIDC technology. The UDI would also be required to be directly marked on the device itself for certain categories of devices, such as those that remain in use for extended periods of time and are likely to become separated from their labeling. The rule would require the submission of information concerning each device to a database that FDA intends to make public, to ensure that the UDI can be used to adequately identify the device through its distribution and use. The FDA database would not include patient information. The rule would also require dates on device labels and packages to be presented in a standard format.

The UDI system proposed by this rule builds on international regulatory cooperation activities and existing, internationally recognized standards relating to unique identification and data exchange. The rule would specify the technical requirements of a UDI, which would consist of a portion that identifies the specific version or model of the device and the labeler of the device (the device identifier), and a portion that more precisely identifies the specific device by providing variable information, such as the lot or batch, the serial number, expiration date, or date of manufacture (the production identifier). Devices exempted from this proposed rule include devices, other than prescription devices, that are sold at retail establishments; this exception also applies to such a device when delivered directly to a hospitals and other health care facilities. Also exempted are class I devices that FDA has by regulation exempted from the good manufacturing practice requirements of part 820 of this chapter. The production identifier would not be required for Class I devices. The proposed rule explains when a UDI is required

and when its use must be discontinued. The rule would require all UDIs to be issued under a system operated by an FDA-accredited issuing agency. The rule would provide a process through which an applicant would seek FDA accreditation. The proposed rule specifies the information that the applicant would provide to FDA and the criteria FDA would apply in evaluating applications. The rule includes provision for the suspension or revocation of the accreditation of an issuing agency, and explains the circumstances under which FDA will, or may, act as an issuing agency.

Whenever a device must bear a UDI, the labeler of that device would be required to submit information concerning the device to FDA to facilitate the rapid identification of the device and the labeler, and to provide links to other FDA data. FDA will make this information available to the public through a variety of channels, including a new database, the GUDID.

The rule provides for appropriate exceptions and alternatives, ensuring that the costs and burdens are kept to a minimum.

A final rule would become effective in stages, over a period of seven years, to ensure a smooth implementation and to spread the costs and burdens of implementation over time, rather than having to be absorbed all at once.

Table 1.--Costs and Benefits

Economic Data: Costs and Benefits Accounting Statement (2010 dollars)

Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes
				Year Dollars	Discount Rate	Period Covered	
Benefits							
Annualized Monetized \$millions/year					7%		
					3%		
Annualized Quantified					7%		
					3%		
Qualitative	More accurate and prompt						

	identification of device related adverse events would lead to more rapid action to reduce the incidence of the adverse events and to more effectively target and manage medical device recalls.						
Costs							
Annualized Monetized \$millions/year	\$68.4	\$34.9	\$101.8	2011	7%	10 years	Costs to foreign labelers are not included.
	\$66.9	\$34.1	\$99.7	2011	3%	10 years	
Annualized Quantified					7%		
					3%		
Qualitative							
Transfers							
Federal Annualized Monetized \$millions/year					7%		
					3%		
From/ To	From:			To:			
Other Annualized Monetized \$millions/year					7%		
					3%		
From/To	From:			To:			
Effects							
State, Local or Tribal Government: No effect							
Small Business: The proposed rule may have a significant economic impact on a substantial number of small entities that label medical devices.							
Wages: No effect							
Growth: No effect							

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I. Background

A. Objectives of the Proposed Rule

This rule is intended to substantially reduce existing obstacles to the adequate identification of medical devices used in the United States. By providing the means to rapidly and definitively identify a device and key attributes that affect its safe and effective use, the rule would reduce medical errors that result from misidentification of a device or confusion concerning its appropriate use. The identification system established under this rule would lead to more accurate reporting of adverse events by making it easier to identify the particular device involved prior to submitting a report. It would also allow FDA, healthcare providers, and industry to more rapidly extract useful information from adverse event reports, pinpoint the particular device at issue and thereby gain a better understanding of the underlying problems, and take appropriate, narrowly-focused, corrective action.

The rule will fulfill a statutory directive to establish a unique device identification system. Section 226 of FDAAA amended the FD&C Act to add new section 519(f), which directs FDA to promulgate regulations establishing a unique device identification system for medical devices: “Unique Device Identification System. The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall

adequately identify the device through distribution and use, and may include information on the lot or serial number.”

Under the system that would be established by this proposed rule, two tools would be used together to identify a device: a UDI on the label and packaging of a device (represented both in plain text and through automatic identification and capture technology), and a new database, the GUDID, containing device identification information for each UDI. Certain devices, such as those that remain in use for extended periods of time and are likely to become separated from their labeling, would also be directly marked with a UDI, allowing accurate identification even when the device is no longer accompanied by its label or package. The principles behind the rule’s requirements and exceptions regarding UDI labeling and the GUDID are discussed in more detail in section I.B of this document.

By requiring adequate identification of medical devices through distribution and use, the rule would serve several important public health objectives--

1. Reduce Medical Errors

Device-related medical errors are a serious problem. The presence of a UDI that is linked to identifying information in the GUDID database will facilitate rapid and accurate identification of a device, thereby removing a cause of confusion that can lead to inappropriate use of a device (e.g., confusing a sterile version or model with a version or model that is not sterile and which requires sterilization prior to use, or failing to recognize that a particular device is the subject of a recall or enforcement action). The presence of AIDC technology as part of a UDI would make it possible to “scan” a device at a patient’s bedside and rapidly compare the device attributes reported to the GUDID with the medical order and the patient’s history, thereby improving the

accuracy of device use and providing greater assurance that a device is appropriate for the patient.

Providing a single, authoritative source of information--the GUDID--to facilitate the unambiguous identification of medical devices used in the United States.

The proposed system would allow anyone to use a device's UDI to look up identifying information in the GUDID concerning the device, including: the FDA premarket submission number of the device; the proprietary, trade, or brand name of the device; any version or model number or similar reference; the Global Medical Device Nomenclature (GMDN) generic descriptor for the device; if the device is available in more than one size, the size of the particular version or model, together with the unit of measure; the total number of devices in the package; and an email address or telephone number for a contact who can provide additional information to FDA. Together, this information will permit positive identification of the device and prevent confusion with any similar device. Health care providers will no longer have to access multiple, inconsistent, and potentially incomplete sources in an attempt to identify a device, its key attributes, and a designated source for additional information.

Ensuring the accurate identification of certain devices, even when the device is separated from its label and package.

The rule would require some devices to be directly marked with a UDI, so that it will always be possible to positively identify the device, regardless of how long the device remains in use. These devices, by their intended or customary use, are typically separated from the labeling that accompanies delivery of the device to users:

- an implantable device;

- a device that is intended for more than one use and to be sterilized before each use;

and

- stand-alone software.

These devices involve unique risks to patients, and consequently it is particularly important to ensure the adequate identification of such devices throughout the entire product life cycle. For example, a device that is intended for more than one use, but which must be sterilized before each use, might be used over several years; during that time, the device package, with its label and any package insert, might be lost, leaving the user of the device uncertain as to whether the device needs to be sterilized, or just given a routine cleaning, and if sterilization is required, what type of sterilization process should be employed. The same is true for implanted devices and stand-alone software — loss of the device package and accompanying labeling can leave the user uncertain as to how to use the device, how to monitor its performance, or what actions should be taken in particular circumstances.

Providing rapid and continuous access to key information relating to the device.

FDA intends to provide Internet access to all data in the GUDID. Furthermore, once data concerning a device has been submitted to the GUDID, it will remain available long after production and marketing of the device has ceased. The GUDID will include information important to the identification of the device, but will not include patient information.

2. Simplify the Integration of Device Use Information into Data Systems

UDIs, particularly when provided through AIDC technology, would allow rapid and accurate data acquisition, recording, and retrieval. The use of UDIs in patient records, particularly electronic patient records, would help avoid confusion among similar devices during an extended treatment period and where more than one health care provider is involved in the

administration of a course of treatment. The use of UDIs in computerized physician order entry systems will help ensure that the intended device will be used in the treatment of a patient, rather than some similar device that may not fully meet the requirements of the health care professional who ordered the use of the device.

3. Provide for More Rapid Identification of Medical Devices With Adverse Events

An essential prerequisite to resolving adverse events is the timely and precise identification of the particular device or devices that may have a connection with an adverse event. The proposed UDI system would make this possible. From 2005 through 2009, FDA received an average of more than 492,000 adverse event reports involving devices each year. During this 5-year period, more than 17,700 reports involved a death, and more than 283,000 reports involved an injury.

Because reports come from multiple sources--manufacturers, device user facilities, importers, and voluntary reports from physicians and other concerned individuals--we often receive more than one report of a particular death or injury. Reviewing a significant number of reports, seeking essential missing information, and resolving inconsistencies among reports are major challenges, particularly when trying to identify recurring problems involving a particular device. Although we do not have precise statistics, many initial reports do not provide a precise identification of the specific device the report concerns and require extensive FDA follow-up to identify the specific device involved. The inclusion of UDIs in adverse event reports would lead to greater accuracy in reporting, and eliminate uncertainty concerning the identity of devices that are the subject of reports.

4. Provide for More Rapid Development of Solutions to Reported Problems

The inclusion of UDIs in adverse event reports would allow manufacturers and FDA to more rapidly review and analyze reports and identify the particular device at issue. This would permit more rapid isolation and identification of the underlying problems, and development of an appropriate solution to a particular concern. UDIs would also allow FDA, manufacturers, and the healthcare community to more accurately target safety alerts, recalls, and other corrective actions on the specific devices that are of concern. UDIs, particularly when provided using AIDC technology, would allow device user facilities and health care professionals to identify those devices more rapidly and with greater assurance, and prevent further patient exposure. At the same time, devices not implicated by the problem would be less likely to be “swept up” in an over-broad attempt to remove potentially hazardous devices.

5. Provide for More Rapid, More Efficient Resolution of Device Recalls

Currently, locating all devices subject to a recall is a time- and labor-intensive process. Manufacturers, distributors, and healthcare facilities often do not know how many recalled devices they have in stock, do not know exactly where those devices are located, and are sometimes uncertain which of several similar devices is the subject of a recall. Consequently, delays in identifying recalled devices can result in the continued use of those devices on patients in a variety of settings (e.g., hospitals, long-term care facilities, homecare environments) and involves an increased risk for patient harm. A device labeled with a UDI can be identified more rapidly and with greater precision than a device that does not bear a UDI. The use of AIDC technology, such as a bar code, would allow increased use of automation to speed efforts to identify specific devices that are the subject of a recall. The more rapidly a recall is implemented and completed, the more rapidly the risks presented are reduced and eliminated.

A class 1 recall is the most serious type of recall, and involves a situation where there is a reasonable probability that use of the device will cause serious injury or death. It is particularly important, therefore, that a class 1 recall be completed as rapidly as possible. The absence of a system that allows rapid and reliable identification of the particular devices that are being recalled means hospitals and health care professionals have to rely on a variety of identification systems and examine a variety of attributes to identify a recalled device. A class 1 recall may direct that a device be returned to the manufacturer for exchange or refund, be destroyed, or be subjected to some other corrective action, such as a software upgrade. Any confusion or lack of complete clarity in identifying the device will undermine the effectiveness of the recall. Therefore, each recall attempts to identify the device as precisely as possible, but the great variation in devices and the terms used to describe them can make it difficult to describe a device with complete clarity. Here are some of the descriptors manufacturers used to identify specific devices subject to class 1 recalls during 2008 and 2009:

Table 2.--Examples of Descriptors Used to Identify Devices Subject to Class 1 Recalls During 2008 and 2009

Descriptor	Example of a Recall that Used the Descriptor
Catalog number	Pointe Scientific, Inc., Liquid Glucose Hexokinase Reagent (October 19, 2009)
Lot number	Covidien Pedi-Cap End-Tidal CO2 Detector (July 17, 2009)
Material Number	Boston Scientific NexStent Monorail, NexStent Carotid Stent and Monorail Delivery System (June 6, 2008)
Model number	Baxter Colleague Single and Triple Channel Volumetric Infusion Pumps (January 23, 2009)
Part number	Synthes USA, Ti Synex II Vertebral Body Replacement (September 14, 2009)
“Product code”	Smiths Medical ASD, Inc., Portex Uncuffed Pediatric-Sized Tracheal Tubes (August 25, 2009) Note: The “product code” used here is a code developed by Smiths Medical; it is not the product code used by FDA.
Product number	Physio Control, Inc. LifePak CR Plus Automated External Defibrillators (August 29, 2008)
Serial number	ZOLL Medical Corporation, ZOLL AED Plus Defibrillator (February 12, 2009)
Universal Product Code (UPC)	Luv N’ Care Gel-Filled Teethers--“Nuby,” “Cottontails,” and “Playschool” (July 17, 2009)

Often, a recall must cite more than one descriptor to identify the specific devices subject to the recall. For example, a September 22, 2009, class 1 recall of the Penumbra, Inc., Neuron 6F 070 Delivery Catheter required reference to both the product catalog number and the lot number to determine whether a particular catheter was subject to the recall, and a June 17, 2009, class 1 recall of Abbott Vascular-Cardiac Therapies/Guidant Corp. POWERSAIL Coronary Dilatation Catheters referred to product designation, product number, lot number, and expiration date. Recalls would be expedited and simplified if a single descriptor, such as the proposed UDI, could serve to adequately identify all devices.

There is no uniformity in the placement or formatting of the descriptors presently used to identify devices, and no assurance that different companies are using a given term in the same way. The inconsistency in methods used to identify a recalled device complicates efforts to identify such devices that remain in possession of a patient, physician, or in a hospital's inventory and to complete the remedial action that would mitigate or eliminate the risk of further harm. These problems would be significantly reduced by the presence of UDIs on the labels and packaging of devices and the inclusion of UDIs in recall notification information. The inclusion of AIDC technology, such as a bar code or a RFID tag, would permit inventories to be checked more rapidly and would result in the more accurate detection and removal of recalled devices.

6. Better-Focused and More Effective FDA Safety Communication

By citing a device identifier, or a range of UDIs, FDA would be able to more precisely focus a safety alert, public health notification, or other communication on the particular device that is the subject of the alert, eliminating confusion with similar devices. Health care professionals and patients would be able to take responsive action more rapidly, and users of

similar devices that are not the subject of the safety alert would not be faced with the uncertainty of not knowing whether they have been exposed to, or are affected by, a problem or risk.

7. Provide an Easily-Accessible Source of Definitive Device Identification Information

While not required, inclusion of device identifiers in informational materials, such as package inserts, could provide a quick and useful means for patients and health care professionals to obtain additional information concerning a device, without having to provide that information in the document. This could allow the document to focus on its important core messages without the distraction of greater complexity, while a reader who wants those additional details could use the UDI to obtain information from the GUDID.

8. Additional Benefits

FDA has concluded that a UDI system has the potential to provide additional benefits. For example, we expect UDIs could be used by other Federal agencies, such as the Centers for Medicare and Medicaid Services, the National Institutes of Health, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Homeland Security, and the Department of Veterans Affairs, for a wide variety of purposes, ranging from management of the Strategic National Stockpile, inventory management, and the provision of high-quality medical services. Other benefits include facilitating the development of more useful electronic patient records by allowing providers to electronically capture and record important information concerning the use of a device on a patient. UDIs could help identify similar devices in the event of a shortage, and could reduce the potential for injury from counterfeit devices by offering a better way to detect a counterfeit product and remove it from the market.

The UDI system would provide a basic infrastructural element, which would allow unambiguous identification of medical devices throughout their lifecycle and would provide the

foundation for a host of benefits. These may include improved device traceability, improved postmarket surveillance, and better security of devices through more effective detection and removal of counterfeit devices, and other improvements that support FDA's public health mission.

Through our work with the Global Harmonization Task Force (GHTF) and foreign regulatory partners, we envision that the UDI system would support global public health initiatives with which FDA is concerned, including more efficient and effective cross-border identification of devices, adverse event reporting and postmarket surveillance, and would improve our ability to communicate and respond to issues and concerns about devices used not only in the United States, but in other nations as well.

B. Certain Public Health Benefits of UDI Depend on the Adoption of IT Systems by Hospitals and Other Healthcare Facilities and on Statistical Methodologies to Interpret the Data Aggregated Using the UDI

The full benefits of UDI require that hospitals and other healthcare facilities concurrently adopt information technology (IT) to fully realize the enhanced ability to identify devices throughout distribution and use. In order to realize its full potential benefits, UDI users must be able to store UDI information in various administrative, clinical and payment information systems, including EHRs. Though many such systems exist today, changes will need to be made in the systems to accommodate UDI.

The use of electronic health technology to reduce medical errors in healthcare facilities would require the use of scanners (many of which are already in place) and standard operating procedures for using newly developed systems that link critical patient information (such as latex sensitivity) with specific medical device information. Hospitals and other health-care facilities

will choose to make investments in the new technology and methods if they expect it to be a cost-effective method to reduce errors and improve patient safety involving medical devices.

Putting a standardized unique device identifier on a device label is one step in creating systems that could reduce device related medical errors. The proposed rule would create a platform that would enhance the value of the new electronic health technologies and thereby encourage their development. But the proposed rule does not require hospitals and other health care facilities to make these changes.

C. Principles That Guided Development of the Proposed Rule

In developing our proposed system for identification of devices, FDA first developed several general objectives, or principles, that we then applied throughout the drafting of our proposed rule. Each of these principles is identified in this section I.B, with a brief discussion of how they are resolved in the proposed rule.

The UDI system should generally include all classes of devices, with appropriate exceptions.

The healthcare community needs to identify a wide range of medical devices in every medical specialty. When fully phased-in, the rule will apply to all three device classes; however, we are proposing to exempt class I devices from production identifiers and proposing full exceptions from UDI labeling and data reporting for certain very low risk devices and other categories of devices; see proposed §§ 801.30, 801.35, and 801.128(f). Although we are not aware of compelling reasons for other exemptions based on the device class or medical specialty, for example, we seek comments on this issue.

The UDI system should be based on existing, broadly-accepted standards.

Basing the UDI system on existing, accepted standards ensures that all UDIs will be unique, broadly compatible, and broadly accepted for use by the U.S. healthcare community and

in international commerce. By incorporating these existing standards into our proposed system, we avoid the confusion, inconsistency, and inefficiency that would result if every labeler created their own device identifiers without regard for the needs of the healthcare community.

Therefore, the UDI system we are proposing would incorporate by reference four international standards: International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 646:1991, Information technology--ISO 7-bit coded character set for information interchange; ISO/IEC 15459-4:2006(E), Information technology--Unique identifiers--Part 2: Registration procedures; ISO/IEC 15459-4:2008, Information technology--Unique identifiers--Part 4: Individual items; and ISO/IEC 15459-6:2007, Information technology--Part 6: Unique identifier for product groupings. See proposed § 830.10. In addition, all widely-used AIDC technologies--e.g., bar codes, RFID tags, and near-field communication are based on established, broadly-supported standards. (Ref. 1) A multiplicity of nonstandardized systems would impose excessive costs on device user facilities and others, would provide no assurance that identifiers would be unique, would run counter to efforts to achieve international harmonization with regard to the identification of devices, and would greatly complicate FDA efforts to identify and resolve adverse events and other problems involving devices.

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 is aware of two existing device identification systems that are based on the ISO/IEC standards discussed in the preceding paragraph. The International not-for-profit association known as “GS1” operates a system that uses a Global Trade Identification Number (GTIN) to

identify a device; GS1 also operates the Universal Product Code (UPC) system that is used to identify most items sold by retail establishments in the United States. (Ref. 2) The Health Industry Business Communications Council (HIBCC) operates a system that encodes an identifier in a Health Industry Bar Code (HIBC) to identify a device. (Ref. 3) We believe roughly 35 to 50 percent of all medical devices used in the United States are already labeled with device identifiers that conform to one of the systems operated by these two organizations (a 2005 ECRI Institute report, “Automatic Identification of Medical Devices,” cited survey data suggesting bar codes were currently found on 25 percent of class I devices, 44 percent of class II devices, and 50 percent of class III devices) (Ref. 4). These existing systems are providing valuable services to device user facilities (hospitals, nursing homes, and other facilities) and to health care professionals. These systems have proven to be successful in creating unique identifiers that are in widespread use in systems used by hospitals, healthcare professionals, and industry.

Because these existing systems include tightly-integrated functions that go far beyond simply identifying devices--functions such as inventory management and enabling commercial transactions that are not part of FDA’s public health responsibilities and are outside our statutory authority--FDA believes it would be inefficient and counterproductive to try to replace the existing systems with a single, FDA-designed system of device identifiers. Because any FDA system would necessarily have a narrow scope limited to the adequate identification of devices, labelers would have to continue to use the existing systems as well as the FDA system, which would result in duplication of effort, substantial additional costs, and potentially confusing identification of devices that would undermine our public health objectives. Consequently, FDA’s proposed UDI system will permit continued use of these existing systems, so long as the

administering organizations apply for and obtain FDA accreditation, as discussed under question 5 of section II.C of this document. The GUDID will allow rapid access to key information concerning any device labeled with a UDI, regardless of the system used to assign the UDI.

Burdens should be minimized

We have honed our proposed data submission requirements to minimize overlap and avoid inconsistency with other existing FDA regulatory requirements, such as establishment registration and device listing. We are proposing to require the submission of fewer types of data than those identified and discussed in the public meetings (Ref. 5) that influenced development of this proposed rule. See proposed § 830.310. We are requesting comments on whether we have adequately minimized overlap and inconsistency, and whether we should require or permit the submission of additional data that may be useful to the healthcare community.

The UDI system should be open to technological advancements.

The proposed rule would require each UDI to be provided in both a plain-text form and a form that uses AIDC technology. See proposed § 801.45. FDA would not require use of any particular technology for the AIDC form of the UDI. The system would permit the use of any type of bar code, RFID tag, near-field communication, or any other technology, whether existing at the present time or developed in the future. This would allow for technological evolution and advancement without prior FDA approval. FDA expects that a new technology would be deployed only after considerable consultation among issuing agencies, device user facilities, healthcare professionals, and device manufacturers, and we believe such decisions are best left in the hands of the healthcare community.

The UDI system should be designed to integrate smoothly with other FDA systems, such as registration and listing, postmarket surveillance, and adverse event reporting.

We have taken care to avoid conflict and minimize overlap with existing regulatory requirements, and we have included several conforming amendments to existing regulatory requirements to ensure UDIs are integrated in our regulatory processes wherever appropriate and feasible. For example, Part 810—Medical Device Recall Authority, Part 820—Quality System Regulation and Part 821—Medical Device Tracking Requirements.

Requirements should be phased in over several years to ensure smooth and effective implementation.

Pursuant to the proposed tiered effective dates, UDI requirements would be phased in over seven years following publication of a final rule (see table 7 of this document). This would allow all participants--FDA, industry, the health care community, and other government agencies--ample time to become familiar with and phase-in the rule's labeling and data submission requirements. This approach also provides FDA the opportunity to identify unforeseen weaknesses or problems in our implementation of the UDI system and to make appropriate mid-course corrections within the scope and authority of this rule, if finalized. We are proposing to phase in the rule's requirements by class because this will allow us to focus first on devices that have higher risks.

The UDI system should foster innovation by, and competition among, issuing agencies.

The proposed rule would allow for accreditation of multiple issuing agencies, see proposed § 830.100, so that the varying needs of labelers and users of different types of devices can be met by different systems with differing levels of complexity and function. Because all issuing agencies would have to employ systems based on the same technical standards, and

would have to meet the same accreditation requirements, each system would still be broadly compatible with other systems. Furthermore, all systems would employ the FDA-administered GUDID database, which would serve as the single authoritative source of information for the positive identification of any device labeled with a UDI. We will maintain a list of all FDA-accredited issuing agencies on our Internet site.

There will be effective FDA oversight of issuing agencies.

Oversight is necessary to ensure that all device identifiers are unique and meet the proposed requirements, and that all system users are treated fairly. FDA is proposing to require that any organization that wishes to issue UDIs be accredited by FDA. See proposed § 830.20(a). We have included accreditation criteria and information submission requirements designed to ensure that only a well-qualified organization that would issue identifiers that comply with the proposed rule would be permitted to serve as an issuing agency. See proposed §§ 830.100 and 830.110.

The UDI system should provide for appropriate regulatory flexibility, including exceptions and alternatives.

Where possible, we have included reasonable flexibility in our proposal. For example, certain categories of devices would be excepted from UDI requirements, see proposed § 801.30, and labelers may request an exception or propose an alternative that would, for example, provide for more effective identification of a device, see proposed § 801.35. Direct marking requirements would apply only to certain narrow categories of devices and there would be some flexibility in how this requirement may be satisfied, see proposed § 801.50. We seek comment on whether these flexibilities achieve the appropriate balance.

Safeguards should be provided to protect small businesses.

We seek to do this in two ways. First, a business can choose to use any system provided by any accredited issuing agency, which will give the labeler a choice among a range of services at a range of fees. We anticipate that the participation of multiple issuing agencies will also lead to competition that will help ensure fees are reasonable. Second, FDA may act as an issuing agency if we find that a significant number of small businesses will be substantially harmed by the fees assessed by all accredited issuing agencies, see proposed § 830.200. If FDA acts as an issuing agency, any business would be permitted to use the FDA system and, under current law, there would be no fee, see proposed § 830.210. We expect this provision will encourage issuing agencies to be sensitive and responsive to the needs of small businesses.

The establishment of a publicly accessible GUDID database is a critical component of an effective UDI system.

It is important to understand that a UDI is simply a numerical or alphanumeric code and on its face is not itself intended to communicate any information directly concerning a device; you would not, for example, be able to parse out a segment that indicates that the device is a cardiovascular device, or that the device is packaged sterile, or that the device is marketed under a particular FDA premarket submission. Instead, the UDI would function as a reference number allowing you to find data concerning the device in an FDA database, the GUDID. The real value of a UDI is derived from its connection to corresponding information identifying the version or model of the device that bears the UDI, and an effective system of device identification requires both a UDI and a database to provide information concerning the particular version or model identified by that UDI. Our proposal would require the submission

of information essential to the identification of a device, which would be provided freely and publicly through a single authoritative source, the GUDID.

In order to serve the public health purposes discussed in section I.A of this document, the UDI system requires a GUDID that is freely and easily accessible to all--hospitals and other device user facilities, health care practitioners, patients, other government agencies, academia, industry, and the general public. None of the information that we are proposing to collect would constitute trade secret information, confidential commercial information, or personal privacy information, and public disclosure of this information would not be prohibited. Open access to the GUDID would also encourage the integration of UDI data into healthcare delivery support systems, electronic medical records, and procurement, inventory management, and accounting systems, and would allow those systems to work together more effectively and efficiently.

D. Prior Consultation with the Health Care Community and Industry

In the Federal Register of February 26, 2004 (69 FR 9120), we published a final rule requiring bar codes on certain human drug and biological products to help reduce medication errors in hospitals and other health care settings. The bar code is intended to enable health care professionals to use bar code scanning equipment in conjunction with computerized medication administration systems to verify that the right drug, in the right dose, is being given to the right patient at the right time. This rule, now codified at 21 CFR 201.25 and 610.67, requires that manufacturers encode the unique National Drug Code (NDC) number in a linear bar code on the product's label. The bar code rule, however, does not apply to medical devices. In the preamble to the bar code rule, we stated that, unlike drugs, medical devices do not have a standardized, unique identifying system comparable to the NDC number, and that the absence of such a system

complicates efforts to put bar codes on medical devices for purposes of preventing medical errors (69 FR 9120 at 9132).

Since the issuance of the final bar code rule, various entities have asked that we revisit the issue of bar coding for medical devices to improve patient safety, quality of care, and cost effectiveness of health care, e.g., by improving delivery and supply chain efficiency. In response to this, in 2005 FDA met with various stakeholders, including device manufacturers and distributors, hospital associations, and other Federal agencies to solicit information and comments about employing a uniform system for the unique identification of medical devices. As a result of these meetings, FDA believes the majority of stakeholders support the development of a uniform system of unique identifiers as a way to improve patient safety and recognize other ancillary benefits such as better management of the purchase, distribution, and use of medical devices. However, there were a variety of experiences and opinions about how best to implement such a system. In 2006, we commissioned a report from Eastern Research Group, Inc. (ERG), concerning the benefits, costs, and issues with developing and implementing a UDI System. (Ref. 6) Thereafter, we published a notice in the Federal Register of August 11, 2006 (71 FR 46233), requesting comments to help us understand how a unique device identification system could improve patient safety, for example, by reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting.

We used the comments responding to the August 2006 Federal Register notice to help develop the agenda and topics for a public meeting held on October 25, 2006. (Ref. 5) The information we received helped us move forward with development of a proposed rule, which was further spurred by enactment of FDAAA.

FDA held a public workshop on February 12, 2009, to discuss issues relating to establishment of a UDI system (see 74 FR 2601, January 15, 2009). (Ref. 5) We asked device identification standards organizations to discuss the development and use of UDI standards, including the use of production identifiers. We asked device manufacturers to discuss the use of standards and the marking of devices with UDIs. We also discussed the potential development and use of a UDI database in general and with respect to particular attributes, as well as issues relating to implementation of a UDI system by interested stakeholders (e.g., distributors, hospitals, payors). We asked device manufacturers to describe their current practices for applying standards to medical devices, including identifiers on medical device labels, and managing medical device identifier data. We also requested information regarding the difficulties and costs involved in adding a UDI to a device's label, including effects on manufacturing and labeling processes and expected capital and operating costs. We asked device user facilities (hospitals, nursing homes, and clinics) to describe how a UDI system could be used, the costs involved, whether a UDI system would require any change in operations, and how UDIs would affect adverse event reporting and recall management. We asked all interested persons to submit comments, including answers to any of these questions, to a regulatory docket, FDA-2008-N-0661, CDRH 200866--Unique Device Identification System; Public Workshop. Comments received by the docket may be reviewed at <http://www.regulations.gov> by searching for "FDA-2008-N-0661" (enter this text in the search field following "Enter Keyword or ID").

We carefully reviewed and considered all comments during our development of this proposed rule.

II. Description of the Proposed Rule

A. Overview

The core requirements summarized here provide context for the more detailed discussions that follow:

- Proposed § 801.18 provides for standardized formatting of dates on medical device labels, eliminating any possibility of confusion from date formats that might be interpreted in more than one way.
- The labeler of each device would be responsible for meeting labeling and data submission requirements under this proposal. The labeler would, in most instances, be the manufacturer of the device. The term “labeler” is defined at proposed § 801.3, and is discussed in section II.B.1 of this document.
- Unless the device is excepted, the label of a medical device, and a device package, marketed in the United States would be required to bear a UDI; this requirement would be phased in over 5 years. See proposed § 801.20.
- The UDI would have to be provided in two forms: easily-readable plain-text and AIDC technology. See proposed § 801.45. These two forms ensure that the UDI of a device would be readily discernable to patients and health care professionals and to automated systems used to identify and manage devices.
- The proposed rule provides several categorical exceptions, proposed § 801.30, as well as case-by-case exceptions and alternatives, proposed §§ 801.35 and 801.128(f)(2).
- Direct marking would be required for certain categories of devices, with exceptions. For each device subject to direct marking, this requirement would go into effect two years after the base UDI labeling requirement goes into effect for that device. See proposed § 801.50.

- Whenever a device must be labeled with a UDI, the labeler (the person who causes the label to be applied to the device) would have to submit data concerning that device to the GUDID database. See proposed § 830.320. This information would have to be submitted no later than the date the label of the device must bear a UDI, and would have to be updated when changes occur. See proposed § 830.330. Exceptions are identified in the detailed discussion of part 830. This data would be freely available to the public and would provide the information necessary to identify a device labeled with a UDI.

- UDI labeling requirements would also apply to--
 - certain combination products;
 - in most instances, to the device constituent parts of combination products;
 - convenience kits; and
 - a device included in a convenience kit, except for a single use device.

The terms “combination product” and “convenience kit” are defined at proposed § 801.3 and are discussed in section II.B.1 of this document.

- UDIs would be issued under systems operated by FDA-accredited “issuing agencies” and conform to certain international standards, incorporated by reference at proposed § 830.10. A different UDI would be required for each version or model of a device. These terms are defined at proposed § 830.3.

- In order to provide for efficient implementation of this rule, we propose to phase in its requirements over several years. Table 7 of this document, Effective Dates of UDI Regulatory Requirements, summarizes how we would phase in the requirements proposed in this rule.

B. UDI Labeling Requirements (Part 801)

Part 801 (21 CFR part 801) provides FDA's general medical device labeling requirements. All devices are subject to subparts A through E of part 801, while subpart H provides special requirements for specific devices; subparts B, F, and G are presently reserved. FDA provides additional labeling requirements in subpart B of part 809 that apply only to in vitro diagnostic products. FDA is proposing amendments to part 801 to provide UDI labeling requirements for devices. The changes we are proposing to part 801 provide a new definitions section, see proposed § 801.3; a new provision standardizing the format of dates provided on medical device labels, see proposed § 801.18; new subpart B, Labeling Requirements for Unique Device Identification; and a proposed amendment to § 801.128, regarding exceptions or alternatives to labeling requirements for medical devices held by the Strategic National Stockpile. Several definitions proposed for inclusion in part 801 would also be included in new part 830, Unique Device Identification. A proposed amendment to § 801.119 (the labeling regulation specifically applicable to in vitro diagnostic devices) would make it clear that all UDI labeling requirements apply to such devices. In order to avoid confusion with regard to the use of National Health Related Item Codes (NHRICs) and NDC numbers currently used to identify some devices, proposed § 801.57 would terminate the use of these legacy identifiers on the date the device must be labeled with a UDI; those dates are specified in proposed § 801.20(b).

1. Definitions

The UDI regulation would not change the meaning of any term currently defined in Part 801. We are proposing, in new § 801.3, several definitions relating to the use of UDIs on device labels. New § 801.3 would not affect the existing definitions in part 801, and would not

consolidate existing part 801 definitions into a single section. Each definition proposed in § 801.3 is discussed in this section II.B.1.

Automatic identification and data capture (AIDC) technology would be any technology that conveys the UDI or the device identifier of a device in a form that can be entered into an electronic patient record or other computer systems via an automated process. AIDC technologies most often use bar codes, RFID, or near field communication, but this rule does not specify the technologies that may be used and does not prohibit the use of any particular technology. We believe it is best to leave decisions concerning the selection and use of any particular AIDC technology to issuing agencies, the labeler, and the health care community in order to avoid unintentional interference with the development and adoption of new and improved AIDC technology.

Center Director--This would be the Director of the Center for Devices and Radiological Health, or the Director of the Center for Biologics Evaluation and Research, depending on which Center has lead responsibility for a particular device.

Combination product--Within the context of the UDI system, a combination product will involve at least one device and at least one drug or one biological product. The term is defined by 21 CFR 3.2(e), and would have the same meaning here. A combination product whose primary mode of action is that of a device is subject to UDI labeling requirements; see proposed § 801.25(a). The constituent parts of a combination product would continue to be subject to all requirements that ordinarily apply to the particular type of product (device; drug; biologic), and this rule would require each device constituent part of a combination product to be labeled with its own UDI, regardless of whether the combination product is subject to UDI labeling. For example, the device constituent parts of a combination product whose primary mode of action is

that of a drug would be subject to UDI labeling requirements; see proposed §§ 801.25(b). However, a device constituent part of a combination product would not be required to have a UDI if it 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; see proposed § 801.30(a)(11). A drug-eluting stent is an example of a combination product where the device constituent part — the bare-metal stent — has been combined with a drug constituent in such a way that it is not possible for the stent to be used except as part of the combination product.

Convenience kit--When two or more different types of medical devices are packaged together for the convenience of the user, the result is a convenience kit. A convenience kit would have to have a UDI; see proposed § 801.25(c). Each device in a convenience kit would have to meet all FDA requirements that normally apply to a device of that type, including having its own UDI distinct from that of the convenience kit, except for single use devices included in a convenience kit; see proposed § 801.25(d).

Device package--This definition is intended to clarify which articles would be required to bear a UDI under proposed § 801.20(a)(2). It is also intended to clarify the scope of the term version or model, which includes this term in its definition (consistent with current business practice, a change to the quantity of devices in a device package is one of the changes that results in a new version or model]; see proposed § 830.50 and related discussion under the heading “Version or model” of this section II.B.1). Since these requirements would be consistent with current practices — the existing GS1 and HIBCC systems, and the standards that underlie both of those systems and the proposed FDA UDI system — they will be well-understood, there will

be no need for multiple identifiers on device packages, and we will avoid any need for duplicative and inconsistent identification.

This term would be defined as a package that contains a fixed quantity of devices. A package may be a box or any other type of container in which devices are distributed or sold, and would include packages within other packages. Unlike a shipping container, whose contents and quantity may vary between shipments, the quantity of a device package would remain constant. If you change the quantity in a device package, you will have created a new device package. FDA is proposing this definition because the existing GS1 and HIBCC systems, and the international standards that underlie those systems, all require differentiation among packages that contain different quantities of a device in order to facilitate inventory management, order processing, and other business purposes. The proposed UDI system needs to recognize and accommodate these existing business systems and practices to avoid creating requirements that would lead the healthcare community and industry to have to devise a supplementary system to implement the UDI system, which would unnecessarily impose added costs and burdens and potentially undermine the effectiveness of the UDI system if multiple types of identifiers were used. We invite comment on this understanding of current systems and the extent to which the proposed definition accommodates current practice. A change to a device package that does not make substantive changes to the information conveyed thereon or to the quantity in the package would not result in a new device package; for example, a change in graphics, fonts, colors, or formatting would not result in a new device package, but a change in quantity would result in a new device package.

Finished device—This term is defined because it is used in the definition of lot or batch, which is discussed below. In turn, the definition of lot or batch is based on a definition in FDA’s Quality System Regulation.

Expiration date--This term is not defined in any other medical device regulation, but is in common use and an expiration date (or “use by” date) is frequently provided on the labels of FDA-regulated products, including medical devices. The proposed definition is intended to capture the term’s ordinary meaning, which we take to be the date by which the label of a device states the device must or should be used. We are defining the term because it is one of four production identifiers that, when provided on a device’s label, would also have to be provided through a UDI (the other production identifiers are: the lot or batch of a device; the serial number of a device; and the date a device was manufactured); see the proposed definition of unique device identifier, which includes production identifier.

FDA, we, or us would mean the Food and Drug Administration.

Global Unique Device Identification Database (GUDID) would mean the FDA administered database that serves as a repository of information to facilitate the identification of medical devices through their distribution and use. This term would have the same definition in both parts 801 and 830; more information is provided later in this preamble, in the discussion of definitions used in part 830.

Implantable device would mean a device that is intended to be placed in a surgically or naturally formed cavity of the human body. A device would be regarded as an implantable device only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health.

Label would have the same meaning as is provided by section 201(k) of the FD&C Act.

Labeler--This term would mean 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. In most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler. The labeler would be responsible for meeting the UDI labeling requirements proposed for inclusion in part 801.

The addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, would not be a modification for the purposes of determining whether a person is the labeler. If a modification to the label extends beyond this narrow latitude, the person who causes the modification to be made will be a labeler and will be subject to the requirements of this rule.

The term labeler does not include a person who labels a device, or who modifies the label of a device, pursuant to the instructions of the person who actually places the device into interstate commerce. Thus, a contractor who labels a device, following the instructions of the specification developer or manufacturer, would not be the labeler. Instead, the person who “causes” the label to be applied or modified --the person who provided the labeling instructions, whose name is on the device, and who actually places the device into interstate commerce (FDA refers to such a person as a specification developer)--would be the labeler and would be responsible for meeting UDI labeling requirements.

Lot or batch--This definition is based on the definition used in the Quality System Regulation (QSR), § 820.3(m), but deletes the QSR language concerning components and the condition “whether or not it is packaged, labeled, or sterilized.” This is because UDI

requirements would not apply until the device is labeled, and sterilization would not be a factor in determining whether a device would have to bear a UDI (the need for sterilization prior to each use would be relevant in determining whether a device must be directly marked under proposed § 801.50). Lot or batch is one of four production identifiers that, when provided on a device's label, must be provided through a UDI. See the proposed definition of unique device identifier.

Shipping container--A shipping container would be 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. This rule would not require a UDI to be placed on any shipping container; see proposed § 801.30(b).

Specification--This definition is intended to clarify the scope of "specification" as used in the definition of version or model. This definition builds on the definition of "specification" provided by the QSR, see § 820.3(y), but uses "device" instead of "product, process, service, or other activity," because the QSR has a wider scope.

Unique device identifier (UDI)--The definition cites proposed § 830.20, which specifies the requirements for a valid UDI, and the statutory mandate of the UDI system: to adequately identify a device through its distribution and use. A UDI may consist of two parts--

- a device identifier that identifies the specific version or model of a device and the labeler of that device; and
- a production identifier that identifies one or more of the following, when present on the label of the device:
 - the lot or batch within which a device was manufactured;
 - the serial number of a specific device;

- the expiration date of a specific device;
- the date a specific device was manufactured.

The production identifier would not be required for class I devices; see § 801.30(c). The device identifier would always have to be present in a UDI. The production identifier must be present whenever a lot or batch number, serial number, date of manufacture, or expiration date appears on the label of the device, except for class I devices. Because most device labels provide at least one of these identifiers, most UDIs would have to include a production identifier. This proposed rule would not itself require any production identifier to appear on a device label, but other FDA regulations and conditions of approval may require one or more to be provided on the label of a particular device or type of device, and many labelers already label their devices with one or more production identifiers.

As discussed in section I.B of this document, the UDI is not structured to provide direct information concerning a device; the device identifier is a reference number that allows you to find data concerning the device in an FDA database, the GUDID. Whenever this proposed rule states that a UDI “identifies” a device, we are referring to the use of the UDI in conjunction with information concerning the device that the labeler of the device has submitted to the GUDID.

Universal product code (UPC)--A universal product code is an identifier used to identify a company and product name for an item sold at retail in the United States. UPCs are based on the GS1 “General Specification,” an international standard.

Version or model--This definition identifies the characteristics that make a device unique. Each version or model would be required to have its own device identifier, and when you add a new version or model, or make a change that results in a new version or model, that addition or change would require use of a new device identifier and would require you to submit information

concerning the version or model to the GUDID. See proposed §§ 830.50 and 830.330. The definition combines elements from definitions in the QSR for finished device and lot or batch, §§ 820.3(l) and (m), and includes language to make clear that each distinct device package (each containing a different quantity of devices) would constitute a different version or model (and would therefore have its own device identifier).

2. When Would the Requirement for UDI Labeling Go Into Effect, and Where Would the UDI Have to Appear?

Proposed § 801.20(a) would require medical device labels and device packages to bear a UDI. Exceptions to this general rule are provided by proposed §§ 801.30, 801.35, and 801.128(f)(2), and are discussed in section II.B.7 of this document.

Thus, if a device is sold in individual device packages, which are sold in boxes of five device packages, which are sold in cartons that contain ten boxes of five devices packages, a UDI would be required to appear on the individual device package, on the box of five packages (which is itself a “device package,” see proposed 801.3, because it contains a fixed number of devices), and on the carton of ten boxes of five device packages (again, because the carton is a “device package”). This reflects existing practice within the health care community; both the existing GS1 and HIBCC systems, and the standards that underline those systems and the proposed FDA UDI system, follow this approach, and place a unique identifier on every distinct device package (Ref. 7).

The presence of a UDI on each device package would improve the effectiveness and efficiency of recalls and other corrective actions targeting potentially harmful devices. For example, the presence of a UDI on outer packaging will enable distributors, hospitals, and others to enter it into their system upon receipt. Then they will know exactly what devices they have or

had in their possession when, and if, there is a recall, tampering, counterfeiting, or other problems with the device at a later date, they can simply type in the applicable UDIs to determine whether they have (or had) the device in their possession. If there were no UDI on the outer packaging, the box or other type of 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.

By requiring a UDI for device packages, the proposed UDI system strives for uniform identification of devices throughout their path of distribution and use. This will facilitate the unambiguous identification of devices wherever they are located and avoid the confusion that would be created by the use of multiple identifiers, and that would undermine the public health purposes of the rule. At present, most manufacturers generally follow this approach, and place an identifier on every device package (Ref. 7). If UDIs were not required to appear on all device packages, manufacturers would continue to use their existing identification systems, which would result in the use of multiple types of identifiers for a particular device. This would produce confusion and inhibit the rapid and precise identification of devices that is the goal of this rule. The fact that the proposed requirements are consistent with existing practices also lowers the burden of compliance.

The requirement for device labels and device packages to bear a UDI would be phased in over several years:

- UDI labeling requirements will take effect for class III devices and devices licensed under the Public Health Service Act beginning 1 year after we publish a final rule; see proposed § 801.20(b)(1).

- UDI labeling requirements will take effect for class II devices beginning 3 years after we publish a final rule; see proposed § 801.20(b)(2).
- UDI labeling requirements will take effect for class I devices and devices not classified into class I, II, or III beginning 5 years after we publish a final rule; see proposed § 801.20(b)(3) and (b)(4).

See table 7 of this document for a summary of these and other effective dates proposed for this rule.

Phasing in UDI labeling requirements over several years allows all parties--FDA, device labelers, hospitals and other device user facilities, and health care professionals--to prepare for, and implement, the requirements in an orderly, efficient manner. It also provides FDA the opportunity to clarify any confusion in implementation within the scope and authority of this rule, after it is finalized. We are proposing to phase in UDI labeling and data submission requirements by class because this will allow us to focus first on devices that have higher risks. Section 801.25 explains how these timeframes apply to convenience kits and combination products.

The data reporting requirements of part 830 would go into effect at the same time as the UDI labeling requirements, see proposed § 830.330(a), using the same phased-in schedule as is set forth in proposed § 801.20(b). These parallel requirements--UDI labeling and data reporting--would go into effect together because, as discussed in section I.B of this document, the UDI would have limited value without the ability to look up information concerning the device in a database.

3. How Would UDI Labeling Requirements Apply to a Combination Product and a Device Constituent Part of a Combination Product?

Proposed § 801.25(a) would require a UDI on the label and device package of every combination product whose primary mode of action is that of a device, regardless of which FDA Center has been designated as having primary jurisdiction for the premarket review and regulation of the product (in the great majority of cases where the combination product has a primary mode of action of a device, the lead Center will be the Center for Devices and Radiological Health). If FDA has determined that the primary mode of action of a combination product is not that of a device, we would not require a UDI on the label or package of the combination product. For a combination product with a primary mode of action other than that of a device, we envision that the combination product generally would be identified by an NDC (see 21 CFR 201.25, 610.67; 71 FR 51276, August 29, 2006).

Proposed § 801.25(b) would require a UDI on the label and (when present) the device package of each device constituent part of a combination product, regardless of the primary mode of action of the combination product, which Center has the lead responsibility for the combination product, and whether the label and package of the combination product are required to bear a UDI, except where the device 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; see proposed § 801.30(a)(11). Thus, whenever it is possible for a device constituent part to be used separately from a combination product with a device primary mode of action, a UDI would be required to identify the combination product, and a different UDI would be required for each device constituent part that can be used separately from the use of the combination product. This approach is necessary both for the accurate identification of the product, and to facilitate effective recalls and adverse event reporting. For example, there may be a problem with a device

constituent part of a drug-device combination product that applies only to the device when it is part of the combination product, or only to the device when used separately from the combination product. We seek comments on this approach to UDI applicability to combination products.

With the exception of those products where it is not possible for the device constituent part to be used except as part of the combination product, the presence of either a UDI or an NDC on the label and package of combination products, and a UDI on the label and any device package of each device constituent part thereof, would assure precise identification.

4. How Would UDI Labeling Requirements Apply to a Convenience Kit?

A convenience kit consists of two or more different types of medical devices packaged together for the convenience of the user. We propose to require a UDI on the label of and device package of each convenience kit. See proposed § 801.25(c). We would also require each device in a convenience kit to bear its own UDI (a UDI distinct from that of the convenience kit) on its label and device package unless the included device is intended for a single use (e.g., an adhesive bandage). See proposed § 801.25(d). The reason for requiring a UDI on the label and device package of each device in a convenience kit is that devices that are intended for more than a single use, such as surgical instruments that are sometimes packaged as parts of kits, often become separated from the convenience kit, and are used at some later time. Without a UDI, there is no assurance that the user will be able to adequately identify the device and be aware of relevant data in the GUDID database concerning that device. Because this potential problem is much less of a concern for a device intended for a single use, a single-use device included in a convenience kit would not need to bear a UDI; see proposed § 801.30(a)(12). Inclusion in a convenience kit would have no effect on whether a device must be directly marked pursuant to

proposed § 801.50; if § 801.50 requires the device to be directly marked, the device must be directly marked regardless of whether it is included in a convenience kit.

5. Exceptions From, and Alternatives To, UDI Labeling Requirements

The proposed rule would provide several exceptions to our UDI labeling requirements. The exceptions derive from statutory provisions or are designed to make the overall UDI system more efficient and to ensure that the burdens imposed by the UDI system are reasonably balanced with its benefits. A labeler that chooses for business or other reasons to voluntarily comply with any provision from which the labeler is excepted may, of course, do so.

Proposed § 801.30(a)(1) provides an exception for devices, other than prescription devices, that are sold at retail establishments, such as drug stores; this exception would also apply to such devices when sold directly to a hospital or other health care facility. A wide range of devices is available at retail, including automatic external defibrillators, insulin syringes, glucometers, tampons, thermometers, toothbrushes, bandages, and more. We are providing this exception to reduce the overall burden of the proposed rule, given that it is the prevailing industry practice to label such devices with a UPC, which may serve as an adequate substitute for devices sold over-the-counter at retail. For those labelers that choose to submit data to the GUDID on a voluntary basis, a UPC may serve as a UDI for devices sold at retail for purposes of submission of data to the GUDID; see proposed § 830.300(c).

Some devices sold over-the-counter at retail have been the subject of recalls and adverse events, and we would likely see significant benefits from participation in the UDI system. It is also possible that many other devices sold over-the-counter at retail would benefit from participating in the UDI system, and that those benefits would outweigh the costs of participation. Because of our uncertainty regarding the balance of interests regarding proposed

§§ 801.30(a)(1), FDA requests comments on the extent to which devices sold in retail establishments should be subject to the requirements of this proposed rule. Should these devices be excepted as provided by proposed §§ 801.30(a)(1), or should they instead be subject to the proposed rule in the same manner and to the same extent as other devices?

Proposed § 801.30(a)(2) would except from UDI labeling requirements 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 a 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.

These are very simple devices, such as —

- tuning fork (product code GWX)
- elastic bandage (product code FQM)
- examination gown (product code FME)
- bedpan (product code FOB)
- manual toothbrush (product code EFW)

We have provided a list of the devices that at present would be eligible for this exception; see Ref 10. FDA is providing this list to illustrate the scope of this exception at the time of this proposed rule.

Proposed § 801.30(a)(3) provides an exception 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. Those devices would not have to be individually

labeled with a UDI. For example, this includes devices that are not individually wrapped (e.g., a box of patient examination gloves) and devices that are individually wrapped and bear identifying information, but which are not intended to be distributed individually (e.g., a box of adhesive bandages). In such cases, applying a UDI on each individual device would not be likely to contribute to better identification of the device and would be an unnecessary burden and cost. The device package containing these individual devices must, however, bear a UDI on its label.

Proposed § 801.30(a)(3) would apply only to class I devices because we believe that only class I devices are currently marketed in the manner contemplated by § 801.30(a)(3). It is not our intent to require changes to current practices regarding the packaging of devices, and we are specifically seeking comment regarding this exception in question 15 of section IX of this document. Labelers of class II devices that would qualify for this exception but for their classification may request an exception or alternative under proposed § 801.35.

Proposed § 801.30(a)(4) provides an exception for a device used solely for research, teaching, or chemical analysis, and not intended for any clinical use, as is consistent with FDA's general approach to the regulation of such articles as set out in 21 CFR section 801.125.

Proposed § 801.30(a)(5) provides an exception for a custom device, or a device made to meet the unique needs of a patient or physician, within the meaning of § 812.3(b). This exception is consistent with FD&C section 520(b), which provides that FD&C sections 514, Performance Standards, and 515, Premarket Approval, do not apply to custom devices. Because a custom device is intended only for use by an individual patient and not generally available for sale, a UDI would not be necessary to uniquely identify the device.

Proposed § 801.30(a)(6) provides an exception for an investigational device within the meaning of part 812 (21 CFR part 812). Investigational devices are subject to a variety of requirements under part 812 that ensure adequate identification of the device.

Proposed § 801.30(a)(7) provides an exception 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.

Proposed § 801.30(a)(8) provides an exception for a device intended for export from the United States. This is because foreign nations have their own regulatory requirements, which may include identification requirements, with which the device must conform.

Proposed § 801.30(a)(9) provides an exception for a device held by the Strategic National Stockpile and granted an exception or alternative under § 801.128(f)(2). This exception is consistent with other labeling exceptions that apply to devices held by the Strategic National Stockpile. 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).

Proposed § 801.30(a)(10) provides an exception for a device for which FDA has established a standard pursuant to section 514(b) of the FD&C Act and has provided therein an exception from the requirement of proposed § 801.20, 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 an exception from the requirement of proposed § 801.20 within the scope of that recognition. This exception is intended to provide FDA flexibility in the application of the UDI system, or an alternative, when we are using a standard as a special control for a particular device.

Proposed § 801.30(a)(11) provides an exception for a device constituent part of a combination product, provided that the device constituent part of a combination product 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. If it is possible for the device constituent part to be used in any way except as part of the use of the combination product, this exception does not apply. See discussion under preceding question 3.

Proposed § 801.30(a)(12) provides an exception for a device that is packaged in a convenience kit, provided that the device is intended for a single use. This exception does not apply if the device is intended for more than one use. See discussion under preceding question 4.

Proposed § 801.30(b) provides an exception for shipping containers, because they often contain different, unrelated devices, and sometimes other items as well. We do not propose to require a UDI be placed on any shipping container, but the device packages within the shipping container would be subject to all UDI labeling requirements unless an exception applies under proposed §§ 801.30(a), 801.35 or 801.128(f)(2).

Proposed § 801.30(c) provides an exception that would permit the labeler of a class I device to label it with a UDI that does not include any production identifiers; the UDI would only have to include the device identifier. Most Class I medical devices include a plain text version of relevant production identifiers (*e.g.*, a lot number or an expiration date) somewhere on the device label. However, the cost of encoding production identifiers in dynamic barcodes for high-volume class I device production lines may outweigh the benefits of this enhanced identification. Furthermore, we believe that hospitals may be less likely to track or document individual class I device use in patient records, and are more likely to simply use a more-generic

identifier; the device identifier portion of the UDI will adequately serve such needs. Labelers of class I devices are not prohibited from using a production identifier, but they would not be required to do so under this proposed rule.

Proposed § 801.35 authorizes additional, case-by-case, labeling exceptions beyond those provided by proposed § 801.30; this section also authorizes alternatives to standard UDI labeling requirements. This provision is intended to ensure that the UDI system has adequate flexibility to accommodate any special circumstances regarding a particular device or type of device that indicate that application of the standard UDI labeling requirements is not technologically feasible or that the objectives of this rule would be better served by application of an alternative approach. Only a device labeler may request an exception or alternative under proposed § 801.35, although FDA may, under proposed § 801.35(d), provide an exception or alternative on our own initiative. A request for an exception or alternative under proposed § 801.35 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;
- Provide an estimate of the number of labelers and the number of devices that would be affected if we grant the requested exception or alternative.

See proposed § 801.35(a). We may request additional information needed to clarify the scope or effects of a request; see proposed § 801.35(a)(6).

A request under proposed § 801.35 could be submitted to FDA as part of a premarket submission, proposed § 801.35(b), or through a written request at any time after a premarket submission has been filed, proposed § 801.35(c). If we grant a request for an exception or alternative, we may include conditions to ensure the adequate identification of the device through its distribution and use, given the anticipated circumstances of use. If we grant an exception or alternative, we would provide information about the exception or alternative on our Internet site. If necessary to facilitate or implement an alternative granted under this section, FDA may, at our discretion, act as an issuing agency; see proposed § 830.200(d).

6. May a Device That is Exempt From UDI Labeling Requirements Nevertheless Be Labeled With a UDI?

Yes. Proposed § 801.40(a) permits the labeler of a device that is not required to bear a UDI to voluntarily include a UDI on the label of that device. We have included this provision because it may be in the interest of both labelers and their customers to use the same identification system for all devices, and not just those devices that this rule requires to bear a UDI. If the labeler voluntarily includes a UDI on the label of a device, the labeler may also voluntarily provide information concerning the device to the GUDID; see proposed § 830.300(c). We expect most labelers who voluntarily label their devices with UDIs will choose to voluntarily submit information to the GUDID in order to facilitate the identification of those devices.

7. How Would a UDI Have to Appear on a Device Label and on a Device Package?

We would require the UDI to be provided on the device label and each device package in an easily-readable, plain-text form. This is so patients, health care professionals, FDA, and other

users of the UDI system would be able to read the UDI and enter it, at their discretion, into patient records, reports to FDA, and data systems without any technological assistance. We do not specify a particular font or point size for the UDI; rather, the UDI would be subject to existing requirements that govern medical device labels, including § 801.15, concerning prominence of required label statements.

The UDI would have to be provided on device labels and device packages through AIDC technology; see § 801.45(a)(2). The AIDC version will facilitate efficient and accurate identification of the device, documentation of the use of the device in electronic records, and potentially many other uses, while reducing the possibility of human error. The AIDC technology may be a bar code, RFID, near-field communications (NFC), or any other technology that serves the same objectives. We do not specify what technologies may be used, because the most appropriate technology will vary considerably depending on the type of device and its intended uses, and because the available technologies are likely to evolve and advance over time.

At present, we believe most device labelers would choose to meet the requirement for AIDC technology by providing a bar code. In such instances, the bar code may be formatted in any way that meets the technical requirements of the bar coding system that is employed.

While the presence of a bar code is immediately obvious, the presence of other AIDC technologies, such as RFID and near-field communication, may not be so obvious. If a device user is not aware of the availability of AIDC technology, this may impair the rapid and accurate identification of the device. To ensure that the presence of AIDC technology is obvious, if the AIDC technology is not visible on the label of the device or on the device package, the labeler would also have to include a symbol on the device label or on the device package that provides notice of the presence of AIDC technology; see proposed § 801.45(c). The symbol may be a

symbol endorsed in an international or national standard recognized by FDA under section 514(c) of the FD&C Act (for example, symbols specified for differing types of RFID systems), a symbol generally recognized by the persons who typically use the device, or the generic symbol shown in proposed § 801.45(c).

8. When Would a Device Have To Be Directly Marked With a UDI?

We restrict our proposed direct marking requirements, proposed § 801.50, to three categories of devices, because these devices present unique risks that we believe would be better controlled through direct marking:

- an implantable device;
- 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.

An implantable device, proposed § 801.50(a)(1)--An implantable device is, by definition, intended to be used for at least 30 days (see the proposed definition of implantable device at § 801.3). Once implanted, the device is separated from its label and labeling, which may prevent accurate identification of the device over time, potentially undermining the accuracy of problem reporting and delaying the identification and resolution of problems with the implanted device. But if the UDI is evident upon explantation of the device, or is retrievable through AIDC technology, it will still be possible to unambiguously identify the implant.

A device that is intended to be used more than once and that is intended to be sterilized before each use, proposed § 801.50(a)(2)--These devices may also be used over an extended period of time, with the need for effective cleaning and sterilization before each new use providing a complicating factor. It is particularly important to understand precisely the identity

of each such device, because effective sterilization methods may be different for different types of devices. If a device is not effectively sterilized, and is then used on a patient, severe harm may result. UDI labeling, and the associated data available from the GUDID, will help ensure device users have the information they need to avoid such harm.

Stand-alone software, proposed § 801.50(a)(3)--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. This includes stand-alone software that meets the definition of “device” under §201(h) of the FD&C Act, e.g., prostate auto-contouring software that assists clinicians in generating estimates of the anatomy boundary contours of the prostate gland in computed tomography scans, magnetic resonance images, and ultrasound scans to aid in patient diagnosis, treatment planning, and post-treatment monitoring. Stand-alone software is unique in that it may be possible to obtain, use, and update it without ever receiving a physical package bearing a physical label. For example, software may be initially obtained via the Internet, and it is very common for patches, updates, and new versions to be provided through the Internet. Furthermore, even when the software is identical to the package and label description, it is typically used only after being installed on a computer (or multiple computers, or on a network) and typically the package and label (and the physical media, such as a CD-ROM or DVD-ROM) are no longer used. Additionally, software may be transferred from one installation to another without any external indication. All of these factors make it highly likely that users of stand-alone software will not have ready access to the package or label, or if they do, that the software differs from the label description. By requiring a simple form of direct marking as part of the software itself, we overcome these problems and ensure that users can readily and precisely

identify stand-alone software. In contrast to stand-alone software, software that is a component of a device will be adequately identified by the UDI on that device's label and package.

The form of direct marking that would be required depends on which of these categories the device falls within. See proposed § 801.50(c). If your device is an implantable device, or is intended to be used more than once and to be sterilized before each use, the direct marking would have to be provided through either or both of the following:

- easily-readable plain-text;
- AIDC technology, or any alternative technology that will allow for identification of the device. Examples include 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 your device is stand-alone software, the direct marking would have to be provided through either or both of the following:

- an easily-readable plain-text statement displayed whenever the software is started;
- an easily-readable plain-text statement displayed in response to a menu command (e.g., an "About * * *" command).

We seek comments about the utility of marking stand-alone software in this manner.

The UDI conveyed by the 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. See proposed § 801.50(b). We permit the use of a different UDI to distinguish the unpackaged device because that is consistent with both current direct marking practices and the objectives of this rule.

The requirement for direct marking of a device would go into effect two years after the date specified by proposed § 801.20 for the device to bear a UDI on its label; see proposed § 801.50(d). We believe this will provide the labeler adequate time to implement an appropriate direct-marking methodology for any device that would be subject to the requirements of proposed § 801.50. We seek comments on whether this is an appropriate amount of time in which to make this provisions effective.

Although our proposed direct marking requirements apply only to the three categories of devices identified by proposed § 801.50(a), we recognize that even within those categories, direct marking will not always be appropriate or feasible. Proposed § 801.50(e) provides reasonable exceptions to the requirement for direct marking; direct marking would not be required when any of the following apply--

- Direct marking would interfere with the safe and effective use of the device; proposed § 801.50(e)(1). For example, it is possible that direct marking would interfere with the safe and effective use of orthopedic bone screws because direct marking could adversely affect the structural integrity of the screw. Direct marking may also interfere with the safe and effective use of instruments used in arthroscopic surgery because direct marking could create irregular surfaces that could reduce the effectiveness of sterilization procedures and harbor bacteria or other pathogens.

- Direct marking is not technologically feasible; proposed § 801.50(e)(2). To be technologically feasible, it must be possible to place a direct marking on the device using readily-available technology, and it must be possible for that direct marking to be read in the environments it is intended to be used, again using readily-available technology (generally meaning technologies that are typically present in the environment where the device is used).

For example, it is not technologically feasible to directly mark polymethylmethacrylate (PMMA) bone cement, classified at § 888.3027, because bone cement is sold in an amorphous state.

Similarly, at the present time it is not technologically feasible to directly mark an aqueous shunt, classified at § 886.3920, because the small size of the device would not permit inclusion of RFID or near-field communication, and any barcode, even if technically possible to apply, would be extraordinarily difficult to read with existing technologies. The technological feasibility of directly marking a device may change over time as new technologies are developed, enabling more direct marking options.

In addition, the “not technologically feasible” exception from direct marking under § 801.50(e)(2) can include circumstances, where, for a very small firm, the capital investment in technology to allow direct part marking so exceeds to benefit of applying the requirement that FDA could find direct part marking to be “not technologically feasible.” Factors to be considered in this instance would include: the number of devices otherwise subject to direct marking across which the capital investment can be amortized, current net earnings on expected sales of such devices, and the number of years required to recover the capital investment based on net earnings. FDA believes, however, when considering whether economic factors justify an exception under the “not technologically feasible” language, FDA should retain discretion to also consider the public health benefits of direct marking for a particular device based on its usage and risks.

- The device is intended to remain implanted continuously for a period of less than 30 days, unless the Commissioner determines otherwise in order to protect human health; proposed

§ 801.50(e)(3). This exception is inherent in the definition of implantable device, but is provided for clarity.

- The device has been previously directly marked; proposed § 801.50(e)(4) We are proposing this exception both because of the practical difficulty and potential for confusion involved in applying a new direct marking when a direct marking already exists, and because multiple markings may compromise the device. We believe that continued use of the original direct marking will provide an adequate means to identify the device through its distribution and use. A labeler may, however, remark a previously-marked device if the labeler concludes, on the basis of its own evaluation, that re-marking the device would not adversely affect the safety or effectiveness of the device.

- The device is sold at retail and bears a Universal Product Code (UPC);

§ 801.50(e)(5).

- The device is software that is not stand-alone software, but is a component of a medical device; § 801.50(e)(6). Examples of a software device that is not stand-alone include software incorporated into devices such as infusion pumps and software integrated and used to control systems such as MRI machines.

If you determine that your device qualifies for an exemption from direct marking, you would have to document the basis of your decision in the design history file as required by § 820.30(j) of the Quality System Regulation, see § 801.50(f). If you determine that your device qualifies for an exemption from direct marking because direct marking would interfere with the safe and effective use of the device, see proposed § 801.50(e)(1), or because you determine the device cannot be marked because it is not technologically feasible, see proposed § 801.50(e)(2),

you would have to send a notice to FDA, see proposed § 801.50(g). Your notice to FDA would have to provide the following information:

- Identification of the exception, or exceptions, authorized by proposed § 801.50(e) that you are invoking.
- An explanation of the factors that make the exception applicable to your device.
- The name of, and contact information for, the person who determined that the exception is applicable to your device.

FDA does not intend to routinely respond to notices submitted under proposed § 801.50(g). If we have a question concerning your notice, we may request additional information, review information in your device history records when we conduct an establishment inspection, or take such other action as may be appropriate.

9. After the Requirement for UDI Labeling Goes into Effect, May I Continue to Identify my Device With The National Health-Related Item Code (NHRIC) or National Drug Code (NDC) Number Assigned to It?

No; see proposed § 801.57. FDA is phasing out the use of NHRIC and NDC numbers to identify medical devices, in favor of the UDI system. On the date your device would have to be labeled with a UDI, any NHRIC or NDC assigned to that device will be rescinded, and you will no longer be permitted to label your device with an NHRIC or NDC. Continued use of NHRIC or NDC codes on device labels and device packages would result in confusion concerning the appropriate identification of the device, and might obscure the distinction between drug and device identification systems. We seek comments on whether there are compelling reasons to continue to permit the use of these numbering systems.

10. Formatting of Dates Provided on Medical Device Labels

Proposed § 801.18 would require all dates provided on medical device labels to conform to a specified format: Month Day, Year, with the month shown as a three-letter abbreviation of the month (e.g. SEP 30, 2012). This format--Month Day, Year (SEP 30, 2012)--is the format most commonly used in the United States and is the format most familiar to patients and consumers. Dates may be printed in any size and font that meet the general labeling requirements of part 801.

When dates are formatted to use only numbers, inconsistencies in formatting from one device to another can lead to confusion concerning the proper interpretation of the date. For example, the expiration date January 12, 2013 may, at present, be expressed as 1-12-2013 (this is the format most commonly used in the United States) or as 12-1-2013 (this is the format most commonly used in Europe). This could cause a patient or a health care professional to mistakenly continue to use the device for more than 10 months past the intended expiration date. Another source of potential confusion is the use of date formats that use only the month and year, such as 12-2011, 12-11, or December 2011. The omission of the precise day of the month creates uncertainty; 12-2011 could indicate that use of the device should cease on the first day of December 2011, or the last day of December 2011. Furthermore, when a date uses a two-digit representation of year, it may not be clear that the number sequence represents a date. Use of a standard format consistent with the usage most often used and most readily recognized by consumers in the United States will eliminate any potential confusion concerning the appropriate interpretation of dates provided on medical device labels. (Ref. 8)

The proposed date format may contribute to more accurate identification of a device by making it possible to distinguish between those devices that have passed an expiration or use-by date and those that have not. More accurate identification would make it easier to both avoid the

risks of using "expired" devices and the costs of premature disposal of devices that have not actually reached an expiration or use-by date.

We provide a limited exception in proposed § 801.18(f) 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 electronic products. We do not believe it is necessary to change this requirement for these products, because that standard uses the month and year of production, which does not involve the potential for confusion that an expiration date or use-by date may present.

Proposed § 801.18 would go into effect one year after we publish a final rule. We believe § 801.18 should be implemented as rapidly as possible because it is designed to correct existing confusion concerning the interpretation of dates on medical device labels. We seek comments on whether this 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.

C. Requirements Relating to Issuing Agencies and Submission of Data to the Global Unique Device Identification Database (Part 830)

New part 830 would provide FDA's requirements for the composition and issuance of UDIs, explain the process FDA would follow to accredit an "issuing agency" to operate a system for the issuance of UDIs, explain when FDA would act as an issuing agency, and would provide requirements pertaining to the GUDID, including when and what data must be submitted to the GUDID and by whom.

1. Definitions

We are proposing, in new § 830.3, definitions for important terms used by FDA's unique device identification system under this rule. The terms proposed for inclusion in § 830.3 are discussed in this section II.C; where a term is also defined in part 801, the definitions are identical.

The following terms would have the same definition in both parts 801 and 830; these terms are discussed earlier in this preamble--

- Automatic identification and data capture (AIDC).
- Device package.
- Expiration date.
- FDA, we, or us.
- Labeler.
- Lot or batch--This definition includes a definition of finished device.
- Specification.
- Shipping container.
- Unique device identifier (UDI).
- Universal product code (UPC).
- Version or model.

The following additional terms are defined in proposed § 830.3--

Issuing agency--This term would mean an organization accredited by FDA to operate a system for the issuance of UDIs. Our proposed rule permits multiple issuing agencies, and under certain circumstances FDA could act as an issuing agency.

Global Unique Device Identification Database or GUDID--This term would mean the FDA-administered database that serves as a repository of information to facilitate the

identification of medical devices through their distribution and use. The device identifier portion of a UDI would not be structured to provide specific information concerning a device; rather, the device identifier would serve as a reference number that would allow you to find information about the device by accessing information reporting to the GUDID. For example, you would not be able to parse out a segment that indicates that the device is a cardiovascular device, or that the device is packaged sterile, or that the device is marketed under a particular FDA premarket submission.

Premarket submission--This term would mean any of the following types of applications:

- premarket approval application--an application for approval of a device submitted under section 515(c) of the FD&C Act.
- product development protocol--the application described in section 515(f) of the FD&C Act.
- premarket report means a report submitted under section 515(c)(2) of the FD&C Act.
- humanitarian device exemption application--an application for approval of a humanitarian use device submitted under section 520(m) of the FD&C Act.
- biologics license application means an application for approval of a device submitted under section 351 of the Public Health Service Act.
- premarket notification submission means a report submitted under section 510(k) of the FD&C Act.
- new drug application for a transitional device means a new drug application for a medical device that was regulated by FDA as a new drug prior to May 28, 1976, the date of enactment of the Medical Device Amendments of 1976.

Small business--This term would mean a medical device manufacturer with 500 or fewer employees, or a medical device relabeler or repackager with 100 or fewer employees. This is consistent with how the Small Business Administration defines "small business" under the Small Business Act (5 U.S.C. 631). We are proposing this definition only to help explain when FDA would act as an issuing agency under proposed subpart D of part 830.

2. What Would Be the Requirements for the Composition and Issuance of a Valid Unique Device Identifier?

In order to ensure that all UDIs will meet the public health objectives of this rule, and to ensure that device user facilities, health care professionals, FDA, and others will be able to make efficient and effective use of the UDI system, we are proposing every UDI must be issued under a system operated by FDA or an FDA-accredited issuing agency, see proposed §§ 830.20(a), and must conform to the international standards that would be incorporated by reference by proposed § 830.10. UDIs would have to be composed only of characters from a single character set defined by one of these incorporated standards; see proposed § 830.20(b). Conformity to these international standards will ensure that each issuing agency's system of assigning UDIs will be broadly compatible and capable of fulfilling our public health objectives.

Incorporation by reference of ISO/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. Incorporation by reference of 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 an Issuing Agency Code (IAC). This assures that multiple issuing agencies can create globally unique identifiers and minimizes the risk of duplicative identifiers. Incorporation by

reference of 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 incorporation by reference of 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.

As explained in section I.B of this document, requiring the use of issuing agencies and conformity with international regulatory cooperation activities and internationally recognized identification standards would best serve the public health objectives of this rule by ensuring the uniqueness, consistency, and broad compatibility of device identification, and avoiding the confusion and inefficiency that would result if every labeler generated their own non-standardized identifiers or if FDA alone issued identifiers.

3. Use and Discontinuation of a Device Identifier

Under proposed § 830.40(a), you 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. If you use systems operated by two or more issuing agencies, you would be permitted to identify that device with one identifier from each system that you use. Under proposed § 830.40(b), you would be prohibited from simultaneously using one device identifier to identify more than one version or model of a device.

If you discontinue a particular version or model of a device, you would be prohibited from reassigning the device identifier to another device; see proposed § 830.40(c). If you re-introduce a discontinued device and no changes have been made that would require a new device identifier, you would be permitted to use the same device identifier that you previously used to identify the device; see proposed § 830.40(c). If your issuing agency ceases to be accredited,

FDA would permit you to continue to label a device using the device identifier issued under the system operated by the issuing agency until such time as this rule requires you to discontinue use of the UDI; see proposed § 830.40(d).

The approach used by proposed § 830.40 is necessary to ensure that each device identifier identifies only one version or model of a device. Use of a given device identifier to identify more than one version or model, or the use of more than one identifier from a particular issuing agency to identify a given version or model, would inevitably lead to confusion in the identification of devices, and would seriously undermine the public health objectives of this rule.

4. What Changes Would Require a New Device Identifier?

It is essential for each distinct version or model of a device to be uniquely identified so that it may be rapidly and accurately distinguished from every other device. You would be permitted to replace one device identifier with another (in other words, discontinue one UDI and begin using another) for a particular version or model of a device for any reason, but you would be required to use a new device identifier in the circumstances discussed under this question 4. The changes that would require a new device identifier are set forth in proposed § 830.50, and include--

- You make a change that has the potential to affect the safety or effectiveness of the device; see proposed § 830.50(c). If a change has the potential to affect safety or effectiveness, it will be important for the health care community to be aware of the change in order to distinguish between the updated version or model and the prior version or model.
- You change from a nonsterile package to a sterile package, or from a sterile package to a nonsterile package; see proposed § 830.50(d). Health care practitioners and patients need to be aware of changes relating to sterility, because of the serious consequences that may result if an

unsterile device is thought to be sterile and is used without undergoing necessary sterilization. Consequently, it is critically important for each sterile and nonsterile version or model of a device to be easily distinguished and correctly identified.

- You change the quantity of devices in a package, which results in a new device package and a new version or model; see proposed §§ 801.3 and 830.50(b). Thus, a different device identifier would be required for an individually packaged device and for a box of five device packages. In order to adequately identify a device throughout distribution and use and to be consistent with current practice and standards, different types of packages would have different identifiers. That way, anyone using the system can know exactly what they sent and received when and can more easily and effectively identify and respond to problems. For example, they would know what to look for if there is a recall or other problems, and would be able to more narrowly target corrective actions by device package.

- You relabel a device that was previously labeled with a UDI by another labeler; proposed § 830.50(e). Because a relabeled device needs to be distinguishable from the version or model that bears the original label and you are responsible for your own labeling, you would not be permitted to use the UDI assigned by the original labeler. In addition, if you relabel a device, proposed § 830.60 would require you to keep a record showing the relationship of the prior device identifier (the identifier assigned by the prior labeler) to the new device identifier (your identifier).

All of these changes would result in a new version or model, and consequently would require a new device identifier; you would not be permitted to continue to use an existing identifier to identify the new version or model.

5. How Would FDA Accredit an Issuing Agency?

An issuing agency would be an FDA-accredited private nonprofit organization or a State agency that operates a system for assignment of UDIs pursuant to this rule. See proposed § 830.100. We selected the term “issuing agency” because it is the term used in the international standards incorporated by reference by proposed § 830.10, and is a term familiar to many labelers. We would require the issuing agency to be a State agency or nonprofit organization in order to minimize potential conflicts of interest and to help assure that the fees assessed are reasonable to small businesses. FDA would accredit a private nonprofit organization or a State agency, see proposed § 830.100(a), if it meets all of the following criteria; see proposed § 830.100(b):

- The system uses UDIs that meet the requirements of the proposed rule to adequately identify a device through its distribution and use. See proposed § 830.100(b)(1).
- The system it operates conforms to the international standards incorporated by reference at proposed § 830.10; see proposed § 830.100(b)(2). Conformance to those standards helps ensure that devices will be uniquely and consistently identified and that each system will be broadly compatible with other systems and will achieve the objectives of this rule.
- The issuing agency makes its system available to all users according to a single set of consistent, fair, and reasonable terms and conditions; see § 830.100(b)(3). This means that the issuing agency would be prohibited from discriminating against, or giving preferential treatment to, a user for any reason that is not directly related to the efficient and orderly operation of the system in a manner that complies with this rule.

An organization or State agency that wishes to be accredited as an issuing agency would have to submit an application to FDA and include all the information listed in proposed § 830.110. This 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. This information is necessary to ensure that each FDA-accredited issuing agency will be capable of effectively managing a system for the assignment of unique identifiers in full compliance with the requirements of this rule.

The initial accreditation will be for a period of 3 years, and renewed accreditation will be for a period of 7 years; see proposed § 830.110(f). 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 six months prior to expiration of its accreditation, see proposed § 830.110(b). These time frames would provide FDA adequate time to evaluate the performance of issuing agencies before each application for renewed accreditation.

Within 60 days of receipt of any application for accreditation, FDA will notify the applicant of any deficiencies and we will request correction of those deficiencies within 60 days. The applicant may request an extension if it needs additional time to correct those deficiencies. If the deficiencies are not resolved to FDA's satisfaction within the specified time period, we may deny the application for accreditation; see proposed § 830.110(c)(2). When we have completed our review, we will notify the applicant whether its application for accreditation has been granted or denied. That notification shall list any conditions associated with approval or state the reasons for denial; see proposed § 830.120(c)(3). If we deny an application for accreditation, we will advise the applicant of the circumstances under which an application may be resubmitted; see proposed § 830.120(c)(4). 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; see proposed 830.120(c)(5).

6. What Would Be the Responsibilities of an FDA-Accredited Issuing Agency?

In order to ensure that all device identifiers are unique and meet the proposed requirements, and that all system users are treated fairly, FDA would need to maintain effective oversight of issuing agencies. Under proposed § 830.120, an issuing agency would be responsible for--

- Operating a system for assignment of UDIs that meets the requirements of proposed § 830.20 and the standards incorporated by reference at proposed § 830.10.
- 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.
- Remaining in compliance with the eligibility and accreditation criteria set forth in proposed § 830.100.

7. How Would an Issuing Agency Relinquish its Accreditation, and How Would FDA Suspend or Revoke an Issuing Agency's Accreditation?

An issuing agency would be permitted to relinquish its accreditation before expiration of its current term of accreditation by submitting a letter stating its intent to FDA at least 9 months before the date it will relinquish its accreditation. See proposed § 830.110(d). If an issuing agency relinquishes its accreditation and duties before expiration of its current term of accreditation, 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 the issuing agency will cease to serve as an issuing agency. See proposed § 830.110(e).

Under proposed § 830.130, FDA may suspend or revoke the accreditation of an issuing agency if we find, 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 outlined in proposed § 830.120; or
- has violated or aided and abetted in the violation of any regulation promulgated pursuant to sections 510(e) or 519(f) of the FD&C Act; these provisions authorize regulations prescribing a uniform system for the identification of devices, and require regulations establishing a unique device identification system.

We modeled these criteria on the approach we use under the Mammography Quality Standards Act, which gives FDA authority to suspend or revoke the accreditation of mammography facilities. See 21 CFR § 900.14.

8. When Would FDA Act as an Issuing Agency?

FDA would act as an issuing agency during any period where there is no accredited issuing agency (for example, if there is no accredited issuing agency by the time UDI labeling requirements go into effect pursuant to proposed § 801.20). See proposed § 830.200(a). In such a circumstance, FDA would have to act as an issuing agency in order for the unique device identification system to function.

FDA would also act as an issuing agency if we determine that a significant number of small businesses would be substantially and adversely affected by the fees required by all

accredited issuing agencies. See proposed § 830.200(b). We have included this provision because we are mindful that small device manufacturers may be concerned that they might face significant, recurring fees required by an issuing agency to participate in its system. We anticipate that issuing agencies will be sensitive to the needs of small businesses, so that FDA will not have to invoke this authority and act as an issuing agency.

If FDA acts as an issuing agency, we would not, under current law, assess a fee for our services. Any labeler would be permitted to use FDA as its issuing agency, regardless of whether the labeler is considered a small business. See proposed § 830.210. If it becomes necessary for FDA to act as an issuing agency, we would expect to issue guidance explaining how FDA's issuing agency would function.

We may end our services as an issuing agency if we determine that the conditions that prompted us to act no longer exist and that ending our services would not be likely to lead to a return of the conditions that prompted us to act. See proposed § 830.220(a). When we end our services as an issuing agency, we would allow a labeler to continue to use a device identifier assigned under FDA's unique device identification system until such time as proposed § 830.50 requires the use of a new device identifier. See proposed § 830.220(b).

9. What Devices Would Be Subject to GUDID Data Submission Requirements?

Under proposed § 830.300(a), any device that would have to be labeled with a UDI under proposed § 801.20 would be subject to GUDID data submission requirements. This would not include a device, other than a prescription device, sold at retail and such devices when delivered directly to a hospital or other health care facility. The UDI itself would not provide any information concerning the device; it would serve as a key to locate information in the GUDID. The labeler would not be required to submit information concerning any device whose label is

not required to bear a UDI because the device is subject to a labeling exception under proposed § 801.30, proposed § 801.35, or proposed § 801.128(f)(2), even when the labeler voluntarily includes a UDI on the label of such a device; see proposed § 830.300(b). When a labeler voluntarily includes a UDI on the label of a device pursuant to proposed § 801.40, the labeler would be permitted, but not required to, submit information concerning that device to the GUDID; see proposed § 830.300(c).

10. Would FDA Ever Reject Data Submitted to the GUDID or Remove Data From the GUDID?

FDA would reject or remove information submitted to the GUDID for any of the reasons outlined in proposed § 830.300(d). These exclusions would prevent misuse of the GUDID for purposes other than those that underlie this rule and would help ensure the accuracy and reliability of information in the GUDID.

We do not intend to remove historical data from the GUDID. Once data has been submitted to the GUDID, unless we act to reject or remove that data pursuant to proposed § 830.300(d), we would retain that data and make it available to the public without regard to whether a device remains in interstate commerce and without regard to any expiration date of a device.

11. What Device Identification Data Would I Have to Submit to the GUDID?

Each labeler would be required to provide minimal information about itself, allowing FDA to communicate with the labeler; see proposed § 830.310(a). For each version or model, the labeler (specifically, the contact for device information) would be required to submit the following information; see proposed § 830.310(b)--

- (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. This would allow us to link all UDIs pertaining to a given device. The requirement will also make it easier to report such changes, because by referencing existing data, only the new identifier will need to be reported, rather than the full data set required for a new device.

(3) If proposed § 801.50 requires the device to bear a UDI as a permanent marking on the device itself, either--

- a statement that the device identifier that appears as a permanent marking on the device is identical to that reported under proposed § 830.310(b)(3)(A), or
- the device identifier portion of the UDI that appears as a permanent marking on the device. We would permit a device marked pursuant to proposed § 801.50 to use a different device identifier than that reported under proposed § 830.310(b)(3)(A) because this approach is already in common use (Ref 7) and the link provided by this reporting requirement will ensure adequate identification of the device.

(4) The proprietary, trade, or brand name of the device as it appears on the label of the device. This, and the following requirement, are very basic, pervasive forms of identification used for practically all devices, and are essential to the adequate identification 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. This information is essential to the adequate identification of the device, because similar devices may be marketed in a sterile form that is essentially ready for immediate use, and in a nonsterile form that requires

the user to sterilize the device prior to use. If a nonsterile device is used on a patient in a situation where sterility is required, serious injury can occur.

(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. This information is essential to the adequate identification of the device, because in many instances a device that contains latex is visually indistinguishable from a similar device that is free of latex. If there is any confusion concerning the presence of latex, there is a risk that a device may be inappropriately used on patients or by users who are sensitive to latex proteins and at risk of severe anaphylactic reaction when exposed to latex proteins.

(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. Confusion concerning the size of a device may result in inappropriate selection and use of a device.

(9) The type of production identifiers that appear on the label of the device. We would not require the reporting of the actual production identifiers to the GUDID. Such an approach would be extraordinarily difficult to administer and would impose significant costs and burdens on labelers. Instead, we would require the labeler to indicate which of the four types of production identifiers the labeler uses to help identify particular devices within a given version or model. By knowing, for example, that a device has an expiration date, a user of that device will be aware that a precise identification of the device will most probably refer to the expiration date. This may be quite important at times, such as when a recall is underway that extends to a certain lot or batch, a certain range of serial numbers, or a certain range of expiration or manufacture dates.

(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. This information is essential to linking data in the GUDID with other existing FDA data sources. This would allow FDA to link the UDI to additional information relevant to the identification of the device, while minimizing the reporting burdens imposed on the labeler.

(11) The FDA listing number assigned to the device. This information is also essential to linking data in the GUDID with other existing FDA data sources.

(12) The GMDN code for the device. GMDN is a comprehensive system of generic descriptors (preferred terms) with definitions used to generically identify medical devices. The main purpose of the GMDN is to provide regulatory authorities and other users with a single naming system that will support patient safety by facilitating data exchange between regulatory authorities, including the exchange of post-market surveillance information. We believe that the use of GMDN in the UDI Database would facilitate the organization of the database and allow users to quickly and efficiently search the database. At this time GMDN data is not available to the public unless a fee is paid to the GMDN Agency. We believe, however, that by the time we publish a final rule, GMDN data will be available to the public at no cost. We will not include this requirement in our final rule if GMDN data is not freely available by the time we publish a final rule.

(13) The number of individual devices contained in each device package. This would allow the GUDID to distinguish among different device packages.

Proposed § 830.310(b) would require information for each version or model of a device, which would include different device packages containing identical devices. To avoid submission of duplicative information, FDA plans to structure the data submission process so

that labelers would only need to provide each piece of information once. For example, if a device is sold in a box of three and a box of five, you would need to provide all of the applicable information that would be required by proposed § 830.310(b) for any one of these device packages. For the other device package (and for any additional device packages added later), you would need to submit only the device identifier portion of the UDI, § 830.310(b)(1), and the number of individual devices in the additional or new device package, § 830.310(b)(13).

12. How Would I Have to Submit Device Identification Data to the GUDID?

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. This contact could be an existing contact, such as the official correspondent of a registered establishment, or any other person. The contact would be responsible for ensuring FDA is provided with all information required by this regulation, but would be permitted to authorize an FDA-accredited issuing agency or some other person to provide information to FDA. See proposed § 830.320(a).

The proposed rule would require electronic submission except where it is not technologically feasible for a labeler to submit information electronically. See proposed § 830.320(b). We expect this will be extraordinarily rare. FDA's current thinking is that we would provide two ways to submit data electronically to the GUDID, and we would describe these methods in a future draft guidance document. We believe this approach will meet the needs of both large and small labelers, will minimize the costs of submitting, receiving, and processing GUDID data, and will ensure a high level of accuracy in the data submitted. We welcome comments on these approaches at this time, and will also solicit comments in any future draft guidance on this issue.

The two submission methods we are considering are--

- Data could be submitted as part of a structured product label (SPL) conforming to an ANSI/Health Level Seven (HL7) format (Ref. 7) that meets specifications set by FDA. We believe this is the approach most larger labelers would prefer, as it is based on an existing international standard that can readily accommodate the efficient submission of multiple records. HL7 SPL is already used for submission of data to FDA, so many labelers are already familiar this approach and would face only minimal difficulty in adapting it for submission of UDI data.
- Each data element could be entered directly into the GUDID through a secure Internet site designed for simple, low-volume data entry with on-line help, similar to the approach currently used for electronic registration and listing. We believe this approach may be preferred by some small labelers that would need to provide data for only a few devices.

We would allow each labeler to use either, or both, of these methods. We intend to provide the GUDID system with a means of detecting erroneous or non-compliant data entry; for example, if you try to submit a device identifier that does not conform with the international standards incorporated by reference at proposed § 830.10, we would reject that submission.

13. When Would I Have to Submit Device Identification Data to the GUDID?

You would first have to submit data concerning a version or model of a device to the GUDID no later than the date the label of the device must bear a UDI; see proposed § 830.330(a). Proposed § 801.20 phases in our UDI labeling requirements over several years, and consequently proposed § 830.330(a) would phase in the rule's data submission requirements following the same schedule. See table 7 of this document, Effective Dates of UDI Regulatory Requirements for an overview of how we would phase in these requirements. A labeler who wishes to submit information concerning a device prior to the effective date under proposed

§§ 801.20 and 830.330(a) may submit a request to FDA to do so. FDA will accommodate such requests when consistent with our ability to process the additional information in an orderly manner.

Once your device becomes subject to UDI labeling and GUDID data reporting requirements, you would be required to update the information you reported to the GUDID whenever the information changes. The 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 label of a device (e.g., the Global Medical Device Nomenclature generic descriptor or the FDA device listing number), the update would have to be submitted within 10 days of the change. See proposed § 830.330(b).

14. Would I Be Permitted to Submit Information to the GUDID That is Not Required by FDA?

Under our proposal, you would not be permitted to submit any information to the GUDID other than that required by proposed § 830.310, except where FDA acts to permit the submission of specified additional information, termed ancillary information; see proposed § 830.340(a). We will provide information concerning the ancillary information that we will accept through the GUDID Web site; see § 830.340(b). You would be permitted, but would not be required, to submit any or all of the ancillary information identified by FDA. We may periodically change the ancillary information that may be submitted to the GUDID; we would announce any change at least 60 days before the change takes effect; see proposed § 830.340(c).

15. What Records Would a Labeler Be Required to Maintain Concerning its UDIs?

Each labeler would be required to retain records linking all UDIs to the associated version or model; see proposed § 830.350. The records would have to be retained until three years after the date the labeler ceases to market the version or model. This will ensure that the

information is readily available to the labeler and to FDA, for example, if needed to conduct a recall or take other corrective actions regarding one version or model or more of a device.

Compliance with this section would not relieve the labeler of the need to comply with recordkeeping requirements of any other FDA regulation.

16. Who Would Have Access to the Information I Submit to the GUDID?

We have determined that free, easy, and unlimited access to information in the GUDID is essential to the adequate identification of devices through their distribution and use, that health care professionals, patients, and the general public all have substantial needs for access to such information, and that the public health objectives of this rule would be significantly harmed if we attempted to impose any restrictions on access. Consequently, FDA intends to post all information in the GUDID (with one exception, discussed at the end of this paragraph) on our Web site so that it will be readily available to the public, and we intend to include features in the UDI Web site to facilitate inquiries concerning a specific device and searches for general or specific information. This includes information that you would be required to submit pursuant to proposed § 830.310 and ancillary information that you would be permitted to submit pursuant to § 830.340. We have determined that none of the information that would be required to be submitted under this rule would constitute trade secret, confidential commercial information, or personal privacy information, or would otherwise be prohibited from public release. We would not add any categories of ancillary information that might include information that is prohibited from public disclosure. The one type of information we would not post is listing numbers because they 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.

D. Conforming Amendments

We are proposing several conforming amendments to explain how we will integrate the use of UDIs and device identifiers, and data from the UDI system's GUDID, into FDA's existing regulatory systems and processes. These amendments are identified and briefly discussed in this section II.D.

Part 16, Regulatory Hearing Before the Food and Drug Administration.

We propose to amend part 16 (21 CFR part 16) to state that an informal regulatory hearing is available when FDA acts under § 830.130 to suspend or revoke the accreditation of an issuing agency.

Part 803, Medical Device Reporting.

We propose to amend §§ 803.32, 803.42, and 803.52 to require UDIs to be included in individual adverse event reports submitted by device user facilities, importers, and manufacturers. We also propose to 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.

Part 806, Medical Devices; Reports of Corrections and Removals.

We propose to 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.

Part 810, Medical Device Recall Authority.

We propose to amend § 810.10(b)(2) to indicate that FDA will include UDIs, when known, in the "pertinent descriptive information" we provide in a cease distribution and notification order issued under FDA's recall authority.

Part 814, Premarket Approval of Medical Devices.

We propose to 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. This would not require any periodic report to include information concerning device identifiers discontinued prior to the effective date of a final rule. We are proposing this change to help ensure that UDIs and UDI data for class III devices are reported to the GUDID. This data will help device reviewers process PMA supplements and related PMAs more rapidly by making it easier to integrate relevant data into their reviews.

Part 820, Quality System Regulation.

We propose to 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.

We propose to amend § 820.184(f) to clarify that the device history record is to include any UDI or UPC that is used to identify the device. We regard this amendment as a clarification, as § 820.184(f) already requires the device history record to include “[a]ny device identification(s) and control number(s) used,” and both a UDI and a UPC are within the scope of that requirement.

We propose to amend § 820.198(e)(3) to clarify that complaint records are to include any UDI or UPC that is used to identify the device. We regard this amendment as a clarification, as § 820.198(e)(3) already requires the complaint record to include “[a]ny device identification(s) and control number(s) used,” and both a UDI and a UPC are within the scope of that requirement.

We propose to amend § 820.200(d)(2) to clarify that a service report is to include any UDI or UPC that is used to identify the device. We regard this amendment as a clarification, as § 820.198(d)(2) already requires the service report to include “[a]ny device identification(s) and control number(s) used,” and both a UDI and a UPC are within the scope of that requirement.

Part 821, Medical Device Tracking Requirements.

We propose to 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 of the devices.

We propose to 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.

We propose to 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.

Part 822, Postmarket Surveillance.

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

III. Legal Authority for the Proposed Rule

Section 226 of FDAAA, Public Law No. 110-85 (2007), amended the FD&C Act by adding a new section 519(f) (21 U.S.C. 360i(f)). This section provides for FDA to issue regulations establishing a unique device identification system for medical devices. In addition, section 510(e) of the FD&C Act (21 U.S.C. 360(e)) authorizes FDA to issue regulations to “prescribe a uniform system for identification of devices” and to require persons to “list such

devices in accordance with such system.” Therefore, FDA is issuing the provisions of this proposed rule that would establish a unique device identification system under sections 510(e), 519(f), and 701(a) (21 U.S.C. 371) of the FD&C Act (which provides FDA the authority to issue regulations for the efficient enforcement of the FD&C Act).

Devices for which there has been a failure or refusal to furnish any material or information required by or under section 519 respecting the device are misbranded under section 502(t)(2) of the FD&C Act, 21 U.S.C. 352(t)(2). The failure or refusal to furnish any material or information required by or under section 519 of the FD&C Act is a prohibited act under section 301(q)(1)(B) of the FD&C Act (21 U.S.C. 331(q)(1)(B)).

Section 701(a) of the act (21 U.S.C 371(a)) gives FDA the authority to promulgate regulations for the efficient enforcement of the act in order to "effectuate a congressional objective expressed elsewhere in the Act" (Association of American, Physicians and Surgeons, Inc. v. FDA, 226 F. Supp. 2d 204 (D.D.C. 2002) (citing Pharm. Mfrs. Ass'n. v. FDA, 484 F. Supp. 1179, 1183 (D. Del. 1980)). By requiring a UDI to appear on the label of devices, and by establishing the GUDID, the proposed rule is designed to improve the accuracy and precision of adverse event reporting, as required by section 519(a) and (b) of the FD&C Act, which will enable FDA to more quickly and precisely identify device problems, such as safety and/or effectiveness concerns. Once a problem is identified, whether through improved reporting or otherwise, the presence of the UDI on the device label, packaging, and in the GUDID will enable FDA to more efficiently and effectively respond, and protect the public health by addressing the problem using one or more of the regulatory tools that Congress has provided for this purpose, such as notification or mandatory recall under section 518 of the FD&C Act (21 U.S.C. 360h), tracking under section 519(e) of the FD&C Act, ensuring the adequacy of a voluntary recall with

the assistance of reports of corrections and removals as required by section 519(g) of the FD&C Act, or seizing a device that is adulterated under section 501 of the FD&C Act (21 U.S.C. 351) and/or misbranded under section 502 of the FD&C Act (21 U.S.C. 352).

Section 510(j) of the FD&C Act (21 U.S.C. 360(j)) requires listing information to be accompanied by, at minimum, the label, package insert, and a representative sampling of any other labeling for the device; see section 510(j)(1)(B)(ii). For certain categories of devices, all labeling must be submitted; see section 510(j)(1)(A) and (j)(1)(B)(i) of the FD&C Act. We expect most of the information that would be required to be submitted to the GUDID, see proposed § 830.310, is information that appears on the device label or in the package insert, and is included in the information that is required to be submitted to FDA by section 510(j) of the FD&C Act.

The provisions of the proposed rule that would require UDIs to be included in various records and reports, allow the use of UDIs to identify devices subject to reports of corrections and removals and records of corrections of removals that are not required to be reported to FDA, and require reporting of UDIs in periodic reports for class III devices, are issued under the authority of sections 519 and 701(a) of the FD&C Act.

The provisions of the proposed rule that would amend the QSR by requiring examination of the accuracy of the UDI as part of the scope of the labeling inspection, that the device history record include any UDI or UPC, that complaint records include any UDI or UPC, and that the service report include any UDI or UPC, are issued under sections 520(f) and 701(a) of the FD&C Act.

The provisions of the proposed rule that would require the inclusion of UDIs on reports regarding tracked devices is authorized by sections 519(e) and 701(a) of the FD&C Act.

Finally, the provision of the proposed rule that would require that postmarket surveillance plans submitted to FDA include the device identifier of the devices involved is issued under sections 522 (21 U.S.C. 360l), and 701(a) of the FD&C Act.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we are uncertain whether the proposed rule would have a significant economic impact on a substantial number of small entities, this and other sections of the preamble and the full RIA (Ref. 10) constitute the Agency's regulatory flexibility analysis.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$139 million, using the most current (2011) Implicit Price

Deflator for the Gross Domestic Product. The estimated costs of this proposed rule would result in a 1-year expenditure that exceeds this amount.

This proposed rule would require the label and package of medical devices to bear a unique device identifier 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 throughout the required recordkeeping and reporting systems would need to be modified to include the UDI. Under this proposed rule FDA would establish the GUDID, a public database containing information about devices labeled with a UDI. The proposed rule would require labelers of medical devices to submit information concerning each device to the GUDID. In addition, the proposed rule would also establish the accreditation requirements for agencies that may operate a system for the issuance of UDIs and establish the conditions for when FDA might act as an issuing agency.

A. Summary of Costs

The detailed data for this cost analysis were developed by ERG under contract to FDA and are presented in the full report “Unique Device Identification (UDI) for Medical Devices,” 2011 (cited in Ref. 10).

Table 3 of this document presents for each affected sector a summary of the estimated present value and the annualized domestic costs of this proposed rule over 10 years using discount rates of 7 percent and 3 percent. Over 10 years, the present value of the domestic costs would be \$514.0 million using a 7 percent discount rate and \$588.6 million using a 3 percent rate, and the annualized costs would be \$68.4 million using a 7 percent discount rate and \$66.9 million using a 3 percent discount rate.

Table 3.--Summary of the Estimated Regulatory Costs of the Proposed Rule (2010 dollars)¹

Affected Sectors	Total Present Value of Cost over 10 Years (\$ million)		Total Annualized Costs Over 10 Years (\$ million)	
	3 Percent	7 Percent	3 Percent	7 Percent
Domestic Labelers	\$571.5	\$499.4	\$65.0	\$66.5
Issuing Agencies	\$1.0	\$0.9	\$0.1	\$0.1
FDA	\$16.1	\$13.7	\$1.8	\$1.8
Imports	Not quantified	Not quantified	Not quantified	Not quantified
Total Domestic Cost of the Proposed Rule	\$588.6	\$514.0	\$66.9	\$68.4

¹ Present value and annualized costs calculated at the beginning of the period.

1. Costs to Domestic Labelers

The majority of the costs of this proposed rule would be incurred by labelers of medical devices. Labelers include manufacturers, reprocessors, specification developers, repackagers and relabelers that cause a label to be applied to a medical device. The estimated present value of the costs for domestic labelers over 10 years would be \$499.4 million at a 7 percent discount rate and \$571.5 million at 3 percent. Over 10 years, the annualized costs for domestic labelers would be \$66.5 million at a 7 percent discount rate and \$65.0 million at 3 percent. 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. In addition, other significant components of one-time costs include costs to redesign labels of devices to incorporate the date format within 1 year and to allow space for the UDI barcode, and 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.

2. Costs to Issuing Agencies

The estimated present value of costs over 10 years for two existing organizations, currently performing functions similar to those of an issuing agency under the proposed rule, to apply for FDA accreditation and comply with the proposed reporting requirements would be \$0.9 million at a 7 percent discount rate and \$1.0 million at 3 percent. The annualized costs over 10 years would be \$0.1 million at both 7 percent and 3 percent discount rates. In addition to these two organizations, there may be other nonprofit organizations or State agencies that might apply to FDA to become an issuing agency. In such cases, the estimated application preparation, legal, and reporting costs would apply to other organizations.

3. Costs to FDA to Establish and Maintain the GUDID

The estimated present value over 10 years of the costs to FDA to establish and maintain the GUDID would be \$13.7 million at a 7 percent discount rate and \$16.1 million at 3 percent. The annualized costs over 10 years would be \$1.8 million at 7 percent and 3 percent.

4. Costs to Foreign Labelers

We lack sufficient information to quantify the potential impact of the proposed rule on foreign establishments and thus exclude these establishments from our cost estimate. However, we include a qualitative discussion of the potential impact of this rule on trade and the cost of imported products, whose value is about one-fourth the value of domestic production. We request comment from affected industries about their expected compliance costs and responses to the proposed rule.

5. Uncertainty

In this analysis, the lower and upper bounds of uncertainty surrounding the central estimate of the costs to domestic labelers are about 50 percent lower and 50 percent higher, respectively. Applying a similar range of uncertainty to the total costs of the proposed rule to domestic labelers, issuing agencies, and the FDA, over 10 years the total annualized domestic costs would range from \$34.9 million to \$101.8 million at 7 percent and \$34.1 million to \$99.7 million at 3 percent.

6. Alternatives

The Agency analyzed a number of alternatives with varied requirements affecting the coverage of devices, the content of the information required to be encoded in a UDI, and specific provisions of the proposed rule. With respect to device coverage, we analyzed applying the UDI requirements to class III devices only, and to class II and III devices only. The Agency also analyzed costs for requiring the UDI to contain only the device identifier across all device classes. Also included was an alternative that required a UDI labeling change without requiring the submission of data to the GUDID.

Over 10 years at 7 percent, the annualized present value of the highest cost alternative is about \$95 million. This alternative would apply the UDI requirements to class I, II and III devices, as well as unclassified devices, unless excepted by proposed 801.30(a)(3)–(12). The lowest cost alternative would apply the UDI requirements to class III devices only. The annualized present value of this alternative is about \$11 million.

B. Summary of Regulatory Flexibility Analysis

FDA conducted a regulatory flexibility analysis of the impact of the proposed rule on small entities. Ninety-six percent of the 4,693 affected labeler firms (i.e., 4,483 firms) are small

according to Small Business Administration (SBA) size standards. 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. Moreover, 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. If direct marking of devices were not required, no firms would experience costs exceeding 1 percent of revenues.

C. Summary of Benefits

The proposed rule would standardize how medical devices are identified and would contribute to future potential public health benefits from initiatives associated with the increased use of automated systems in healthcare. Most of these benefits, however, require complementary developments and innovations in the private and public sectors, and investments by the healthcare industry that are beyond the scope of this rule. Because such actions are uncertain, we restrict our discussion of the potential public health benefits to those most likely to occur as results of probable responses to the proposed rule in the private and public sectors.

The public health benefits from the UDI would be related to reductions in medical device-related patient injuries and deaths. More accurate and prompt identification of problems would enable more rapid action to reduce the incidence of the adverse events. Public health safety alerts, for example, could be more accurate and timely. Recall actions could more effectively target the problem device. The increased accuracy of adverse medical device reporting and improved recalls should reduce the total number of adverse medical device events, although we are unable to quantify that reduction.

FDA presents the required ROCIS accounting information in table 4 of this document.

Table 4.--Economic Data: Costs and Benefits Accounting Statement (2010 dollars)

Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes
				Year Dollars	Discount Rate	Period Covered	
Benefits							
Annualized Monetized \$millions/year					7%		
					3%		
Annualized Quantified					7%		
					3%		
Qualitative	More accurate and prompt identification of device related adverse events would lead to more rapid action to reduce the incidence of the adverse events and to more effectively target and manage medical device recalls.						
Costs							
Annualized Monetized \$millions/year	\$68.4	\$34.9	\$101.8	2011	7%	10 years	Costs to foreign labelers are not included.
	\$66.9	\$34.1	\$99.7	2011	3%	10 years	
Annualized Quantified					7%		
					3%		
Qualitative							
Transfers							
Federal Annualized Monetized \$millions/year					7%		
					3%		
From/ To	From:			To:			
Other Annualized Monetized \$millions/year					7%		
					3%		
From/To	From:			To:			
Effects							
State, Local or Tribal Government: No effect							
Small Business: The proposed rule may have a significant economic impact on a substantial number of small entities that label medical devices.							
Wages: No effect							
Growth: No effect							

The full discussion of the economic impacts (Ref. 10) is available in docket FDA-2011-N-0090 and at

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

V. Information Collection Requirements

This proposed rule contains information collections that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (the PRA). A description of these provisions is given below with an estimate of the reporting, recordkeeping, and third party disclosure burden. It should be noted that the burden assumptions for some of these requirements reflect one possible manner of compliance, and have only been identified for the purposes of estimating the PRA burden.

FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Description of Respondents: The recordkeeping, reporting, and third-party disclosure requirements referenced below are imposed on 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. In most instances, the labeler would be the device manufacturer, but the labeler may be a

specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler. Respondents may also include any private nonprofit organization or State agency that applies for accreditation by FDA as an issuing agency.

Requirements Reflected in the Burden Estimates: FDA has identified the following requirements as having burdens that must be accounted for under the PRA; the burdens associated with these requirements are summarized in the tables that follow:

- (1) Proposed § 801.18 Format of dates provided on a medical device label.
- (2) Proposed § 801.20 Label to bear a unique device identifier.
- (3) Proposed § 801.35 Request for an exception from or alternative to the requirement for the label of a device to bear a unique device identifier.
- (4) Proposed § 801.40 Voluntary labeling of a device with a unique device identifier.
- (5) Proposed § 801.50 Devices that must be directly marked with a unique device identifier.
- (6) Proposed § 830.60 Relabeling or modification of the label of a device that bears a UDI.
- (7) Proposed § 830.110 Application for and renewal of accreditation as an issuing agency.
- (8) Proposed § 830.120 Responsibilities of an issuing agency.
- (9) Proposed § 830.310 Information required for unique device identification.
- (10) Proposed § 830.320 Submission of unique device identification information (Waivers).
- (11) Proposed § 830.350 Records to be maintained by the labeler.
- (12) Proposed conforming amendments to Part 803--Medical Device Reporting
- (13) Proposed conforming amendments to Part 806--Reports of Corrections and Removals.
- (14) Proposed conforming amendments to Part 814--Premarket Approval of Medical Devices
- (15) Proposed conforming amendments to Part 820--Quality System Regulation
- (16) Proposed conforming amendments to Part 821--Medical Device Tracking Requirements
- (17) Proposed conforming amendments to Part 822 --Postmarket Surveillance

Table 5.--1ST Year Estimated Burdens¹

	No. of Respondents ²	No of Responses per Respondent ³	Total Annual Responses ⁴	Average Burden per Response (in hours) ⁵	Total Hours ⁶
Reporting	372	102	37,938	0.070 [4 minutes]	2,662
Recordkeeping	366	371	135,652	0.081 [5 minutes]	11,055
Third-Party Disclosure (UDI)	359	5,304	1,905,303	0.012 [1 minute]	23,790
Third-Party	6,199	102	632,298	1.000	632,298

Disclosure (Date Format)				[60 minutes]	
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¹ Table 5 shows the burden to labelers affected in the first year.

² Maximum No. of Respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.

³ Maximum No. of Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer responses.

⁴ Maximum Total Annual Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

⁵ Rounded to three decimals. Total Hours reflects a more precise, non-rounded Average Burden per Response. An approximate (non-rounded) conversion to minutes is shown in square brackets.

⁶ Total Hours is based on a more precise Burden per Response than the rounded value shown in these tables.

Table 6.--Ongoing Estimated Annual Burdens

	No. of Respondents ¹	No of Responses per Respondent ²	Total Annual Responses ³	Average Burden per Response (in hours) ⁴	Total Hours ⁵
Reporting	6,199	51	316,149	0.023 [1 minute]	7,289
Recordkeeping	5,987	51	305,337	0.989 [59 minutes]	302,121
Third-Party Disclosure	5,987	51	305,337	0.885 [53 minutes]	270,143

¹ Maximum No. of Respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.

² Maximum No. of Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer responses.

³ Maximum Total Annual Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

⁴ Rounded to three decimals. Total Hours reflects a more precise, non-rounded Average Burden per Response. An approximate (non-rounded) conversion to minutes is shown in square brackets.

⁵ Total Hours is based on a more precise Burden per Response than the rounded value shown in these tables.

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). A copy of the supporting statement for this information collection will be available on the Internet at <http://www.reginfo.gov/public/do/PRAMain> and will be posted to the docket at

<http://www.regulations.gov>, in docket FDA-2011-N-0090 (Ref. 11). Please email comments to

the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for FDA, oir_submission@omb.eop.gov. Please send a copy of your comments to FDA, using one of the methods described under ADDRESSES at the beginning of this document. Interested persons are requested to email comments regarding information collection by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

VI. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Proposed Effective Dates

FDA proposes that any final rule based on this proposal become effective as summarized in the following table of this document.

Table 7.--Effective Dates of UDI Regulatory Requirements

Effective Date	Requirement
Immediately upon publication of a final rule.	Requests for an exception or alternative to UDI labeling requirements may be submitted pursuant to § 801.35.
	§§ 830.100 - 830.130 (subpart C of part 830, concerning accreditation of issuing agencies) and § 830.10 (incorporation by reference of certain standards) go into effect. This will allow applications for accreditation as an issuing agency to be submitted to FDA immediately.
One year after publication of a final rule	Dates on medical device labels must be formatted as required by § 801.18.
	The label and package of class III medical devices and devices licensed under the Public Health Service Act must bear a UDI. § 801.20(b)(1).
	Data for class III devices and devices licensed under the Public Health Service Act that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
Three years after publication of a final rule	Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is 1) an implantable device, 2) a device intended to be used more than once and intended to be sterilized before each use, or 3) stand-alone software regulated as a medical device. § 801.50.
	The label and package of class II medical devices must bear a UDI. § 801.20(b)(2).
	Data for class II devices that are required to be labeled with a UDI, must be submitted to the GUDID database. § 830.320.
Five years after publication of a final rule	Class II devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is 1) an implantable device, 2) a device intended to be used more than once and intended to be sterilized before each use, or 3) stand-alone software regulated as a medical device. § 801.50.
	The label and package of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. § 801.20(b)(3), (4).
	Data for class I devices and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.320.
Seven years after publication of a final rule	Class I devices and devices that have not been classified into class I, class II, or class III required to be labeled with a UDI must bear UDI as a permanent marking on the device itself if the device is 1) an implantable device, 2) a device intended to be used more than once and intended to be sterilized before each use, or 3) stand-alone software regulated as a medical device. § 801.50.
90 days after publication of a final rule	All other provisions go into effect, although some will have no practical effect until other provisions listed in this table go into effect.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as

defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Request for Comments

A. Submission of Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

B. Specific Questions

FDA is seeking comment on questions that may affect requirements we include in a final rule. You do not need to respond to any of these questions in order to submit a comment; you may respond to any, all, or none of these questions, and you may submit comments on any topic relating to the purposes of this rule, regardless of whether a topic is addressed by these questions. Objectives of the UDI System and Potential Uses of UDIs.

Section I.A of this document discusses the objectives of the UDI system and some of the 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.

The proposed rule phases in its requirements over several years; see table 7 of this document for a summary of the 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.

The proposed effective date for the requirement to provide dates on medical devices that conform to a specific format, is 1 year after the publication of the final rule. Not all device labels would require date format changes.

3. Will the 1-year effective date result 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

The proposed rule would require the label of each medical device and device package to bear a UDI, except where an exception is available or FDA has authorized an alternative; see proposed § 801.20. The rule would further require that every UDI be provided in two forms: an easily-readable plain-text form and through inclusion of AIDC technology (e.g., a bar code, RFID tag, or any other technology) that conveys the equivalent of the UDI; see proposed § 801.45.

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.

We propose to require a UDI for every combination product for which the primary mode of action is that of a device. See proposed § 801.25(a). Furthermore, we propose to require a UDI for each device constituent part of a combination product, regardless of whether a UDI is required for the combination product, except for a device constituent part that is physically, chemically, or otherwise combined with other constituents of a 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. See proposed § 801.25(b).

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

Proposed § 801.25(a) would require a UDI on the label and device package of every combination product whose primary mode of action is that of the device. A combination product

whose primary mode of action is that of the drug or biologic would not be subject to this requirement, but would be subject to drug and biologic labeling requirements. Many, but not all, drugs and biologics must include a barcode on the product's label. See 21 CFR 201.25. The barcode must contain, at a minimum, the appropriate NDC. See 21 CFR 201.25. FDA has also proposed a rule that would require an NDC in human readable form on the label of certain drugs and biologics. See 71 FR 51276, August 29, 2006. When an NDC is present, FDA intends to make it possible to determine whether the combination product has a device constituent part and, if so, the identity of each device constituent part. However, if a combination product has a primary mode of action of a drug or biologic but is not required to include an NDC, there will be a gap in the medical community's ability to easily and accurately identify any devices within a combination product without opening the package and examining its contents; device constituent parts within this labeling gap will not be subject to the same benefits this rule offers for other devices.

We may be able to fill this labeling gap by requiring a UDI for 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.

Only in those circumstances would a UDI not be required on the label and package of the combination product. Such a provision would ensure that there is always either an NDC or a UDI on every combination product, and would facilitate the identification of those combination products that would otherwise not be labeled with either an NDC or UDI identifier. This alternative would not interfere with any future FDA initiative to require NDCs on any

combination product (because, if a product bears an NDC, the alternative provision would not require a UDI on the combination product).

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.

We propose to require a UDI on each convenience kit and each device in a convenience kit, except for single use devices. The reason for requiring a UDI on each device in a convenience kit is that such devices often become separated from the convenience kit, and are then put to use. Some convenience kits, such as a basic first aid kit, may include devices that do bear a UDI because of the exception of proposed § 801.30(a)(11); that exception would exempt a device packaged in a convenience kit from our UDI labeling requirements if that device is intended for a single use.

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 of the exception of proposed § 801.30(a)(11))?

Direct marking.

We propose to require certain medical devices to bear a UDI as a “direct marking” on the device. The devices that would be subject to this requirement are: (1) an implantable device; (2) a device that is intended for more than one use, and that is intended to be sterilized before each use; and (3) stand-alone software. We provide alternatives to direct marking in proposed § 801.50(e) and exceptions in § 801.50(f).

Direct marking will help ensure the accurate identification of the device, even if separated from its label and labeling. We would not require direct part marking of all devices, because we believe the costs and challenges of such an approach substantially exceed the potential benefit to the UDI system.

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.” The exception provided by proposed § 801.50(e)(6) makes it clear that “stand-alone software” 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 software 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.

Proposed § 801.30 provides categorical exceptions to the requirement for a device to bear a UDI, and proposed § 801.35 provides for case-by-case exceptions and alternatives to the UDI regulatory system. Procedures for requesting an exception or alternative are provided at proposed § 801.35(a).

16. Are any of the categorical exceptions provided by proposed § 801.30 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 the exception provided by proposed § 801.30(a)(1), a class I device that FDA has exempted from our GMP requirements would not be required to bear a UDI. To help reviewers understand the scope of this exception, we have provided a list of class I devices, by product code, that currently would qualify for this exception; see Ref. 9. Our questions regarding this exception are: 18.1. Is this exception — for class I devices that are exempt from

GMP requirements — appropriate? 18.2. Referring to the devices listed in reference 10, are there any devices for which this exception is not appropriate and which should be required to bear a UDI? 18.3. Are there other class I devices that are exempt from GMP requirements that do not appear to have been identified in the reference 10 list?

19. Class I devices are very diverse, and include devices available only at retail, basic but critical dental and surgical instruments and medical equipment, and products used in testing and diagnosis. Under proposed 801.30(c), we propose 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. For example, devices, including class I devices sold at retail like dental floss, menstrual pads, hot/cold compresses, adhesive bandages, reading glasses, and sunglasses are exempt under proposed 21 CFR 801.30(a)(1). Although Class I devices are generally low risk or very well understood devices, we note 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 comment 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 procedure in proposed § 801.35(a) provide a reasonable basis for accommodating requests for exceptions from, or alternatives to, the general rule for UDI labeling?

Form of a Unique Device Identifier.

We propose to require use of AIDC technology whenever a device is labeled with a UDI. We do not specify what technology may be used. Our intent is to allow for the advancement of such technologies, leaving the decision to the healthcare community and issuing agencies. When the AIDC technology is not visible on the label or package (e.g., an RFID tag or near-field communication), the label would have to include a symbol that provides notice of the presence of the AIDC technology.

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?

22. We propose to permit use of a generic symbol to provide notice of the presence of AIDC technology that provides a UDI:



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 those recognized symbols when that form of AIDC technology is used?

Roles of the Issuing Agency.

We are proposing a system that would permit multiple issuing agencies to offer differing UDI systems, so long as each system meets our UDI system requirements (see proposed § 801.45, Form of a UDI, and proposed § 830.20, Requirements for a unique device identifier).

This is intended to allow for competition, which may have benefits, both in terms of UDI system features and the costs to device labelers.

23. Do the accreditation requirements outlined in proposed § 830.100 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.

We are proposing to require an issuing agency to be either a private nonprofit organization or a State agency. The reason for this is to minimize potential conflicts of interest and to help assure that the fees assessed by an issuing agency are reasonable to small businesses.

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

Data Submission Requirements and the GUDID.

Proposed § 830.330 would require each device labeler to designate a contact who would be responsible for providing FDA with information relating to the identification of the labeler's medical devices. For each device labeled with a UDI, the contact would have to provide information concerning the labeler and each version or model of a device labeled with a UDI.

27. If you believe any of the information that would be required by proposed § 830.330 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:

- a. Prescription and/or over-the-counter;
- b. Magnetic Resonance Imaging (MRI) Compatibility Type (safe, unsafe, conditional); if conditional, the description of the conditions;
- c. Storage and handling conditions (e.g., maximum storage temperature, needs to be refrigerated, keep out of light);
- d. Country of origin, manufacturer, and/or intended sale
- e. Short and/or long descriptions
- f. Marketed for home use
- g. Labeled as hazardous
- h. Contains radioactive isotopes (radioactive element and atomic number)
- i. 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 (proposed § 830.310), or should it be collected on a voluntary basis as ancillary information (proposed § 830.340)?

We are proposing to require submission of UDI data no later than the date the label of the device must bear a UDI. See proposed § 830.330. We believe that the availability and speed of Internet connections makes any delay unnecessary and counterproductive.

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.

Our proposed rule does not specify the process for the electronic submission of information to the GUDID. Instead, we plan to explain the submission process in guidance. Our current thinking is that we would provide two ways to submit data to the GUDID:

- Data could be submitted as part of a structured product label (SPL) conforming to an ANSI/Health Level Seven (HL7) format (Ref. 7) that meets specifications set by FDA; we believe this is the approach most larger labelers would prefer, as it is based on an existing international standard that is already used for submission of data to FDA, and can readily accommodate the efficient submission of multiple records.

- Each data element could be entered directly into the GUDID through a secure Internet site designed for simple, low-volume data entry with on-line help, similar to the approach currently used for electronic registration and listing; we believe this approach may be preferred by some small labelers that would need to provide data for only a few devices.

30. Do these two 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.

Proposed § 801.18 would require all dates provided on medical device labels to conform to a specified format: Month Day, Year, with the month shown as a three-letter abbreviation of the month (e.g. SEP 30, 2011). This is the format most commonly used in the United States. But internationally, a different format--Day Month Year (30 SEP 2011)--is more prevalent.

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 (e.g., SEP 30, 2011), or the “international” format (e.g., 30 SEP 2011)?

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

X. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register).

1. See referenced ISO standards and ISO Technical Committees listed at http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=45332.

2. For information about UPC and other barcodes and GS1, go to <http://www.gs1us.org/standards/barcodes>.
3. “The Health Industry Bar Code (HIBC) Supplier Labeling Standard,” ANSI/HIBC 2.3-2009, Health Industry Business Communications Council, 2009, at <http://www.hibcc.org/AUTOIDUPN/ANSI%20HIBC%202.3%20SLS%202009.pdf>.
4. “Automatic Identification of Medical Devices,” ECRI Institute, August 17, 2005.
5. See record and public comments related to the October 25, 2006, and February 12, 2009, public meetings, referenced at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/>.
6. See ERG’s 2006 report at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm054169.htm>.
7. See discussion of HL7 implementation of SPL model for medical product information at [http://wiki.hl7.org/index.php?title=Medical_Product_Information_\(SPLr5\)](http://wiki.hl7.org/index.php?title=Medical_Product_Information_(SPLr5)).
8. Letter from Michael D. Maves, MD, MBA, Executive Vice President and CEO, American Medical Association, regarding confusion caused by inconsistencies in the presentation of expiration dates on medical devices, August 27, 2008.
9. 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.

10. Unique Device Identification System; Proposed Rule: Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis.

11. Supporting Statement for Unique Device Identification (UDI) System, 21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830, OMB No. 0910-NEW.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Parts 803, 806, and 821

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 810

Administrative practice and procedure, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Parts 820 and 822

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 830

Administrative practice and procedure, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq., as amended) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 be amended to read as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG
ADMINISTRATION

1. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

2. Amend § 16.1(b)(2) by numerically adding an entry for “§ 830.130” to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 830.130, relating to suspension or revocation of the accreditation of an issuing agency.

* * * * *

PART 801—LABELING

3. The authority citation for part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

4. Amend subpart A of part 801 by adding new §§ 801.3 and 801.18 to read as follows:

Subpart A—General Labeling Provisions

Sec.

801.1 Medical devices; name and place of business of manufacturer, packer
or distributor.

801.3 Definitions.

801.4 Meaning of intended uses.

801.5 Medical devices; adequate directions for use.

801.6 Medical devices; misleading statements.

801.15 Medical devices; prominence of required label statements.

801.16 Medical devices; Spanish-language version of certain required statements.

801.18 Format of dates provided on a medical device label.

§ 801.3 Definitions.

Automatic identification and data capture (AIDC) means any technology that conveys the unique device identifier (UDI) or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process.

Center Director means the Director of the Center for Devices and Radiological Health or the Director of the Center for Biologics Evaluation and Research, depending on which Center has been assigned lead responsibility for the device.

Combination product has the meaning set forth in § 3.2(e) of this chapter.

Convenience kit means two or more different types of medical devices packaged together for the convenience of the user.

Device package means a package that contains a fixed quantity of devices.

Expiration date means the date by which the label of a device states the device must or should be used.

Finished device means any device or accessory to any device that is suitable for use or capable of functioning.

FDA, we, or us means the Food and Drug Administration.

Global Unique Device Identification Database (GUDID) means the database that serves as a repository of information about devices to facilitate the identification of medical devices through their distribution and use.

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

Label has the meaning set forth in section 201(k) of the Federal Food, Drug, and Cosmetic Act.

Labeler means:

(1) Any person who causes a label to be applied to a device with the intent that the device will be introduced into interstate commerce without any intended subsequent replacement or modification of the label; and

(2) Any person who causes the label of a device to be modified with the intent that the device will be introduced into interstate commerce 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.

Lot or batch means one finished device or more that consists of a single type, model, class, size, composition, or software version that is manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

Shipping container means a package, container, or pallet used during the shipment or transportation of devices from one point to another, and whose contents may vary from one shipment to another.

Specification means any requirement with which a device must conform.

Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is 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 specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

Universal product code (UPC) means the product identifier used to identify a company and product name of an item sold at retail in the United States.

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

§ 801.18 Format of dates provided on a medical device label.

(a) Whenever the label of a medical device includes an expiration date, a date of manufacture, or any other date intended to be brought to the attention of the user of the device, the date shall be presented in the following format: Month Day, Year (e.g., JAN 1, 2012).

(b) All dates must include a day; a date composed only of a month and year does not meet the requirements of this section.

(c) The month shall be shown as a three-letter abbreviation of the name of the month, presented in capital letters as follows:

<u>Month</u>	<u>Abbreviation</u>
January	JAN
February	FEB
March	MAR
April	APR
May	MAY
June	JUN
July	JUL
August	AUG
September	SEP
October	OCT
November	NOV
December	DEC

(d) The day shall be shown in modern Arabic numerals, with no leading zeros (e.g., 1, 2, 3, * * * 29, 30, 31).

(e) The year shall be shown in modern Arabic numerals, using the civil calendar in use in the United States, using four digits (e.g. 2012).

(f) The following is an exception for date of manufacture of an electronic product to which a standard is applicable under subchapter J, Radiological Health: If the device is an electronic product to which a standard is applicable under subchapter J, Radiological Health of

this chapter, the date of manufacture shall be presented as required by § 1010.3(a)(2)(ii) of this chapter.

5. Add subpart B consisting of §§ 801.20 to 801.57 to read as follows:

Subpart B—Labeling Requirements for Unique Device Identification

Sec.

801.20 Label to bear a unique device identifier (UDI).

801.25 Unique device identifiers for combination products, device constituents parts of a combination product, convenience kits, and devices packaged in a convenience kit.

801.30 General exceptions from the requirement for the label of a device to bear a unique device identifier.

801.35 Request for an exception from or alternative to the requirement for a device to bear a unique device identifier.

801.40 Voluntary labeling of a device with a unique device identifier.

801.45 Form of a unique device identifier.

801.50 Devices that must be directly marked with a unique device identifier.

801.57 Discontinuation of legacy FDA identification numbers assigned to devices.

Subpart B—Labeling Requirements for Unique Device Identification

§ 801.20 Label to bear a unique device identifier (UDI).

(a) In general:

(1) The label of every medical device shall bear a unique device identifier (UDI) that meets the requirements of this subpart and part 830.

(2) Every device package shall bear a UDI that meets the requirements of this subpart and part 830.

(b) Effective dates. The requirements of paragraph (a) of this section become effective:

(1) If the device is a class III medical device or is a device licensed under the Public Health Service Act, [A DATE WILL BE ADDED 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER];

(2) If the device is a class II medical device, [A DATE WILL BE ADDED 3 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER];

(3) If the device is a class I medical device, [A DATE WILL BE ADDED 5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER];

(4) If the device is not classified into class I, II, or III, [specific date, 5 years after publication of a final rule].

(c) Exceptions. Exceptions to the general rule of paragraph (a) of this section are provided by §§ 801.30, 801.35, and 801.128(f)(2).

§ 801.25 Unique device identifiers for combination products, device constituent parts of a combination product, convenience kits, and devices packaged in a convenience kit.

(a) Application to combination products. The label and each device package of every combination product for which the primary mode of action is that of a device shall bear a unique device identifier (UDI) as provided by § 801.20. The requirements of § 801.20 become effective on the earlier of:

(1) If FDA has classified the combination product under a medical device classification regulation or other classification action, the date that applies to such classification under § 801.20(b); or

(2) The earliest date that applies under § 801.20(b) to any device constituent part of the combination product.

(b) Device constituent parts of a combination product. The label and each device package of each device constituent part of a combination product shall bear its own unique device identifier (UDI), distinct from any UDI assigned to the combination product, and regardless of whether the combination product is required to have a UDI, except that a UDI is not required for a device constituent part that is physically, chemically, or otherwise combined with other constituents of a 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.

(c) Application to convenience kits. The label and each device package of every convenience kit shall bear a UDI as provided by § 801.20. The requirements of § 801.20 become effective with regard to a convenience kit on the earlier of:

(1) If FDA has classified the convenience kit under a medical device classification regulation or other classification action, the date that applies to such classification under § 801.20(b); or

(2) The earliest date that applies under § 801.20(b) to any device included in the convenience kit.

(d) Devices included in a convenience kit. The label and each device package of each device that is packaged in a convenience kit shall bear its own UDI, distinct from that of the convenience kit, unless the device is intended for a single use.

§ 801.30 General exceptions from the requirement for the label of a device to bear a unique device identifier.

(a) In general. The following types of devices are excepted from the requirement of § 801.20; a device within one or more of the following exceptions is not required to bear a unique device identifier (UDI):

(1) A device, other than a prescription device, that is made available for purchase at a retail establishment. This exception shall also apply to such a device when delivered directly to a hospital, ambulatory surgical facility, nursing home, outpatient treatment facility, or other health care facility.

(2) A class I device that FDA has by regulation exempted from the good manufacturing practice requirements of part 820 of this chapter.

(3) Individual class I, single-use devices, all of a single version or model, that are distributed together in a single device package, whose uses are generally known to the persons by whom they are intended to be used, and which are not intended for individual sale. The device package containing these individual devices is not exempt from the requirement of § 801.20, and must bear a UDI.

(4) A device used solely for research, teaching, or chemical analysis, and not intended for any clinical use.

(5) A custom device within the meaning of § 812.3(b).

(6) An investigational device within the meaning of part 812.

(7) 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.

(8) A device intended for export from the United States.

(9) A device held by the Strategic National Stockpile and granted an exception or alternative under § 801.128(f)(2).

(10) A device for which FDA has established a performance standard under section 514(b) of the Federal Food, Drug, and Cosmetic Act and has provided therein an exception from

the requirement of § 801.20, or for which FDA has recognized all or part of a performance standard under section 514(c) of the Federal Food, Drug, and Cosmetic Act and has included an exception from the requirement of § 801.20 within the scope of that recognition.

(11) 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.

(12) A device that is packaged in a convenience kit, provided that the device is intended for a single use.

(b) Exception for shipping containers. This rule does not require a unique device identifier to be placed on any shipping container.

(c) The unique device identifier (UDI) of a class I device is not required to include a production identifier.

§ 801.35 Request for an exception from or alternative to the requirement for a device to bear a unique device identifier.

(a) A labeler may submit a request for an exception from or alternative to the requirement of § 801.20 or any requirement of this subpart for a specified device or a specified type of device. A written request for an exception or alternative must:

(1) Identify the device that would be subject to the exception or alternative;

(2) Identify the provisions of this subpart that are the subject of the request for an exception or alternative;

(3) If requesting an exception, explain why you believe the requirements of this subpart are not technologically feasible;

(4) If requesting an alternative, describe the alternative and explain why it would provide for more accurate, precise, or rapid device identification than the requirements of this subpart or how the alternative would better ensure the safety or effectiveness of the device that would be subject to the alternative;

(5) Provide an estimate of the number of labelers and the number of devices that would be affected if we grant the requested exception or alternative; and

(6) Provide other requested information that the Center Director needs to clarify the scope and effects of the requested exception or alternative.

(b) A request for an exception or alternative under paragraph (a) of this section may be submitted as part of a device premarket submission.

(1) FDA may grant a request for an exception or alternative submitted as part of an FDA premarket submission within the context of our approval or clearance of the device that is the subject of the premarket submission.

(2) FDA will not respond to a request for an exception or alternative submitted as part of an FDA premarket submission if we do not approve or clear the device that is the subject of the premarket submission.

(c) A written request that is not submitted as part of an FDA premarket submission should be submitted to: Division of Small Manufacturers, Consumer, and International Assistance (DSMICA), Center for Devices and Radiological Health, Bldg. 66, rm. 4621, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(d) The Center Director may grant a request for an exception or alternative, either in response to a request or on his or her own initiative, if the Center Director determines that an exception is appropriate because the requirements of this subpart are not technologically feasible,

or that an alternative would provide for more accurate, precise, or rapid device identification than the requirements of this subpart or would better ensure the safety or effectiveness of the device that would be subject to the alternative. If we grant an exception or alternative, we may include any safeguards or conditions deemed appropriate to ensure the adequate identification of the device through its distribution and use.

§ 801.40 Voluntary labeling of a device with a unique device identifier.

(a) The labeler of a device that is not required to bear a unique device identifier (UDI) may voluntarily comply with § 801.20. If a labeler voluntarily includes a UDI for a device, the labeler may voluntarily provide information concerning the device under subpart E of part 830.

(b) The labeler of a device that is sold at retail may label that device with both a Universal Product Code (UPC) and a UDI.

§ 801.45 Form of a unique device identifier.

(a) Every unique device identifier (UDI) must meet the technical requirements of § 830.20 of this chapter. The UDI must be presented in two forms:

- (1) Easily-readable plain-text, and
- (2) Automatic identification and data capture (AIDC) technology.

(b) The UDI must include a device identifier segment. Whenever a device is labeled with a lot or batch number, a serial number, a manufacturing date, or an expiration date, the UDI must include a production identifier segment that conveys such information.

(c) If the AIDC technology is not evident upon visual examination of the label or device package, the label or device package must bear a symbol that provides notice of the presence of AIDC technology. The symbol may be a symbol approved by the issuing agency, a symbol endorsed in a national or international standard recognized by FDA under section 514(c) of the

FD&C Act and pertaining to the AIDC technology, a symbol generally recognized by the persons who typically use the device, or the following generic symbol:



§ 801.50 Devices that must be directly marked with a unique device identifier.

(a) In general. A device that must be labeled with a unique device identifier (UDI) must also bear a permanent marking providing the UDI on the device itself if the device is:

- (1) An implantable device;
- (2) Intended to be used more than once, and intended to be sterilized before each use; or
- (3) Stand-alone software.

(b) UDI for direct marking. The UDI provided through a direct marking on a device may be:

- (1) Identical to the UDI that appears on the label the device, or
- (2) A different UDI used to distinguish the unpackaged device from any package containing the device.

(c) Form of a UDI when provided as a direct marking. When a device must bear a UDI as a direct marking, the UDI must be provided in the following manner:

(1) If the device is an implantable device, or the device is intended for more than one single use and intended to be sterilized before each use, the UDI must be provided through either or both of the following:

- (A) Easily-readable plain-text;
- (B) Automatic identification and data capture (AIDC) technology, or any alternative technology, that will provide the UDI of the device on demand.

(2) If the device is stand-alone software, the UDI must be provided through either or both of the following:

(A) An easily-readable plain-text statement displayed whenever the software is started;

(B) An easily-readable plain-text statement displayed through a menu command (e.g., an “About * * *” command).

(d) Effective dates. The requirements of this section apply to a device 2 years after the date that applies to the device under § 801.20.

(e) Exceptions. The requirement of paragraph (a) of this section shall not apply to any device that meets any of the following criteria:

(1) Direct marking would interfere with the safety or effectiveness of the device;

(2) The device cannot be directly marked because it is not technologically feasible;

(3) The device is intended to remain implanted continuously for a period of less than 30 days, unless the Commissioner determines otherwise in order to protect human health;

(4) The device has been previously marked under paragraph (a);

(5) The device is sold at retail and bears a Universal Product Code (UPC);

(6) Software that is not stand-alone software, but which is a component of a medical device.

(f) Exception to be noted in design history file. If you decide not to mark a device after determining that an exception applies under paragraph (e) of this section, you must document the basis of your decision in the design history file required by § 820.30(j) of this chapter of the Quality System Regulation.

(g) Submission of notice to FDA. If you decide not to mark a device after determining that an exception applies under paragraph (e)(1) or (e)(2) of this section, you must send a notice to FDA:

(1) Your notice to FDA must provide the following information:

(A) Identification of the exception, or exceptions, that you are invoking;

(B) An explanation of the factors that make the exception appropriate for your device;

(C) The name of, and contact information for, the person who determined that the exception is appropriate for your device.

(2) Your notice must be submitted to FDA no later than the date you begin distribution of the device that is the subject of the notice.

(3) Your notice should be submitted to: Division of Small Manufacturers, Consumer, and International Assistance (DSMICA), Center for Devices and Radiological Health, Bldg. 66, rm. 4621, 10903 New Hampshire Ave., Silver Spring, MD 20993.

§ 801.57 Discontinuation of legacy FDA identification numbers assigned to devices.

On the date your device must be labeled with a unique device identifier (UDI), any National Health-Related Item Code (NHRIC) or National Drug Code (NDC) number assigned to that device is rescinded, and you may no longer provide an NHRIC or NDC number on the label of your device or on any device package.

6. Revise § 801.119 to read as follows:

§ 801.119 In vitro diagnostic products.

A product intended for use in the diagnosis of disease and which is an in vitro diagnostic product as defined in § 809.3(a) of this chapter shall be deemed to be in compliance with the

requirements of this part and section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if it meets the requirements of subpart B of this part and the requirements of § 809.10 of this chapter.

7. Amend § 801.128 by redesignating paragraphs (f)(2) through (f)(7) as (f)(3) through (f)(8), and by adding new paragraph (f)(2) to read as follows:

§ 801.128 Exceptions or alternatives to labeling requirements for medical devices held by the Strategic National Stockpile.

* * * * *

(f) * * *

(2) Subpart B of this part and part 830 in its entirety;

* * * * *

PART 803—MEDICAL DEVICE REPORTING

8. The authority citation for part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

9. Amend § 803.3 by alphabetically adding the definition for “Unique device identifier (UDI)” to read as follows:

§ 803.3 How does FDA define the terms used in this part?

* * * * *

Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is 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 specific device;
- (iii) The expiration date of a specific device;
- (iv) The date a specific device was manufactured.

* * * * *

10. Amend § 803.32 by redesignating paragraphs (c)(6) through (c)(10) as paragraphs (c)(7) through (c)(11), and by adding new paragraph (c)(6) to read as follows:

§ 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?

* * * * *

(c) * * *

(6) The unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

11. Amend § 803.33 by redesignating paragraphs (a)(7)(iv) through (a)(7)(vi) as paragraphs (a)(7)(v) through (a)(7)(vii), and by adding new paragraph (a)(7)(iv) to read as follows:

§ 803.33 If I am a user facility, what must I include when I submit an annual report?

(a) * * *

(7) * * *

(iv) The unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

12. Amend § 803.42 by redesignating paragraphs (c)(6) through (c)(10) as paragraphs (c)(7) through (c)(11), and by adding new paragraph (c)(6) to read as follows:

§ 803.42 If I am an importer, what information must I submit in my individual adverse event reports?

(c) * * *

(6) The unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

13. Amend § 803.52 by redesignating paragraphs (c)(6) through (c)(10) as paragraphs (c)(7) through (c)(11), and by adding new paragraph (c)(6) to read as follows:

§ 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

(c) * * *

(6) The unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

PART 806—MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

14. The authority citation for part 806 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

15. Amend § 806.2 by adding paragraph (m) to read as follows:

§ 806.2 Definitions.

* * * * *

(m) Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter.

A unique device identifier is 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 specific device;
- (iii) The expiration date of a specific device;
- (iv) The date a specific device was manufactured.

16. Amend § 806.10 by revising paragraph (c)(5) to read as follows:

§ 806.10 Reports of corrections and removals.

* * * * *

(c) * * *

(5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

* * * * *

17. Amend § 806.20 by revising paragraph (b)(2) to read as follows:

§ 806.20 Records of corrections and removals not required to be reported.

* * * * *

(b) * * *

(2) The unique device identifier (UDI) of the device, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

* * * * *

PART 810—MEDICAL DEVICE RECALL AUTHORITY

18. The authority citation for part 810 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 332, 333, 334, 351, 352, 355, 360h, 360i, 371, 374, 375.

19. Amend § 810.2 by adding paragraph (l) to read as follows:

§ 810.2 Definitions.

* * * * *

(l) Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is 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 specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

20. Amend § 810.10 by removing the word “and” at the end of paragraph (b)(2)(iii) and by adding paragraph (b)(2)(v) to read as follows:

§ 810.10 Cease distribution and notification order.

* * * * *

(b) * * *

(2) * * *

(v) The unique device identifier (UDI) that appears on the device label or on the device package; and

* * * * *

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

21. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

22. Amend § 814.3 by adding paragraphs (p) and (q) to read as follows:

§ 814.3 Definitions.

* * * * *

(p) Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is 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 specific device;
- (iii) The expiration date of a specific device;
- (iv) The date a specific device was manufactured.

(q) Universal product code (UPC) means the product identifier used to identify a company and product name of an item sold at retail in the United States.

23. Amend § 814.84 by adding paragraph (b)(4) to read as follows:

§ 814.84 Reports.

* * * * *

(b) * * *

(4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

PART 820—QUALITY SYSTEM REGULATION

24. The authority citation for part 820 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

25. Amend § 820.3 by adding paragraphs (bb) and (cc) to read as follows:

§ 820.3 Definitions.

* * * * *

(bb) Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter.

A unique device identifier is 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 specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

(cc) Universal product code (UPC) means the product identifier used to identify a company and product name of an item sold at retail in the United States.

26. Amend § 820.120 by revising the first sentence of paragraph (b) to read as follows:

§ 820.120 Device labeling.

* * * * *

(b) Labeling inspection. Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct unique device identifier (UDI) or universal product code (UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions.

* * *

* * * * *

27. Amend § 820.184 by revising paragraph (f) to read as follows:

§ 820.184 Device history record.

* * * * *

(f) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.

28. Amend § 820.198 by revising paragraph (e)(3) to read as follows:

§ 820.198 Complaint files.

* * * * *

(e) * * *

(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;

* * * * *

29. Amend § 820.200 by revising paragraph (d)(2) to read as follows:

§ 820.200 Servicing.

* * * * *

(d) * * *

(2) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;

* * * * *

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

30. The authority citation for part 821 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, 374.

31. Amend § 821.3 by adding paragraph (n) to read as follows:

§ 821.3 Definitions.

* * * * *

(n) Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is 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 specific device;
- (iii) The expiration date of a specific device;
- (iv) The date a specific device was manufactured.

32. Amend § 821.25 by revising paragraphs (a)(2)(i) and (a)(3)(i) to read as follows:

§ 821.25 Device tracking system and content requirements: manufacturer requirements.

* * * * *

(a) * * *

(2) * * *

(i) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

* * * * *

(3) * * *

(i) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

* * * * *

33. Amend § 821.30 by revising paragraphs (a)(2), (b)(2), and (c)(1)(i) to read as follows:

§ 821.30 Tracking obligations of persons other than device manufacturers: distributor requirements.

(a) * * *

(2) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;

* * * * *

(b) * * *

(2) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;

* * * * *

(c) * * *

(1) * * *

(i) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;

* * * * *

PART 822—POSTMARKET SURVEILLANCE

34. The authority citation for part 822 continues to read as follows:

Authority: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

35. Amend § 822.3 by adding paragraph (n) to read as follows:

§ 822.3 How do you define the terms used in this part?

* * * * *

(n) Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is 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 specific device;
- (iii) The expiration date of a specific device;
- (iv) The date a specific device was manufactured.

36. Amend § 822.9 by revising paragraph (a)(4) to read as follows:

§ 822.9 What must I include in my submission?

* * * * *

(a) * * *

(4) Premarket application/submission number and device identifiers for your device;

* * * * *

37. Add part 830 to read as follows:

PART 830—UNIQUE DEVICE IDENTIFICATION

Subpart A—General Provisions

Sec.

830.3 Definitions.

Subpart B—Requirements for a Unique Device Identifier (UDI)

830.10 Incorporation by reference—Technical standards applicable to part 830.

830.20 Requirements for a unique device identifier.

830.40 Use and discontinuation of a device identifier.

830.50 Changes that result in a new version or model.

830.60 Relabeling of a device that is required to bear a unique device identifier.

Subpart C—FDA Accreditation of an Issuing Agency

830.100 FDA accreditation of an issuing agency.

830.110 Application for accreditation as an issuing agency.

830.120 Responsibilities of an FDA-accredited issuing agency.

830.130 Suspension or revocation of the accreditation of an issuing agency.

Subpart D—FDA as an Issuing Agency

830.200 When FDA will act as an issuing agency.

830.210 Eligibility for use of FDA as an issuing agency.

830.220 Termination of FDA service as an issuing agency.

Subpart E—Global Unique Device Identification Database

830.300 Devices subject to device identification data submission requirements.

830.310 Information required for unique device identification.

830.320 Submission of unique device identification information.

830.330 Times for submission of unique device identification information.

830.340 Voluntary submission of ancillary device identification information.

830.350 Records to be maintained by the labeler.

Authority: 21 U.S.C. 321, 331, 352, 353, 360, 360d, 360i, 360j, 371.

Subpart A—General Provisions

§ 830.3 Definitions.

Automatic identification and data capture (AIDC) means any technology that conveys the unique device identifier (UDI) or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process.

Center Director means the Director of the Center for Devices and Radiological Health or the Director of the Center for Biologics Evaluation and Research, depending on which Center has been assigned lead responsibility for the device.

Device package means a package that contains a fixed quantity of devices.

Expiration date means the date by which the label of a device states the device must or should be used.

FDA, we, or us means the Food and Drug Administration.

Federal Food, Drug, and Cosmetic Act means 21 U.S.C. 321 *et seq.*, as amended.

Global Unique Device Identification Database (GUDID) means the database that serves as a repository of information to facilitate the identification of medical devices through their distribution and use.

Issuing agency means an organization accredited by FDA to operate a system for the issuance of unique device identifiers.

Label has the meaning set forth in section 201(k) of the Federal Food, Drug, and Cosmetic Act.

Labeler means:

(1) Any person who causes a label to be applied to a device with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label; and

(2) Any person who causes the label of a device to be modified with the intent that the device will be introduced into interstate commerce 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.

Lot or batch means one finished device (any device or accessory to any device that is suitable for use or capable of functioning) or more that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

Premarket submission means 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:

(1) Premarket approval application means an application for approval of a device submitted under section 515(c) of the Federal Food, Drug, and Cosmetic Act;

(2) Product development protocol means the application described in section 515(f) of the Federal Food, Drug, and Cosmetic Act.

(3) Premarket report means a report submitted under section 515(c)(2) of the Federal Food, Drug, and Cosmetic Act;

(4) Humanitarian device exemption application means an application for approval of a humanitarian use device submitted under section 520(m) of the Federal Food, Drug, and Cosmetic Act;

(5) Biologics license application means an application for approval of a device submitted under section 351 of the Public Health Service Act.

(6) Premarket notification submission means a report submitted under section 510(k) of the Federal Food, Drug, and Cosmetic Act;

(7) New drug application for a transitional device means a new drug application for a medical device that was regulated by FDA as a new drug prior to May 28, 1976, the date of enactment of the Medical Device Amendments of 1976.

Shipping container means a package, container, or pallet used during the shipment or transportation of devices from one point to another, and whose contents may vary from one shipment to another.

Small business means a medical device manufacturer with 500 or fewer employees, or a medical device relabeler or repackager with 100 or fewer employees.

Specification means any requirement with which a device must conform.

Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20. A unique device identifier is 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 specific device;
- (iii) The expiration date of a specific device;
- (iv) The date a specific device was manufactured.

Universal product code (UPC) means the product identifier used to identify a company and product name of an item sold at retail in the United States.

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

Subpart B—Requirements for a Unique Device Identifier (UDI)

§ 830.10 Incorporation by reference--technical standards applicable to part 830.

(a) The following technical standards are incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51:

(1) ISO/IEC 646:1991, Information technology—ISO 7-bit coded character set for information interchange (third edition, December 15, 1991).

(2) ISO/IEC 15459-2:2006(E), Information technology—Unique identifiers—Part 2: Registration procedures (second edition, March 1, 2006);

(3) ISO/IEC 15459-4:2008, Information technology—Unique identifiers—Part 4: Individual items (second edition, July 7, 2008);

(4) ISO/IEC 15459-6:2007, Information technology—Unique identifiers—Part 6: Unique identifier for product groupings (first edition, June 15, 2007);

(b) Copies are available for purchase from: ISO Central Secretariat, International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, Switzerland, telephone (dialing from the United States): 011-41-22-749-0111, Internet: www.standardsinfo.net, and are available for inspection at: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860, and at the National Archives and Records Administration (NARA). For information on how to review these standards at NARA, call 202-741-6030, or go to: www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

§ 830.20 Requirements for a unique device identifier.

A unique device identifier (UDI) must:

- (a) Be issued under a system operated by FDA or an FDA-accredited issuing agency;
- (b) Conform to international standards incorporated by reference by § 830.10;
- (c) Use only characters and numbers from the invariant character set of ISO/IEC 646:1991, Information technology—ISO 7-bit coded character set for information interchange.

§ 830.40 Use and discontinuation of a device identifier.

(a) Only one device identifier from any particular system for the issuance of unique device identifiers may be used to identify a particular version or model of a device. A particular version or model may be identified by unique device identifiers (UDIs) from two or more systems for the issuance of UDIs.

(b) A device identifier shall be used to identify only one version or model.

(c) In the event that a version or model of a device is discontinued, its device identifier may not be reassigned to another device. If a discontinued version or model is re-introduced and

no changes have been made that would require the use of a new device identifier, the device identifier that was previously in use may be used to identify the device.

(d) In the event that an issuing agency relinquishes or does not renew its accreditation, you may continue to label a device with a previously-issued UDI until such time as § 830.50 requires you to discontinue use of the UDI.

§ 830.50 Changes that result in a new version or model.

If you make any of the following changes to a device that is required to bear a UDI on its label, the change results in a new version or model and you must assign a new device identifier to the new version or model:

(a) You change the specifications, performance, size, or composition of the device to an extent greater than the specified limits;

(b) You change the quantity in a device package or add a new device package;

(c) You make a change that could significantly affect the safety or effectiveness of the device;

(d) You change from a nonsterile package to a sterile package, or from a sterile package to a nonsterile package; or

(e) You relabel the device.

§ 830.60 Relabeling of a device that is required to bear a unique device identifier.

If you relabel a device that is required to bear a unique device identifier (UDI), you must keep a record showing the relationship of the prior device identifier to your new device identifier.

Subpart C—FDA Accreditation of an Issuing Agency

§ 830.100 FDA accreditation of an issuing agency.

(a) Eligibility. A private nonprofit organization or a State agency may apply for accreditation as an issuing agency.

(b) Accreditation criteria. FDA may accredit an organization as an issuing agency, if the system it will operate:

(1) Will employ unique device identifiers (UDIs) that meet the requirements of this part to adequately identify a device through its distribution and use;

(2) Conforms to the international standards incorporated by reference at § 830.10;

(3) Will be available to all users according to a single set of consistent, fair, and reasonable terms and conditions.

§ 830.110 Application for accreditation as an issuing agency.

(a) Application for initial accreditation. (1) An applicant seeking initial FDA accreditation as an issuing agency shall notify FDA of its desire to be accredited by sending a notification to: Division of Small Manufacturers, Consumer, and International Assistance (DSMICA), Center for Devices and Radiological Health, Bldg. 66, rm. 4621, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(2) Following receipt of the notification. FDA will provide the applicant with additional information to aid in submission of an application for approval as an issuing agency, together with an email address for submission of an application.

(3) The applicant shall furnish to FDA, via email to the email address we provide, an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant and, if the applicant is not a State agency, evidence of nonprofit status (for example, how it meets Internal Revenue Service requirements for a nonprofit organization);

(ii) Detailed descriptions of any standards or criteria the applicant will apply to participating labelers;

(iii) A detailed description of the guidelines that govern assignment of a unique device identifier (UDI) to a device;

(iv) A detailed description of the review and decision-making process the applicant will apply when determining whether a particular labeler may use the applicant's UDI system, including:

(A) Copies of the application forms, guidelines, instructions, and other materials the applicant will send to medical device labelers who wish to use the applicant's unique device identification system;

(B) Policies and procedures for notifying a labeler of deficiencies in its use of unique device identifiers;

(C) Procedures for monitoring a labeler's correction of deficiencies in its use of unique device identifiers;

(D) Policies and procedures for suspending or revoking a labeler's use of the applicant's UDI system, including any appeals process.

(v) Description of the applicant's electronic data management system with respect to its review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems;

(vi) Fee schedules, if any, together with an explanation of any fee waivers or reductions that are available; and

(vii) Other information required by FDA to clarify the application for accreditation.

(b) Application for renewal of accreditation. An accredited issuing agency that intends to continue to serve as an issuing agency beyond its current term shall apply to FDA for renewal or notify FDA of its plans not to apply for renewal in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of its accreditation, an issuing agency shall inform FDA, at the address given in paragraph (a)(1) of this section, of its intent to seek renewal.

(2) FDA will notify the issuing agency of the relevant information, materials, and supporting documentation that we will require the issuing agency to submit as part of the renewal procedure. We will tailor these requirements to reflect our experience with the issuing agency during the current and any prior period of accreditation. We will limit our request to the types of the information required by paragraph (a)(3) of this section, and we will require less information if experience shows that we need only a subset of that information.

(3) At least 6 months before the date of expiration of its accreditation, an issuing agency shall furnish to FDA, at the email address we provide, a copy of a renewal application containing the information, materials, and supporting documentation requested by FDA in accordance with paragraph (b)(2) of this section.

(4) Any issuing agency that does not plan to renew its accreditation shall so notify FDA at the address given in paragraph (a)(1) of this section at least 9 months before the expiration of the issuing agency's term of accreditation and shall include a description of its plans for allowing

continued use of unique device identifiers issued prior to the expiration of the current term of accreditation.

(c) FDA action on an application for initial or renewal accreditation. (1) FDA will conduct a review and evaluation to determine whether the applicant meets the requirements of this subpart and whether the UDI system proposed by the applicant will meet the requirements of this subpart.

(2) Within 60 days of receipt of an application for accreditation, FDA will notify the applicant of any deficiencies in its application and will request correction of those deficiencies within 60 days. The applicant may request an extension if it needs additional time to correct deficiencies in its application. If the deficiencies are not resolved to FDA's satisfaction within the specified time period, the application for accreditation as an issuing agency may be denied.

(3) FDA shall notify the applicant whether the application for accreditation has been granted or denied. That notification shall list any conditions of approval or state the reasons for denial.

(4) If FDA denies an application, we will advise the applicant of the circumstances under which a denied application may be resubmitted.

(5) If FDA does not reach a final decision on a renewal application before the expiration of an issuing agency's current accreditation, the approval will be deemed extended until FDA reaches a final decision on the application.

(d) Relinquishment of accreditation. If an issuing agency decides to relinquish its accreditation before expiration of the current term of accreditation, it shall submit a letter of such intent to FDA, at the address provided in paragraph (a)(1) of this section, at least 9 months before relinquishing its accreditation.

(e) Notice of termination of accreditation. An issuing agency that does not apply for renewal of its accreditation, is denied renewal of accreditation by FDA, or relinquishes its accreditation and duties before expiration of the current term of accreditation, shall notify all labelers that are using the issuing agency's UDI system, in a manner and time period approved by FDA, of the date that the issuing agency will cease to serve as an FDA-accredited issuing agency.

(f) Term of accreditation. The initial term of accreditation for an issuing agency shall be for a period of 3 years. An issuing agency's term of accreditation may be periodically renewed for a period of 7 years.

§ 830.120 Responsibilities of an FDA-accredited issuing agency.

To maintain its accreditation, an issuing agency must:

- (a) Operate a system for assignment of unique device identifiers that meets the requirements of § 830.20 and the standards incorporated by reference at § 830.10;
- (b) Make available information concerning its system for the assignment of unique device identifiers;
- (c) Maintain a list of labelers that use its system for the assignment of unique device identifiers and provide FDA a copy of such list in electronic form by December 31 of each year;
- (d) Upon request, provide FDA with information concerning a labeler that is employing the issuing agency's system for assignment of unique device identifiers; and
- (e) Remain in compliance with the eligibility and accreditation criteria set forth in § 830.100.

§ 830.130 Suspension or revocation of the accreditation of an issuing agency.

FDA may suspend or revoke the accreditation of an issuing agency if FDA finds, after providing the issuing agency with notice and opportunity for an informal hearing in accordance with part 16 of this chapter, that the issuing agency or any employee of the issuing Agency:

- (a) Has been guilty of misrepresentation in obtaining accreditation;
- (b) Has failed to fulfill the responsibilities outlined in § 830.120; or
- (c) Has violated or aided and abetted in the violation of any regulation issued under section 510(e) or section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e) and 21 U.S.C. 360i(f), respectively).

Subpart D—FDA as an Issuing Agency

§ 830.200 When FDA will act as an issuing agency.

- (a) During any period where there is no accredited issuing agency, FDA will act as an issuing agency.
- (b) If FDA determines that a significant number of small businesses would be substantially and adversely affected by the fees required by all accredited issuing agencies, FDA will act as an issuing agency.
- (c) FDA may, in its discretion, act as an issuing agency if we determine it is necessary for us to do so to ensure the continuity or the effectiveness of the system for the identification of medical devices.
- (d) FDA may, in its discretion, act as an issuing agency if we determine it is appropriate for us to do so in order to facilitate or implement an alternative granted under § 801.35 of this chapter.

§ 830.210 Eligibility for use of FDA as an issuing agency.

When FDA acts as an issuing agency, any labeler will be permitted to use FDA's unique device identification system, regardless of whether the labeler is considered a small business.

§ 830.220 Termination of FDA service as an issuing agency.

(a) FDA may end our services as an issuing agency if we determine that the conditions that prompted us to act no longer exist and that ending our services would not be likely to lead to a return of the conditions that prompted us to act.

(b) If FDA has ended our services as an issuing agency, a labeler may continue to use a device identifier assigned under FDA's unique device identification system until such time as § 830.50 requires the use of a new device identifier.

Subpart E—Global Unique Device Identification Database

§ 830.300 Devices subject to device identification data submission requirements.

(a) In general. The labeler of a device must provide the information required by this subpart for each version or model required to be labeled with a unique device identifier.

(b) Exception. The labeler is not required to submit information concerning any device whose label is not required to bear a unique device identifier (UDI) because the device is subject to a labeling exception under § 801.30, § 801.35, or § 801.128(f)(2) of this chapter, regardless of whether the labeler voluntarily includes a UDI on the label of the device.

(c) Voluntary submission of information. If a labeler voluntarily includes a UDI on the label of a device under § 801.40, or, for devices sold at retail, the label includes a Universal Product Code (UPC), the labeler may also voluntarily submit information concerning that device under this part.

(d) Exclusions. FDA may reject or remove any device identification data where:

(1) The device identifier submitted does not conform to § 830.20;

(2) The information concerns a device that is neither manufactured in the United States nor in interstate commerce in the United States,

(3) The information concerns a product that FDA determines is not a device or a combination product that includes a device constituent part,

(4) The information concerns a device or a combination product that requires, but does not have, FDA premarket approval or clearance;

(5) A device that FDA has banned under section 516 of the Federal Food, Drug, and Cosmetic Act; or

(6) FDA has suspended the accreditation of the issuing agency that operates the system used by the labeler.

§ 830.310 Information required for unique device identification.

The contact for device identification shall provide FDA with the following information concerning each version or model of a device required to be labeled with a unique device identifier (UDI):

(a) Concerning the labeler:

(1) The name of the labeler;

(2) A telephone number or email address that will allow FDA to communicate with the contact for device identification designated under § 830.320(a); and

(3) The name of each issuing agency whose system is used by the labeler to assign unique device identifiers used by the labeler.

(b) Concerning each version or model of a device labeled with a UDI:

(1) The device identifier portion of the unique device identifier assigned to 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 version or model;

(3) If § 801.50 of this chapter requires the device to bear a UDI as a permanent marking on the device itself, either:

(A) A statement that the device identifier that appears as a permanent marking on the device is identical to that reported under paragraph (b)(1) of this section, or

(B) The device identifier portion of the unique device identifier that appears as a permanent marking on the device;

(4) The proprietary, trade, or brand name of the device as it appears on the label 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, as described by §§ 801.437(b)(1), 801.437(b)(3), and 801.437(f) of this chapter, 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 of production identifiers that appear on the label of the device;

(10) The FDA premarket submission number of a cleared or approved device, or a statement that FDA has by regulation exempted the device from premarket notification;

(11) The FDA listing number assigned to the device;

(12) The Global Medical Device Nomenclature (GMDN) code for the device;

(13) The total number of individual devices contained in the device package.

§ 830.320 Submission of unique device identification information.

(a) Designation of contact for device identification. Each labeler must designate an individual to serve as the point of contact with FDA on matters relating to the identification of medical devices marketed by the labeler. The contact for device information is responsible for ensuring FDA is provided with all information required by this part. The contact for device information may authorize an issuing agency or any other person to provide information to FDA on behalf of the labeler.

(b) Information shall be submitted via electronic means. All information required by this subpart shall be submitted electronically to FDA's Global Unique Device Identification Database (GUDID) in a format that we can process, review, and archive, unless the labeler has obtained a waiver from electronic submission of unique device identifier (UDI) data.

(c) Waiver from electronic submission.

(1) A labeler may request a waiver from electronic submission of UDI data by submitting a letter addressed to the appropriate Center Director explaining why electronic submission is not technologically feasible; send the letter to: Division of Small Manufacturers, Consumer, and International Assistance (DSMICA), Center for Devices and Radiological Health, White Oak Bldg. 66, rm. 4621, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(2) If the establishment where the labeler is located has obtained a waiver from electronic submission of registration and listing information under section 510(p) of the Federal Food, Drug, and Cosmetic Act, the labeler is deemed to have a waiver from electronic submission of UDI data.

(3) A labeler that has a waiver from electronic submission of UDI data must send a letter containing all of the information required by § 830.310, as well as any ancillary information permitted to be submitted under § 830.340 that the labeler wishes to submit, within the time permitted by § 830.330, addressed to: Division of Small Manufacturers, Consumer, and International Assistance (DSMICA), Center for Devices and Radiological Health, White Oak Bldg. 66, rm. 4621, 10903 New Hampshire Ave., Silver Spring, MD 20993.

§ 830.330 Times for submission of unique device identification information.

(a) The labeler shall submit to FDA the information required by § 830.310 no later than the date the label of the device must bear a unique device identifier under § 801.20 of this chapter.

(b) The labeler of a device shall submit to FDA an update to the information required by § 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.

§ 830.340 Voluntary submission of ancillary device identification information.

(a) You may not submit any information to the Global Unique Device Identification Database (GUDID) other than that specified by § 830.310, except where FDA acts to permit the submission of specified additional types of information, termed ancillary information.

(b) FDA will provide information through the FDA Web site at <http://www.fda.gov/udi> concerning the types of ancillary information that may be submitted to the GUDID.

(c) FDA may periodically change the types of ancillary information that may be submitted to the GUDID. We will seek comment on any proposed change in accordance with the Paperwork Reduction Act and on the FDA Web site at <http://www.fda.gov/udi> at least 60 days before making the change.

§ 830.350 Records to be maintained by the labeler.

(a) Each labeler shall retain, and submit to FDA upon specific request, records showing all unique device identifiers (UDIs) used to identify devices that must be labeled with a UDI, and the particular version or model associated with each device identifier. These records must be retained for 3 years from the date the labeler ceases to market the version or model.

(b) Compliance with this section does not relieve the labeler of the need to comply with recordkeeping requirements of any other FDA regulation.

Dated: July 2, 2012.

Leslie Kux,

Assistant Commissioner for Policy.