



FEDERAL REGISTER

Vol. 78

Tuesday,

No. 185

September 24, 2013

Part V

Department of Health and Human Service

Food and Drug Administration

21 CFR Parts 16, 801, 803, et al.

Unique Device Identification System; Final Rule

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:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to establish a system to adequately identify devices through distribution and use. This rule requires the label of medical devices to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement. The labeler must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID), unless subject to an exception or alternative. The system established by this rule requires the label and device package of each medical device to include a UDI and requires that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. The UDI will be required to be directly marked on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

DATES: This rule is effective December 23, 2013, except §§ 801.55, 830.10, 830.100, 830.110, 830.120, and 830.130 are effective October 24, 2013. The incorporation by reference of § 830.20 listed in the rule is approved by the Director of the Office of the Federal Register as of December 23, 2013. The incorporation by reference of §§ 830.10 and 830.100 listed in the rule is approved by the Director of the Office of the Federal Register as of October 24, 2013. Certain provisions have later compliance dates as discussed in section VII. B. "Compliance Dates."

FOR FURTHER INFORMATION CONTACT: Jay Crowley, UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-5995, email: udi@fda.hhs.gov.

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

This final rule will 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 will reduce medical errors that result from misidentification of a device or confusion concerning its appropriate use. The identification system established under this rule will lead to more accurate reporting of adverse events by making it easier to identify the device prior to submitting a report. It will allow FDA, health care 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 fulfills a statutory requirement of section 519(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(f)) that directs FDA to issue regulations establishing a unique device identification system for medical devices. The rule also meets statutory requirements added by section 614 of the Food and Drug Administration Safety and Innovation Act (FDASIA), including a deadline for publication of this final rule and requirements concerning when the rule must apply to devices that are implantable, life-supporting, or life-sustaining.

Under the UDI system established by this rule, the health care community and the public will be able to identify a device through a UDI that will appear on the label and package of a device. The UDI will function as the key that can be used to obtain critical information from the GUDID about the medical product. The GUDID will include only information that is important to the identification of devices, and will not include any information that would identify a patient. 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. If a device is intended to be used more than once, and intended to be reprocessed before each use, it must also be directly marked with a UDI, allowing accurate identification even when the device is

no longer accompanied by its label or package.

By establishing a system for the adequate identification of medical devices through distribution and use, the rule will serve several important public health objectives:

Reduce Medical Errors. The presence of a UDI that is linked to device information in the GUDID will facilitate rapid and accurate identification of a device, thereby removing a cause of confusion that can lead to inappropriate use of a device. 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, will allow rapid and accurate data acquisition, recording, and retrieval. For example, 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 needs 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 requires the inclusion of UDIs in adverse event reports that are required under part 803 (21 CFR part 803). This will 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. The more rapidly a recall is implemented and completed, the more rapidly the risks presented are reduced or eliminated.

Better Focused and More Effective FDA Safety Communication. By citing UDIs, FDA will 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.

Additional Benefits. FDA expects the UDI system will provide additional benefits. For example, UDIs can be used in educational and informational materials to allow readers to quickly obtain additional information from the GUDID and other FDA databases; UDIs could play an important role in inventory management; and UDIs may be useful in the provision of high-quality medical services. UDIs and GUDID data, when linked with other FDA data, will help identify alternative devices in the event of a shortage and will contribute to better detection of counterfeit devices.

In addition, while not required, FDA anticipates that providers will include the UDIs of a wide variety of devices in patients' Electronic Health Records (EHRs) and Personal Health Records (PHRs). This information will strengthen the health care community's ability to identify the specific devices implanted into patients and will improve response to postmarket surveillance activities, including adverse event reporting and recalls. For example, this information will contribute to the rapid identification of risks and benefits associated with a device within specific subpopulations. By linking clinical detail and information regarding device use, more effective device safety surveillance and evaluation studies could be conducted, contributing to a more complete safety and effectiveness profile for devices and

enabling more appropriate and timely remedies when potential safety concerns are identified.

Standard Format for Dates Provided on a Device Label. The rule will also better ensure dates on device labels are not confusing or misleading to users thereby ensuring the safe use of devices, by requiring that dates on medical device labels conform to a standard format consistent with international standards and international practice—year-month-day (e.g., 2013–09–30). This will ensure dates on medical device labels are unambiguous and clearly understood by device users.

Summary of the Major Provisions of the Regulatory Action in Question

This rule will require the label and device packages of medical devices to include a UDI, except where the rule provides for an exception or alternative placement. Each UDI must be provided in a plain-text version and in a form that uses AIDC technology. The UDI will also be required to be directly marked on a device that is intended for more than one use, and intended to be reprocessed before each use. The rule requires the submission of information concerning each device to the new GUDID. FDA plans to make most of the data reported under this rule available to the public. The GUDID will not include patient information. The rule will also require dates on device labels and packages to be presented in a standard format that is consistent with international standards and international practice.

The UDI system established by this rule builds on international regulatory cooperation activities and makes use of internationally recognized standards relating to unique identification and data exchange. The rule specifies the technical requirements of a UDI. Each UDI will consist of two portions:

- A *device identifier* that corresponds to the specific version or model of the device and the labeler of the device (the labeler is the 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), and

- A *production identifier* that more precisely identifies the specific device by providing variable information, such as the lot or batch, the serial number, expiration date, the date of manufacture, and, for human cells, tissues, or cellular and tissue-based products (HCT/Ps) regulated as devices, the distinct identification code required in § 1271.290(c) (21 CFR 1271.290(c)).

The rule explains when a UDI is required and when its use must be discontinued. The rule requires all UDIs to be issued under a system operated by an FDA-accredited issuing agency. The rule provides a process through which an applicant would seek FDA accreditation as an issuing agency, specifies the information that the applicant must provide to FDA, and the criteria FDA will apply in evaluating applications. The rule provides for the suspension and 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 is required to submit information concerning the device to the GUDID, which will facilitate the rapid identification of the device and the labeler and provide links to other FDA data. FDA plans to make this information available to the public through a variety of channels.

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

As discussed in Section VII.B, "Compliance Dates," FDA has established a set of compliance dates that will phase-in the requirements of this rule in stages, over a period of 7 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.

Costs and Benefits

ECONOMIC DATA: COSTS AND BENEFITS ACCOUNTING STATEMENT
[2012 dollars]

Category	Primary estimate	Low estimate	High estimate	Units			
				Year dollars	Discount rate (percent)	Period covered	Notes
Benefits:							
Annualized	7	
Monetized \$millions/year	3	
Annualized	7	
Quantified	3	
Qualitative	More accurate and prompt identification of device related adverse events should 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	\$85.7	\$48.8	\$122.5	2012	7	10 years	Costs to foreign labelers are not included.
Monetized \$millions/year	84.1	47.9	120.2	2012	3	10 years	
Annualized	7	
Quantified	3	
Qualitative	
Transfers:							
Federal	7	
.....	3	
Annualized Monetized \$millions/year.	3	
From/To	From			To			
Other	7	
Annualized Monetized \$millions/year.	3	
From/To	From:			To:			
Effects:	State, Local or Tribal Government: No effect						
Small Business:	The final rule may have a significant economic impact on a substantial number of small entities that label medical devices.						
Wages:	No effect						
Growth:	No effect						

Table of Contents

I. Background	Establishment, Including Such a Device Delivered Directly to a Hospital, Ambulatory Surgical Center, Nursing Home, Outpatient Treatment Facility, or Other Health Care Facility. Proposed § 801.30(a)(1)	Model, That Are Distributed Together in a Single Device Package—§ 801.30(a)(3)
II. Comments on the Proposed Rule and FDA's Responses		J. General Exceptions from the Requirement for the Label of a Device to Bear a Unique Device Identifier—Exception for a Custom Device Within the Meaning of § 812.3(b)—§ 801.30(a)(5)
A. Definitions—21 CFR 801.3, 803.3, 806.2, 810.2, 814.3, 820.3, 821.3, 822.3, and 830.3	G. General Exceptions from the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for Existing Inventories of Finished Devices That Have Been Labeled Prior to the Applicable Compliance Date—Final § 801.30(a)(1)	K. General Exceptions from the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for a Device Intended for Export from the United States—§ 801.30(a)(8)
B. Applicability of § 801.20	H. General Exceptions from the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for Class I Devices That FDA Has Exempted from Good Manufacturing Practices—§ 801.30(a)(2)	L. General Exceptions from the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for a Device Packaged Within the Immediate Container of a Combination Product or Convenience Kit—Similar Requirements Proposed at § 801.25; Revised Requirements at § 801.30(a)(11)
C. Compliance Dates of Unique Device Identifier Regulatory Requirements	I. General Exceptions from the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for Individual Single-Use Devices, All of a Single Version or	M. Medical Procedure Kits and Trays
D. Formatting of Dates Provided on Medical Device Labels—§ 801.18		
E. General Exceptions from the Requirement for the Label of a Device to Bear a Unique Device Identifier—Broad Comments Concerning Proposed § 801.30		
F. General Exceptions from the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for a Device, Other Than a Prescription Device, That Is Made Available for Purchase at a Retail		

- N. General Exceptions from the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for a Device Held by the Strategic National Stockpile and Granted an Exception or Alternative Under § 801.128(f)(2)—§ 801.30(a)(9)
- O. General Exceptions from the Requirement for the Label of a Device To Bear a Unique Device Identifier. The Unique Device Identifier of a Class I Device Is Not Required to Include a Production Identifier—§ 801.30(c)
- P. Requests for Additional General Exceptions from the Requirement for the Label of a Device To Bear a Unique Device Identifier
- Q. Request for Modification of Unique Device Identifier Labeling Requirements for Devices That Have Small Labels
- R. Voluntary Labeling of a Device With a Unique Device Identifier—Proposed § 801.40; Revised Requirements at § 801.35
- S. Form of a Unique Device Identifier—Technical Requirements—Proposed § 801.45(a); § 801.40(a) of the Final Rule
- T. Form of a Unique Device Identifier—Unique Device Identifier to Include Device Identifier and Production Identifier—Proposed § 801.45(b); Revised Requirements at § 801.40(b) of the Final Rule
- U. Form of a Unique Device Identifier—Proposed Symbol to Indicate the Presence of Automatic Identification and Capture Technology—Proposed § 801.45(c); Revised Requirements at § 801.40(c) of the Final Rule
- V. Form of a Unique Device Identifier—Effect of Labeling a Class I Device With a Universal Product Code—New § 801.40(d) of the Final Rule
- W. Changes to Codified Text in Response to Comments on Requirements Proposed in § 801.50—Devices That Must Be Directly Marked With a Unique Device Identifier
- X. Devices That Must Be Directly Marked With a Unique Device Identifier—Proposed Requirement for an Implantable Device To Bear a Permanent Marking Providing the Unique Device Identifier on the Device Itself—Proposed § 801.50(a)(1)
- Y. Revision of Direct Marking Requirements—Proposed § 801.50; § 801.45 of the Final Rule
- Z. Devices That Must Be Directly Marked With a Unique Device Identifier—Proposed Requirement for Submission of a Notice to FDA Upon Determining That an Exception Applies—Proposed § 801.50(g)
- AA. Requirements for Stand-Alone Software—Final § 801.50
- BB. Request for an Exception from or Alternative to a Unique Device Identifier Requirement—Proposed § 801.35; § 801.55 of the Final Rule
- CC. Discontinuation of Legacy Identification Numbers Assigned to Devices (National Drug Code and National Health-Related Item Code Numbers)—§ 801.57
- DD. Requests for Clarification Concerning Whether Compliance With Any Unique Device Identifier Requirement Will Require Submission of a 510(k) Premarket Notification or Premarket Approval Supplement
- EE. Human Cells, Tissues, or Cellular or Tissue-Based Products That are Regulated as Devices—§§ 801.3 and 801.20(a)(1)
- FF. Technical Standards Applicable to Part 830—§ 830.10
- GG. Requirements for a Unique Device Identifier—§ 830.20
- HH. Use and Discontinuation of a Device Identifier—§ 830.40
- II. Changes That Require Use of a New Device Identifier—§ 830.50
- JJ. FDA Accreditation of an Issuing Agency—§ 830.100
- KK. Information Required for Unique Device Identification—§ 830.310
- LL. Information Required for Unique Device Identification—Information Concerning Each Version or Model of a Device—§ 830.310(b)
- MM. Enforcement Authority
- NN. Questions and Comments Suggesting the Need for Additional Guidance
- OO. Requests for Additional Opportunity for Comment Prior to Issuing a Final Rule
- III. Legal Authority for the Final Rule
- IV. Analysis of Impacts
- A. Summary of Impacts
- B. Summary of Regulatory Flexibility Analysis
- C. Summary of Benefits
- V. Information Collection Requirements
- VI. Environmental Impact
- VII. Effective Dates
- A. Effective Dates
- B. Compliance Dates
- VIII. Federalism
- IX. References
- I. Background**

On July 10, 2012, FDA published a proposed rule to establish a unique device identification system, as required by section 519(f) of the FD&C Act (see 77 FR 40736). On July 9, 2012, FDASIA was signed into law; section 614 of FDASIA amended section 519(f) of the FD&C Act, requiring modification of the timeframe for implementation of the proposed rule's requirements as they apply to devices that are implantable, life-saving, or life-sustaining. On November 19, 2012, FDA published a document amending our July 10, 2012, proposed rule to meet the requirements of amended section 519(f) of the FD&C Act (see 77 FR 69393).

The preamble to the July 2012 proposal describes the objectives of the

rule (see 77 FR 40736 at 40740 through 40743), and we refer readers to that preamble if they wish to obtain details on the events, recommendation, meetings, and literature that shaped the development of the proposed rule. The preamble to the November 2012 amended proposal describes changes that were required by the enactment of FDASIA, including revision of the compliance dates proposed for implantable, life-supporting, and life-sustaining devices.

We received approximately 270 submissions of comments from approximately 225 sources (some submitted more than one set of comments)—individuals (health care professionals, academics, consumers, and others), organizations (consumer groups, hospitals, health care associations, military and government sources, and others), and private industry (device manufacturers, industry associations, distributors, and others). These comments provided approximately 1,700 pages of feedback and commentary concerning the proposed rule. Almost all comments supported the objectives of the rule in whole or in part. For example, one comment stated it “strongly supports” the implementation of a UDI system, and that “UDI is the missing link to protect patient safety.” Another comment stated, “We support FDA’s objective to substantially reduce existing obstacles to the adequate identification of medical devices used in the United States. We agree that a medical device identification system has the potential to rapidly and definitively identify a medical device and the key attributes that could affect its safe and effective use.” The great majority also suggested changes to the proposed rule, stating, for example, that they were “providing comments on this proposed rule, and we wish to voice our support of the efforts to implement the regulatory framework for a unique device identification system.” Some of the suggested changes were very minor and others were very broad and sweeping. Comments suggesting changes to the proposed rule and FDA’s responses are discussed later in this document.

After reviewing the comments, FDA made several changes to the rule. The principal changes between the amended proposed rule of November 19, 2012, and this final rule are as follows:

TABLE 1.—PRINCIPAL CHANGES BETWEEN THE AMENDED PROPOSED RULE OF NOVEMBER 19, 2012, AND THIS FINAL RULE

Proposed Rule (As Amended)	Final Rule
<p>The proposed rule used the term “effective date” in an incorrect manner when denoting the dates by which a labeler would have to comply with certain provisions. A consequence of setting an effective date for a particular requirement is that the requirement will not be published in the <i>Code of Federal Regulations</i> (CFR) until the effective date has passed. This would have made it very difficult for labelers to understand and comply with the final rule, for example because the CFR would not have provided the full text of the regulatory requirements of a final rule for several years. The proposed rule should have used the term “compliance date” to indicate when a labeler would not be required to comply with certain provisions.</p>	<p>The final rule uses “compliance date” to explain when a labeler is required to comply with a regulatory requirement. The final rule has only two effective dates: The final rule is effective 90 days after publication (December 23, 2013), except §§ 801.55, 830.10, 830.100, 830.110, 830.120, and 830.130 are effective 30 days after publication (October 24, 2013).</p> <p>To clarify changes from the proposed rule to the final rule, we use the term “compliance date” throughout this document wherever the proposed rule incorrectly used “effective date.”</p> <p>Section VII.B., “Compliance Dates,” explains in detail the compliance dates FDA has established for the final rule. A device does not have to comply with the final rule if it is in commercial distribution, see § 807.3(b) (21 CFR 807.3(b)), prior to the applicable compliance date.</p>
<p>The proposed rule did not explain whether it would be possible to extend the 1-year compliance date applicable to a class III device or a device licensed under the Public Health Service Act in circumstances where rapid implementation of the rule could lead to device shortages or other significant problems.</p>	<p>The final rule explains that FDA may grant a 1-year extension of the compliance date applicable to a class III device or a device licensed under the Public Health Service Act when in the best interest of the public health. See the discussion in section VII.B., “Compliance Dates.”</p>
<p>The proposed rule did not explain how it would apply to inventories of devices manufactured and labeled prior to the compliance date of the final rule.</p>	<p>The final rule provides an exception for a finished device that is manufactured and labeled prior to the compliance date that applies to that device, but the exception expires 3 years after the compliance date that applies to the particular device. See § 801.30(a)(1).</p>
<p>Dates provided on device labels would have been presented as Month Day, Year, using a three-letter abbreviation of the month (e.g., SEP 30, 2013). Proposed § 801.18.</p>	<p>Dates provided on device labels are to be presented as Year-Month-Day, with the year expressed as four digits, the month expressed as two digits, and the day expressed as two digits (e.g., 2013–09–30). This format is consistent with international standards and the requirements of the European Union and other nations. See § 801.18.</p>
<p>The date formatting requirements of § 801.18 would have gone into effect for all devices 1 year after publication of a final rule.</p>	<p>The date formatting requirements of § 801.18 will have the same compliance dates as UDI labeling requirements. If a device is not subject to UDI labeling requirements, the date formatting requirements of § 801.18 will apply 5 years after the publication of this final rule. See the discussion in section VII.B., “Compliance Dates.”</p>
<p>The proposed rule would have provided an exception from UDI labeling requirements for a device, other than a prescription device that is made available for purchase at a retail establishment, including such a device delivered directly to a hospital, ambulatory surgical center, nursing home, outpatient treatment facility, or other health care facility. Proposed § 801.30(a)(1).</p>	<p>The final rule provides that a class I device labeled with a Universal Product Code (UPC) may use the UPC as its UDI; see § 801.40(d).</p>
<p>The proposed rule would have required certain combination products, and certain device constituent parts of every combination product, to bear a UDI on their label. Proposed § 801.25(a) and (b).</p>	<p>The final rule excepts the device constituent part packaged within a combination product from the requirement that its label bear a UDI, if the combination product bears a UDI. § 801.30(a)(11).</p>
<p>The proposed rule would have required the label and device package of each device packaged in a convenience kit to bear its own UDI, distinct from that of the convenience kit, unless intended for a single use. Proposed § 801.25(d).</p>	<p>The final rule does <i>not</i> require devices contained within a convenience kit to bear a UDI but does require the label and each device package of every convenience kit to bear a UDI. § 801.30(a)(11).</p>
<p>The proposed rule would have provided an exception for a class I device that FDA has by regulation exempted from the good manufacturing practice requirements of part 820. Proposed § 801.30(a)(2).</p>	<p>The final rule provides an exception for a class I device that FDA has by regulation been exempted (but for the continuing requirement for recordkeeping under §§ 820.180 and 820.198) from the good manufacturing practice requirements of part 820 of this chapter. See § 801.30(a)(2).</p>
<p>The proposed rule would have provided an exception for individual <i>class I</i> single-use devices (SUDs), all of a single version or model, that are distributed together in a single device package, and which are not intended for individual sale. Proposed § 801.30(a)(3).</p>	<p>The final rule extends this exception to <i>all</i> individual SUDs, regardless of class, <i>except</i> that this exception is not available for any implantable device. The device package containing these individual devices is not excepted, and must bear a UDI. See § 801.30(a)(3).</p>
<p>The proposed rule would have provided an exception for a device constituent part of a combination product, <i>if</i> 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 it to be used except as part of the use of the combination product. Proposed § 801.30(a)(11).</p>	<p>The final rule provides that a device packaged within the immediate container of a combination product is excepted from the requirements of § 801.20 if the combination product bear a UDI.</p>

TABLE 1.—PRINCIPAL CHANGES BETWEEN THE AMENDED PROPOSED RULE OF NOVEMBER 19, 2012, AND THIS FINAL RULE—Continued

Proposed Rule (as amended)	Final Rule
<p>The proposed rule would have required a combination product for which the primary mode of action is that of a medical device to bear a UDI on its label. Proposed § 801.25(a).</p>	<p>The final rule also makes clear that the device constituent of a combination product whose components are physically, chemically, or otherwise combined or mixed and produced as a single entity as described by § 3.2(e)(1) (21 CFR 3.2(e)(1)) is not subject to the requirements of § 801.20 if the combination product properly bears a National Drug Code (NDC) number. See § 801.30(b)(2). The final rule provides that a combination product that properly bears a National Drug Code (NDC) number is not required to bear a UDI. See § 801.30(b)(1). However, the final rule also makes clear that each device constituent of a combination product, other than one described by § 3.2(e)(1), that properly bears an NDC on its label must also bear a UDI on its label unless the combination product bears a UDI on its label. See § 801.30(b)(3).</p>
<p>The proposed rule would have provided an exception for a device that is packaged in a convenience kit, provided that the device is intended for a single use. Proposed § 801.30(a)(12).</p>	<p>The final rule broadens and simplifies this exception, and extends it to the label of any device that is packaged in a convenience kit as long as the label of the convenience kit bears a UDI. See § 801.30(a)(11).</p>
<p>The proposed rule would have required use of a symbol to indicate the presence of AIDC technology, and provided a generic symbol that could have been used in lieu of any other symbol. Proposed § 801.45(c).</p>	<p>The final rule renumbers proposed § 801.45 as § 801.40. The final rule does not require use of a symbol to indicate the presence of AIDC technology, no longer provides for use of a generic symbol, and instead requires only that a label “disclose” the presence of AIDC technology. See § 801.40(c).</p>
<p>The proposed rule would have required an implantable device required to bear a UDI on its label to also bear a permanent marking providing the UDI. See proposed § 801.50(a)(1).</p>	<p>This provision has been removed; an implantable device will not be required to be directly marked with a UDI.</p>
<p>The proposed rule would have required a device required to bear a UDI on its label to also bear a permanent marking providing the UDI if the device is intended for more than one use and must be sterilized before each use. See proposed § 801.50(a)(1).</p>	<p>The final rule renumbers proposed § 801.50 as § 801.45. The final rule changes this provision to apply to devices that are “reprocessed” before each use; this broadens the scope of the provision. See § 801.45(a)(1).</p>
<p>The proposed rule did not fully explain how UDI labeling requirements would apply to stand-alone software regulated as a medical device. Proposed § 801.50, concerning direct marking, was the only provision that specifically addressed stand-alone software.</p>	<p>The final rule includes a new section that provides special labeling requirements for stand-alone software regulated as a medical device, including:</p> <ul style="list-style-type: none"> • An explanation of how stand-alone software can meet UDI labeling requirements when it is not distributed in package form (e.g., when it is downloaded from a labeler’s Web site); • a requirement for all stand-alone software to include means of displaying its UDI; and • an explanation that stand-alone software that is distributed in both packaged form and in a form that is not packaged (e.g., when downloaded from a Web site) may be identified with the same device identifier. <p>See § 801.50.</p>
<p>The proposed rule was not clear regarding the process for requesting an exception or alternative to some UDI labeling requirements, and provided one process for requests that concern the use of UDIs on a device label and device package, proposed § 801.35, and an entirely different process concerning direct marking of medical devices, proposed § 801.50.</p>	<p>The final rule provides a single process for all types of requests, and provides a more comprehensive process. See § 801.55. The final rule adds these provisions:</p> <ul style="list-style-type: none"> • FDA may grant a 1-year extension of the compliance date applicable to class III devices and devices licensed under the Public Health Service Act; see § 801.55(b), discussed previously; • FDA may initiate and grant an exception or alternative if we determine that the exception or alternative is in the best interest of the public health; see § 801.55(e); • FDA may rescind an exception or alternative; see § 801.55(e); • any labeler may make use of an exception or alternative that FDA has granted (FDA plans to make all decisions available to the public on FDA’s Web site); see § 801.55(d).
<p>The proposed rule was unclear whether the discontinuation of legacy FDA identifiers for devices (National Health-Related Item Code (NHRIC) and NDC numbers) would apply to devices that are exempted from UDI labeling requirements. Proposed § 801.57.</p>	<p>The final rule explains that every NHRIC and NDC number assigned to any device (even a device that is not required to bear a UDI) will be rescinded no later than September 24, 2018. See § 801.57.</p>
<p>The proposed rule did not explain how the discontinuation of legacy FDA identifiers would affect FDA-issued labeler codes that are already in use in the private sector and whose use might be permitted under an FDA-accredited system for the issuance of UDIs.</p>	<p>The final rule will permit continued use of an FDA-issued labeler code under an FDA-accredited system for the issuance of UDIs, provided that such use is permitted by the issuing agency that administers that system, and provided the labeler submits a request for continued use of a labeler code; FDA must receive the request no later than September 24, 2014. See § 801.57(c).</p>
<p>The proposed rule more prescriptively defined the types of changes that resulted in a new version or model, and which therefore required a new device identifier to be used to identify the changed device. See proposed § 830.50, which was then titled “Changes that result in a new version or model.”</p>	<p>The final rule gives labelers more flexibility to determine when a change to a device will require use of a new UDI. § 830.50 is now entitled “Changes that require use of a new device identifier.”</p>

TABLE 1.—PRINCIPAL CHANGES BETWEEN THE AMENDED PROPOSED RULE OF NOVEMBER 19, 2012, AND THIS FINAL RULE—Continued

Proposed Rule (as amended)	Final Rule
The proposed rule did not require information concerning magnetic resonance imaging (MRI) compatibility of a device to be submitted to the GUDID. See proposed § 830.310(b).	The final rule requires information to be submitted to the GUDID concerning whether a patient may be safely exposed to MRI or similar technologies while using the device or while the device is implanted in the patient. See § 830.310(b)(8).
The preamble to the proposed rule stated that the GUDID would not collect the Global Medical Device Nomenclature (GMDN) code for a device under proposed § 830.310(b) unless GMDN codes were made freely available.	The GMDN Agency has agreed to provide free access to GMDN nomenclature within the context of the GUDID data submission process. A labeler who reports data to the GUDID will be able to enter a GMDN code if the labeler knows it, or may use a module integrated in the GUDID reporting system to search for and select an appropriate GMDN term. See § 830.310(b)(13).
The proposed rule did not explain the process for correcting misinformation submitted to the GUDID.	The final rule explains that FDA may inform the labeler that information submitted to the GUDID appears to be incorrect or potentially misleading, and request that the labeler correct the information or provide a satisfactory explanation of why it is correct. The labeler would have 10 days to correct the information or explain why it is correct. If FDA determines that information is incorrect or could be misleading, we may delete or replace the information. See § 830.350.

We describe and respond to the comments in section II of this document. We have grouped comments into several broad topics that reflect the primary concerns of similar comments, and have identified the section or sections of the final rule (or the proposed rule, when appropriate) that are most closely related to each topic. The order in which each topic or comment is discussed is purely for organizational purposes and does not signify a comment's value or importance.

II. Comments on the Proposed Rule and FDA's Responses

A. Definitions—21 CFR 801.3, 803.3, 806.2, 810.2, 814.3, 820.3, 821.3, 822.3, and 830.3

FDA received many comments (approximately 42) suggesting changes to, or clarification concerning, the definitions proposed for inclusion in the rule.

Convenience kit—A comment suggested we should restrict the scope of this definition by including additional language: “A group of reusable devices bearing and identified by an ordering number, appearing only on shipping container(s) and/or invoices, does not constitute a convenience kit.”

FDA does not agree that this additional language would clarify the definition; rather, we believe this addition would be more likely to confuse labelers than help them understand how the rule applies to convenience kits. A convenience kit, or any other device subject to this rule, may be identified by a wide variety of numbers or other identifiers for a wide variety of purposes. The use of catalog

numbers, inventory numbers, ordering numbers, or any other identification number is neither prohibited nor regulated by this rule, except that § 801.57 rescinds certain legacy FDA identification numbers and requires discontinuation of their use on a device label.

Comments suggested FDA should “remove all references to convenience kits” because kits (apart from their regulated device parts) are not themselves devices subject to UDI. Commenters also expressed concern that the requirement for a UDI on both components and kits is duplicative. The same comments went on to suggest that, if the final rule would apply to convenience kits, FDA should “modify the definition . . . to clarify that the term refers to convenience kits that have been determined to be and are classified as a medical device.”

FDA does not agree that convenience kits should be excluded from the final rule. Convenience kits are in wide use and are medical devices in their own right, apart from their constituent devices; their exclusion would leave a significant gap in the coverage of the rule and would undermine the effectiveness of the UDI system because they are controlled in the supply chain by the kit rather than by constituent part. FDA removed proposed § 801.25 from the final rule but only because convenience kits are by definition devices and therefore are required to meet UDI requirements. However, we do include an exception for the label of devices contained within the immediate container of a convenience kit at § 810.30(a)(11).

The final rule adopts the definition of *convenience kit* provided by the proposed rule, without change. The

final rule does, however, include important changes that we believe address the underlying concerns of these comments. Section 801.30(a)(11) now provides that the label of *devices packaged within* the immediate container of a convenience kit do not have to bear a UDI as long as the label of the convenience kit bears a UDI. This change will make clear that labelers do not have to change the way they label convenience kits, including in vitro diagnostic kits, except for including a UDI on the kit label.

Device package—We received several comments concerning this definition and the application of the rule to device packages other than the “immediate container” of the device. For example, one comment suggested the definition is “too broad and requires clarification to ensure that it does not apply to a group of devices that are shipped together only as logistics or shipping units such as orthopedic trays.” Another comment suggested that a UDI should be required on “regulated packaging” and noted that manufacturers commonly change quantities at higher levels of packaging for storage, logistics, and transportation purposes. Another comment did not specifically object to providing a UDI on varying device packages, but did not see a need for different UDIs on device packages that contain different quantities.

FDA disagrees that the UDI rule should not apply to device packages other than the immediate container, and that different device packages should not be identified by different UDIs. UDIs on all device packages are essential for rapid and efficient identification of devices that are the subject of a recall, a key objective of the UDI rule. The use of separate UDIs for higher level

packaging reflects prevailing industry practices (Refs. 3, 14, and 15). Similarly, different UDIs are useful for each different device package because a device recall might target a specific device package while excluding other device packages; in addition, the requirement for different UDIs on different device packages recognizes current industry practices, which generally use different identifiers for each level of packaging and for packages with different quantities of devices. Accordingly, we have not modified the definition of *device package* in response to comments. Because packages that contain a convenience kit, an in vitro diagnostic product, an HCT/P regulated as a device, or a combination product with a device constituent part all contain a particular version or model of a device, such packages also meet the definition of “device package” and are required to bear a UDI by § 801.20.

Six comments argued that a UDI should be required to appear only on the label of a device, and not on higher levels of packaging based on the premise that section 519(f) of the FD&C Act narrowly requires a UDI only on the device label.

FDA disagrees with this comment. As explained in the preamble to the amended proposed rule, the presence of a UDI on the higher-level packaging of a device will enable FDA to more efficiently and effectively respond to a reported device problem by using its regulatory tools, such as notification or mandatory recall under section 518 of the FD&C Act (21 U.S.C. 360h), tracking under section 519(e), ensuring the adequacy of a voluntary recall with the assistance of reports of corrections and removals as required by section 519(g), or seizing a device that is adulterated under section 501 (21 U.S.C. 351) and/or misbranded under section 502 (21 U.S.C. 352). Thus, the provisions of the final rule requiring a UDI on higher-level packaging are issued in aid of FDA’s authority under all of these sections of the FD&C Act, as well as under the Agency’s broad authority to issue enforcement regulations under section 701(a) (21 U.S.C. 371(a)) and its specific authority to implement UDI requirements to identify devices “through distribution and use” of the device under section 519(f). (See 77 FR 69393 at 69395.) Requiring a UDI on device packages enables the UDI to serve its purposes of assisting with tracking, recalls, and enforcement with respect to devices that have not yet been removed from their package, for example for devices located at distributors or in hospital inventory,

while avoiding any need to open or tamper with the device packaging.

Finished device—We did not receive any comments concerning this definition. This term is used in the definition of *lot or batch*, and is included to clarify the meaning of that term. This term is also useful when determining the “date of manufacture” that should be used as a production identifier; see the discussion of *Unique device identifier (UDI)*—Production identifier, in this document.

HCT/P regulated as a device—We have added this definition, and made other changes that are discussed later in this document, to explain how the final rule applies to HCT/Ps that are regulated as devices.

Implantable device—Comments suggested FDA should remove the 30-day threshold that restricts the direct marking requirement to devices intended to remain implanted continuously for a period of 30 days or more.

Such a change would result in unwarranted inconsistency with longstanding regulatory practice. For example, the definitions of *implant* used in 21 CFR parts 812 (investigational device exemptions) and 860 (medical device classification procedures) use the same 30-day criterion. The final rule adopts the definition provided by the proposed rule, without change. We note further that because FDA has removed the requirement of direct marking for implants, the definition of *implantable device* under the final rule is no longer relevant to the scope of the direct marking requirement.

Labeler—A comment suggested that the definition’s use of language referring to “the intent that the device will be introduced into interstate commerce” is not appropriate. Another comment suggested that the final rule should make clear that a health care system assembling “convenience kits” for distribution within its own system should not be a “labeler” and that such distribution is not interstate commerce. A somewhat similar comment suggested that “Hospitals, health care systems, and other entities that repackage devices, assemble kits, or reprocess single-use devices for internal use only . . . should not be subject to UDI-related requirements. . . .”

We believe that all of these concerns can be resolved by modifying the definition to refer to “commercial distribution,” a term that has been in use for many years and which is used extensively in FDA’s medical device regulations. The term “commercial distribution” is defined by § 807.3(b) and we intend for that definition to

apply here. “Commercial distribution” means any distribution of a device intended for human use which is held or offered for sale, but does not include internal transfer of a device between establishments within the same parent, subsidiary, or affiliate company.

Comments suggested FDA should modify the definition to include a “relabeler” or should define “relabeler.”

FDA agrees a relabeler is a labeler under this rule. We expected that our use of “modified” in paragraph (2) of the definition would have been understood to include “replaced.” FDA does not believe that introducing the term “relabeler” would provide greater clarity. Instead FDA believes we can better clarify our intended meaning by amending paragraph (2) of the definition to begin, “Any person who causes the label of a device to be *replaced or modified*. . . .” The final rule adopts this change.

Another comment suggested that the final rule “must more specifically describe when a repackager, device reprocessor, or other non-manufacturer would be . . . considered a ‘labeler’ for UDI purposes.”

FDA disagrees. This rule is not changing the meanings of repackager or reprocessor; those terms will have the same meanings as they now have within other regulatory contexts, such as registration and listing and premarket review, and thus would be considered labelers.

Lot or batch—A comment requested clarification regarding how this term should be applied to HCT/Ps, “where the donor identification is of singular importance.” Other comments mirrored this concern, stating that devices “derived from human tissue cannot be labeled by lot or batch, unless the lot or batch identification is associated with a single donor, as [21 CFR] 1271.220(b) disallows the pooling of human cells or tissue from two or more donors during manufacturing.”

FDA agrees that these are valid concerns, but we believe that the phrases “manufactured under essentially the same conditions” and “intended to have uniform characteristics and quality within specified limits” in the definition of *lot or batch* are flexible enough to include the distinct identification code required by § 1271.290(c). FDA has, however, addressed the concerns of these comments in another way. To clearly accommodate HCT/Ps regulated as devices, the final rule includes additional language in the definition of *production identifier* (part of the definition of *unique device identifier*);

this change is discussed in this document.

Shipping container—We did not receive any comments suggesting changes to this definition, but we have included minor edits in the definition provided in the final rule. Deletion of the words “package” and “pallet,” is meant to help to simplify the definition and avoid any confusion involving the defined term *device package*. These edits are not intended to change the meaning of the term.

Specification—A comment suggested that it would be better to define this term to mean a requirement with which a device must conform as documented in the Device Master Record consistent with § 820.30, Design controls.

FDA disagrees. The definition we proposed is built on language drawn from the Quality Systems Regulation, is consistent with existing practice, and is clear. The final rule adopts the definition provided by the proposed rule, without change.

Unique device identifier (UDI)—A comment suggested, “If HCT/PS regulated as medical devices are subject to the rule, we believe the donation identification number must also be considered a production identifier.” The concern underlying this comment is similar to that of a comment cited previously, concerning *lot or batch*.

FDA agrees that this definition needs to be modified to address existing practices concerning the labeling and tracking of HCT/PS regulated as devices. Accordingly, the final rule adds language to the definition of *production identifier*, which is part of the definition of *unique device identifier (UDI)*. At the end of paragraph (2), we have added the following additional production identifier: “(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c).”

Unique device identifier (UDI)—Production identifier. Comments requested clarification concerning one type of production identifier, the “date a specific device was manufactured.” For example, one comment stated that “it would be beneficial for FDA to clarify . . . which date FDA is referring to (i.e., date of assembly, product date, release date, etc.).”

FDA believes it is the responsibility of each labeler to determine the most appropriate date to use for each specific device, and to be consistent in application of that policy.

That said, FDA has provided a definition of *finished device* that we believe provides a sound benchmark when determining the date of manufacture.

A comment suggested that stand-alone software should be able to use its version number as its production identifier.

We agree that for stand-alone software, the version number falls within the meaning of *lot or batch*, which is one type of production identifier. Therefore, when the labeler of stand-alone software includes a version number on the label, it must be conveyed by the production identifier. Further, because it is important for the version number to be included in stand-alone software that is not distributed in packaged form, we are adding a requirement to § 801.50(a) that the version number must be conveyed as part of the production identifier for such software.

Universal product code (UPC)—We did not receive any comments concerning this definition, but we have included a minor edit in the definition used in the final rule. The revised definition refers only to identification of “an item sold at retail in the United States.” Reference to use of a UPC to identify the company associated with an item has been removed because this rule focuses on the adequate identification of devices, not companies.

Version or model—A comment stated: “The definition says that version or model means a package. This is not easy to follow because version or model normally refers to a device.”

FDA agrees. The final rule adopts a definition that we believe is clearer and better reflects the common understanding of this term. The final rule removes the reference to a “device package.” The final rule defines *version or model* to mean “all devices that have specifications, performance, size, and composition, within limits set by the labeler.”

Undefined terms—A few comments suggested that additional terms should be defined to clarify the scope and intent of the rule. For example, a few comments stated that FDA has not clearly defined the term “device.”

Although the proposed rule did not provide a definition of “device,” none is required. “Device” is defined by statute, (see section 201(h) of the FD&C Act (21 U.S.C. 321(h)), has been in common use for decades, and has been a core concept inherent in every medical device regulation ever issued. Its meaning should be clear to every person affected by this rule. This rule does not require any further definition or clarification of this term, and the final rule does not include a definition of “device.”

Another comment suggested FDA should define “device accessory.”

FDA disagrees. Section 201(h) of the FD&C Act makes clear that the term “device” includes an accessory. No other medical device regulation has defined “accessory” (the term is defined within the context of radiological health; see 21 CFR 1020.30(b)), and the final rule does not include any requirement that specifically applies only to an accessory to a device and does not distinguish between accessories and other devices in any way.

A comment pointed out that FDA has not defined “direct mark.”

We believe the meaning of this phrase is made clear by the language of § 801.45 in the final rule, and we specifically direct readers to § 801.45(c), *Form of a UDI when provided as a direct marking*.

A comment that was primarily concerned with medical procedure kits (discussed later in this document) suggested FDA should provide definitions for “set,” “kit,” “tray,” and “pack.”

The final rule provides definitions for *convenience kit* and *device package*. We do not believe the additional definitions are needed, and we believe section II. M., “Medical Procedure Kits and Trays” provides adequate information for a reader to understand how these items are regulated under the final rule.

Because FDA does not agree that any of the suggested additional terms need to be defined for an understanding of this rule, the final rule includes only one additional term that was not included in our July 10, 2012, proposed rule: “HCT/P regulated as a device”, which is discussed previously.

B. Applicability of § 801.20

There were a number of comments regarding the applicability of the UDI requirements of § 801.20 to combination products with a device constituent part, convenience kits, in vitro diagnostic products, and HCT/PS regulated as devices.

These products are devices, contain devices, or are regulated as devices, and are therefore subject to the requirements of this rule.

C. Compliance Dates of Unique Device Identifier Regulatory Requirements

FDA received many comments (approximately 100) suggesting changes to the compliance dates we proposed in our July 10, 2012, proposed rule and November 19, 2012, amended proposed rule (mistakenly referred to as “effective dates” in the proposed rule and amended proposed rule). Roughly one-third of the comments that expressed a specific view recommended a more

rapid implementation of the rule's requirements in order for the rule's benefits and goals to be more rapidly achieved; for example, these comments suggested the proposed phased implementation timeframe is "far too long," that the rule's requirements should go into effect "quickly—not years from now," and that "UDI needs to be implemented as quickly as possible." Roughly two-thirds recommended FDA allow more time in order to better manage the tasks required to meet the rule's requirements and to spread the costs of implementation over a longer period of time; for example, these comments suggested that FDA should "reconsider the schedule for implementation . . . as some of the defined time periods are not possible for companies that may have thousands of products containing various levels of packaging," and that "the proposed effective dates [meaning compliance dates] do not allow adequate time to prepare to meet the rule's requirements."

Several comments suggested that the compliance date of § 801.18 should be tied to the date the device must bear a UDI on its label; for example, a comment suggested that the compliance date of § 801.18 should be "aligned with the date the label of the device must bear a UDI."

FDA agrees with these comments, and we have established a set of compliance dates that are the same for § 801.18 and the rule's UDI labeling requirements. This avoids the need to change a device label more than once to implement the rule's requirements. We discuss the comments on § 801.18 and provide a full response in section II.D, "Formatting of Dates Provided on Medical Device Labels—§ 801.18."

Section VII.B, "Compliance Dates," explains the compliance dates FDA has established for this and other provisions of the final rule. This section makes clear that the requirements of the rule apply to devices put in commercial distribution after the applicable compliance date, and not to devices put in commercial distribution prior to such date. As discussed in section II.A in the context of the definition of "labeler," commercial distribution is defined at § 807.3(b) and the same meaning applies here.

Several comments suggested several changes to the timeframes proposed in our July 10, 2012, proposed rule and our November 19, 2012, amended proposed rule. The specific changes suggested varied considerably. For example, comments suggested several different ways to implement the requirements for UDI labeling and GUDID reporting.

Comments suggested that all devices should be subject to these requirements within 2 years, or 3 years. Other comments suggested that class II devices should be subject to these requirements after 3 years, or 5 years, or 7 years; that class III devices should be subject to these requirements after 1 year, or 2 years, or 3 years, or 5 years; that class I devices should be subject to direct marking requirements after 5 years instead of 7 years. A comment suggested that the implementation timeframe be tied to each issuing agency's "establishment and communication of processes to support the . . . Rule." We also received comments that simply recommended we implement the rule's requirements more quickly, or to allow more time for implementation, or to provide "adequate" time, but without suggesting specific timeframes. One comment suggested that if the compliance dates were not delayed "for several years," the rule should be repropose. Other comments agreed that the phased in implementation proposed by FDA would minimize the burdens. A comment stated that the proposed timeline for implementation of direct marking requirements is "reasonable and necessary," and another comment agreed that it is reasonable to require submission of GUDID data on the date a device must bear a UDI on its label.

Some comments were particularly concerned about requirements that would apply 1 year after publication of a final rule—The date formatting requirements of § 801.18 and the requirements for UDI labeling and GUDID reporting for class III devices. The comments concerning § 801.18 are discussed previously. Several comments concerning the compliance dates for class III devices requested more time; for example, a comment stated that the compliance date for class III devices "should be extended to 2 years from the date the rule is finalized" because the proposed 1-year timeframe "may not allow enough time for manufacturers to comply with the UDI requirements if their product portfolio contains a large number of those products." Other comments stated that revision of labeling "will be extensive and time consuming," that labelers will need more time "for the preparation and submission of device related data," and that the "timeframe . . . for class III device manufacturers to submit . . . data to the GUDID is too short. We believe the deadline . . . should be extended an extra year."

In summary, while many comments wanted some change to the implementation schedule proposed by FDA, there were many different views

concerning the precise timeframe those changes should take effect. Some comments recommended that labelers should be allowed to comply with the date formatting requirements of § 801.18 and basic UDI labeling requirements (labeling requirements other than direct marking) on the same date. On this latter comment, FDA agrees, as discussed in more detail in this document.

However, FDA does not agree with any comment that seeks broad changes to the proposed timeframes for implementation of UDI labeling or GUDID reporting requirements. Overall, we believe the schedule laid out in the amended proposed rule not only meets the statutory requirements of FDASIA, but also strikes a realistic balance between desires to quickly see benefits from the UDI system and the challenges that must be met to design, deploy, and test the systems that will be required to meet the new regulatory requirements and for effective and efficient administration of UDI processes. FDA also continues to believe that the implementation timeframe should be tied to the risk of the device. Consequently, FDA is establishing compliance dates as proposed in our amended proposed rule, except, as discussed previously, we have changed the compliance date of § 801.18 to coincide with the date a device must bear a UDI on its label.

There were 24 comments specifically requesting FDA to extend the 1-year compliance date for Class III devices, mostly to 2 years and mostly because the 1-year timeframe is inadequate to locate, rework, and validate new labeling for disparate inventories of existing devices. Separately three comments warned of possible withdrawal or export of non-complying inventory devices and resulting domestic product shortages if UDI requirements were imposed on inventory devices. We have addressed the latter concern by excepting inventory devices for an additional 3 years, during which time these devices can remain on the market without having to comply with UDI requirements. See revised § 801.30(a)(1) of the final rule; section II.G (Exception for Existing Inventories of Finished Devices That Have Been Labeled Prior to the Applicable Compliance Date) of this document. Although FDA is not aware of anything to substantiate, specifically, that the 1-year implementation timeframe for class III devices could lead to shortages, FDA has included a new process in the final rule through which FDA may, on our own initiative or upon the written

request of the labeler of a class III device or a device licensed under the Public Health Service Act, grant a 1-year extension of the compliance dates for UDI labeling and GUDID reporting when FDA determines that the extension would be in the best interest of the public health. For example, if the sole labeler of a particular class III device provides information showing that it will not be able to comply with UDI labeling requirements within the 1-year timeframe, and showing that a medical device shortage will result if it is unable to continue to ship the device until such time as it can comply with UDI labeling requirements, FDA would consider an extension of the 1-year compliance date. The process for requesting this extension is explained in § 801.55(b) of the final rule. FDA believes the availability of this limited exception will allow appropriate flexibility in implementing the final rule, while making it clear that FDA expects most class III devices will remain subject to the 1-year compliance date established by FDA in this document.

Several comments requested clarification concerning whether or when the rule would apply to devices manufactured and labeled prior to the applicable compliance date, or suggested that the final rule should provide an exception for such devices; for example, one comment suggested the rule should provide “an exception for all medical devices which have been manufactured prior to the issue of the final rule.”

FDA agrees that it is important to take into account these concerns, and we have done so by providing a limited exception in § 801.30(a)(1) of the final rule. We discuss comments on this topic and provide a full response in section II. G., “General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for Existing Inventories of Finished Devices That Have Been Labeled Prior to the Applicable Compliance Date—Final § 801.30(a)(1).”

Comments suggested that the proposed rule was not clear when the conforming amendments to parts other than 801 and 830 take effect. Under the amended proposed rule, and this final rule, any provision that does not have a more specific effective date would go into effect 90 days after publication of a final rule. One comment also suggested that there is not an immediate need to implement the amendments to part 820, Quality System Regulation, and part 822, Postmarket Surveillance, as “there will be few UDIs to track,” and that changes to computer systems will need validation.

FDA does not agree that there is a need to provide a different compliance date for the conforming amendments to parts other than 801 and 830. The proposed rule pointed out that some provisions that go into effect 90 days after publication of the final rule “will have no practical effect” until other provisions must be complied with. That is the case here. For example, the amendments to parts 820 and 822 will have no practical effect until 1 year after publication of the final rule, when class III devices become subject to UDI labeling requirements. We believe that this provides adequate time to prepare to meet the requirements added to these parts.

We received comments on the implementation timeframe for direct marking of implantable devices under proposed § 801.50(a)(1).

Because we decided to withdraw this proposed requirement, there is no need to discuss comments on the proposed implementation timeframe. We discuss other comments on proposed § 801.50(a)(1) and provide a full response in section II.W., “Changes to Codified Text in Response to Comments on Requirements Proposed in § 801.50—Devices That Must Be Directly Marked With a Unique Device Identifier.”

We received a few comments objecting to the compliance date FDA proposed in our November 19, 2012, amended proposed rule as applied to implantable, life-supporting, and life-sustaining devices. These comments disagreed with FDA’s interpretation of section 614 of FDASIA to require compliance with the rule within 2 years of publication of a final rule for three categories of devices—devices that are implantable, devices that are life-sustaining, and devices that are life-saving (life-supporting). These comments interpret section 614 of FDASIA to require the final rule to apply to a *single* category of device that is at once implantable, life-sustaining, and life-saving.

FDA disagrees with these comments. Although the statute uses the conjunctive “and” and not the disjunctive “or,” the phrasing is ambiguous, and it is reasonable to interpret the requirement to apply conjunctively to all three categories of devices, as detailed in the preamble to the amended proposed rule. There is no legislative history indicating a Congressional intent inconsistent with this interpretation.

Further, regardless of whether these changes to section 519(f) of the FD&C Act made by section 614 of FDASIA apply to one or three categories of devices, FDA’s implementation of this

rule complies with the statute since the single category preferred by the comments is included within each of FDA’s three categories, and it is within FDA’s authority to change the compliance date for UDI requirements to apply to different categories of devices. This includes accelerating the compliance date for devices that are implantable, devices that are life-sustaining, and devices that are life-saving or life-supporting, all of which are of particular importance from a public health standpoint and thus have been singled out in several places in the FD&C Act for heightened oversight, as explained in the preamble to the proposed rule. Thus the final rule adopts the compliance dates proposed in our November 19, 2012 amended proposed rule for implantable, life-supporting, and life-sustaining devices (see table 6).

D. Formatting of Dates Provided on Medical Device Labels—§ 801.18

FDA proposed that all dates provided on a medical device label that are “intended to be brought to the attention of the user of the device. . . shall be presented in the following format: Month Day, Year (e.g., JAN 1, 2012).” We also proposed that labelers would have to comply with the requirements of proposed § 801.18 1 year after publication of a final rule. FDA received many comments (approximately 110) on the proposed date format and the proposed compliance date of the date format. Nearly all of these comments opposed the proposed date format, considered the time provided to implement this labeling change to be inadequate, or both. Although many comments recognized the benefits of standardized dates, most viewed FDA’s proposal as too restrictive, too burdensome, inconsistent with the needs of international commerce, and inconsistent with existing industry practices. Comments noted that FDA’s proposed date format would require different labels for a device when marketed in the United States and the same device when marketed in the European Union or other international markets. For example, comments noted that the date format required by the proposed rule “is not consistent with global requirements” and “perpetuates an opportunity for confusion” by not implementing “standardized international dating systems.”

FDA agrees with these comments and has revised § 801.18 as discussed in this document.

One comment suggested that FDA should permit a manufacturer to use any date format it chooses, “as long as the

manufacturer makes clear” what format it is using, and a similar comment suggested FDA should “should allow for multiple data formats” but should give “priority . . . to international standards.” Several comments suggested that FDA should permit truncated dates, using only the year and month (YYYY–MM). This is one of the formats permitted under some international standards, such as International Organization for Standardization (ISO) 8601:2004, that were cited by comments.

FDA disagrees with all of these suggestions. Any approach that allows for multiple formats would require patients and health care professionals to spend time and effort to determine how a given labeler’s dates should be interpreted. A date format that provides only the year and month could still leave users uncertain as to whether an expiration date refers to the first day of the month, or the last day of the month. This is little different from the current situation, where variation in the presentation of date confuses users and can lead to incorrect decisions, such as determining whether a device has reached an expiration date.

FDA agrees with a comment that suggested a “single specified date format will reduce confusion” concerning interpretation of dates on medical device labels, and with the many comments that suggested that FDA should abandon its proposed date format and should instead adopt a date format specified in an international standard, such as ISO 8601:2004, and consistent with international usage, including that of the European Union. If all dates were formatted in this way, “one label can be used globally for all product identification.” These comments were consistent with a comment that suggested, “The manufacturing date, expiration date, and any other necessary date should be written as YYYY–MM–DD to harmonize with the ISO 8601 requirements.” FDA agrees, and the final rule provides that all dates on medical device labels intended to be brought to the attention of the user must be presented as year-month-day (for example, 2013–09–30). FDA does not, however, agree with comments that suggested we should incorporate ISO 8601:2004 or any other international standard, because the standards we examined all permit multiple formats, for example, by permitting dates that use only the year and month (YYYY–MM), and truncated dates are not permitted by the final rule. In the event that a medical device expires in a particular month, but not a particular date, the labeler may choose

the last day of the month for the date field.

Proposed § 801.18(f) provided that for a device that is an electronic product to which a standard is applicable under subchapter J of this chapter, Radiological Health, the date of manufacture shall be presented as required by § 1010.3(a)(2)(ii). One comment suggested the date format proposed in § 801.18 should also apply to those products.

FDA does not agree. Section 1010.3(a)(2)(ii) provides a consistent date format, specifies that the date is the date of manufacture, has been the standard practice for many years, and has proven to be adequate for electronic products regulated under subchapter J. At this time, no need for an alternative approach for electronic products has been shown. Section 801.18(b) of the final rule provides an exception for an electronic product to which a standard is applicable under subchapter J, and such devices will continue to be required to present the date of manufacture as provided by § 1010.3(a)(2)(ii).

A few comments suggested that the date format should not apply to data communicated by AIDC technologies (e.g., bar codes and radiofrequency identification (RFID)).

FDA agrees that we should not attempt to regulate how data is communicated by AIDC technologies, or the order in which specific information is communicated by AIDC.

In response to comments that suggested the proposed 1 year compliance date for § 801.18 “does not provide adequate time” to make label changes for all devices covered by the rule, FDA is establishing compliance dates for § 801.18 that will phase in the date format requirement at the same time as the UDI labeling goes into effect for a particular device. This will reduce the costs and burdens of the final rule by allowing both the date format and UDI labeling changes to be made in a single revision.

A comment, though generally very supportive of the UDI proposed rule, argued that the FD&C Act, and section 510(e) (21 U.S.C. 360(e)) in particular, does not provide authority for the uniform date format provision, noting that the legal authority section of the proposed rule did not specifically explain FDA’s authority for this provision. The focus of this comment was disagreement with the date format chosen by FDA and the compliance date for this provision, both of which have been modified as detailed in this preamble.

FDA disagrees that the FD&C Act does not provide legal authority for § 801.18. Under section 502(a) of the FD&C Act, a device is misbranded if its labeling, which includes its label, is false or misleading. As discussed in this preamble and the preamble to the proposed rule, the variety of inconsistent date formats currently in use can be confusing and misleading to device users. Many comments agreed with FDA that requiring a uniform date format for all device labels that is consistent with international standards should, in time, eliminate any such confusion or misunderstanding, ensuring that the label is not misleading to users. To the extent dates are required to appear on the label, for example under a premarket approval (PMA) order, section 502(c) of the FD&C Act requires that they be in such terms as to render them likely to be understood by the ordinary individual under customary conditions of purchase and use. Requiring a uniform format will, in time, ensure that dates on labels intended to be brought to the attention of users will be likely to be correctly understood by them. In addition, section 701(a) of the FD&C Act provides authority for FDA to issue § 801.18.

E. General Exceptions from the Requirement for the Label of a Device To Bear a Unique Device Identifier—Broad Comments Concerning Proposed § 801.30

We received comments that expressed broad support for the exceptions provided by proposed § 801.30, and comments that expressed broad opposition to the exceptions provided by proposed § 801.30. Comments that expressed broad opposition included comments that recommended all exceptions from UDI requirements should be on a case-by-case basis, and comments that recommended that all of the exceptions provided by § 801.30 should be eliminated. Comments that expressed broad support included comments to the effect that the proposed exceptions are “appropriate” or “not inappropriate,” and a comment that FDA should not implement any UDI requirement that creates a burden that is not offset by corresponding value.

FDA disagrees with the comments that suggest we should not provide any categorical exceptions. We agree that the UDI rule should take into account both its benefits and its costs. Similarly, we do not agree that it would be best to rely entirely on case-by-case exceptions. A case-by-case approach alone would be far more burdensome than providing carefully crafted categorical exceptions,

and would be more likely to result in regulatory inconsistencies and confusion that would hamper the objectives of the UDI system. However, as described in this document, we made certain changes to the exceptions in response to comments.

F. General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for a Device, Other Than a Prescription Device, That Is Made Available for Purchase at a Retail Establishment, Including Such a Device Delivered Directly to a Hospital, Ambulatory Surgical Center, Nursing Home, Outpatient Treatment Facility, or Other Health Care Facility. Proposed § 801.30(a)(1)

FDA received many comments (approximately 35) on this proposed exception. Roughly half of these comments requested or suggested a clarification of some aspect of the exception. For example, comments requested clarification concerning the meaning of “retail establishment,” and whether the exception would apply to devices sold through any retail channel, including online, and “not simply those sold in brick-and-mortar-type stores.” Other comments suggested FDA needed to clarify whether the exception would be available for a device that is available for purchase at a retail establishment when that device is sold directly to a hospital or physician. Some comments supported the exception as proposed. For example, a comment stated, “applying a UDI on each individual device [sold at retail and labeled with a UPC] would not improve identification of devices . . . and would amount to an unnecessary burden and cost.” Another comment stated, “Providing an exception for non-prescription devices sold at retail is both wise and appropriate.” Other comments opposed the exception as proposed. For example, a comment stated that this exception would be “ill-advised” and recommended that these devices “should be subject to UDI requirements, but . . . their UPC codes should be deemed to be the UDI. . . . In particular, we believe it is essential that labelers of the affected retail products be required to submit UPC data to the GUDID.” Another comment recommended that the proposed exception should not be available for devices that “may have a significant impact on patient health.”

FDA believes the comments criticizing the proposed exception are persuasive in that the availability of a device for purchase in retail establishments has little relationship to

the potential for risk of the device. Indeed, devices available at retail include moderate and even high risk devices such as automatic external defibrillators. Further, devices sold through retail channels may have unusually broad distribution resulting in correspondingly broad impact when the device is defective and needs to be recalled. Accordingly, we are limiting the proposed exception to provide, in § 801.40(d), that a class I device that bears a UPC on its label and device packages is deemed to meet all UDI labeling requirements and that the UPC will serve as the UDI required by § 801.20. This excepts a class I device with a UPC on its label and packages from UDI labeling requirements regardless of to whom or through what channels it is sold. Such a device will be subject to GUDID reporting requirements. We note that the lowest risk devices available for sale at retail establishments will in any case be excepted from UDI requirements by virtue of § 801.30(a)(2).

G. General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for Existing Inventories of Finished Devices That Have Been Labeled Prior to the Applicable Compliance Date—Final § 801.30(a)(1)

We received several comments (approximately 22) requesting clarification concerning how the rule will apply to devices that were manufactured prior to the applicable compliance date of the rule, but which have not yet been sold to a hospital or other purchaser. For example, a comment recommended, “the implementation effective date [meaning compliance date] should be tied to the date of manufacture rather than date of distribution.” Another comment also recommended that the date of manufacture should be used “to determine compliance with the UDI requirements” and stated this was the approach FDA used in implementing FDA’s final rule, “Bar Code Label Requirements for Human Drug Products and Biological Products” (69 FR 9120; February 26, 2004). These comments were concerned that applying UDI labeling requirements to finished devices that have already been labeled and ready for delivery to a purchaser would require costly relabeling, and would add to the burdens required to implement the rule’s requirements.

FDA agrees with these comments and recognizes the precedent set by the earlier bar code label rule. Section 801.30(a)(1) of the final rule provides an exception for a “finished device

manufactured and labeled prior to the compliance date that applies” to the device, but this exception “expires with regard to a particular device 3 years after the compliance date that applies” to the device. We believe that 3 years after the compliance date, which provides (depending on the compliance date that applies to a particular device) for a total lead time of 4 to 8 years from now, is sufficient time to exhaust existing inventories of finished devices that have been labeled prior to the applicable compliance date. This exception would be available for devices held in inventory by a labeler; it would also be available for devices consigned to a hospital or other potential purchaser and held in inventory by the potential purchaser, but which have not yet been sold to that potential purchaser. If a device has not yet been labeled, this exception will not be available. Similarly, if any actions remain to be completed before the device is considered a finished device, this exception will not be available.

FDA recognizes that there may be rare and unusual circumstances where the limited period provided by this exception might be problematic. For example, it may not be possible to relabel a particular cryopreserved HCT/P regulated as a device held in inventory longer than 3 years to add a UDI without damaging the HCT/P. In such rare and unusual circumstances, FDA may exercise enforcement discretion to permit continued distribution of a device, particularly if a device shortage would be likely if we rigorously enforced the UDI labeling requirements upon expiration of the exception period. Any manufacturers who are currently aware of the need for a longer period of time than is afforded by this rule to deplete existing inventory are encouraged to contact FDA.

H. General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for Class I Devices That FDA Has Exempted From Good Manufacturing Practices—§ 801.30(a)(2)

FDA received several comments (approximately 18) on this proposed exception. One comment recommended that FDA limit the number of devices that are exempt from UDI requirements. Nearly all of the remaining comments supported the proposed exception and most also recommended expansion of the proposed exception to all class I devices.

FDA does not agree that this exception should be extended to all class I devices. Class I devices, which constitute the majority of medical

devices, play important functions in the health care system and in the lives of patients and consumers. Class I devices are frequently subject to adverse events and recalls, and without UDI the resolution of these issues would be impeded. If all class I devices were excepted, the objectives of the UDI system would be seriously compromised. We have, however, amended this exception to clarify that it is available even when a good manufacturing practice (GMP) exemption includes a requirement for continued recordkeeping under §§ 820.180 and 820.198.

I. General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for Individual Single-Use Devices, All of a Single Version or Model, That Are Distributed Together in a Single Device Package—§ 801.30(a)(3)

FDA received several comments (approximately 22) on this proposed exception. FD&C Act section 201(I)(1) (21 U.S.C. 321(I)(1)) defines “single-use device” to mean any device that is intended for one use, or on a single patient during a single procedure. One comment recommended that all categorical exceptions, whether for single-use devices, class I devices, or otherwise, should be avoided, and that exceptions should be considered on a case-by-case basis. Seven comments supported the proposed exception (one of these comments conditioned its support on an assumption that MRI compatibility would not be a concern). Thirteen comments recommended expanding the exception—four comments suggested the exception be extended to all class I devices (one of these suggested that if there is a category of class I devices that warrants inclusion in the UDI system, then only that category should be subject to UDI requirements and all other class I devices should be exempted); seven comments suggested the exception be extended to class II single-use devices; and two comments suggested the exception should be extended to all single-use devices.

FDA agrees it is appropriate to extend the exception to all classes of devices, except implants, and the final rule does so.

One comment requested clarification concerning how this exception would apply to reprocessed single-use devices. With respect to a single-use device, the term “reprocessed” means that the device has been subjected to additional processing or manufacturing after use on a patient for the purpose of rendering the device fit for an additional use on

a patient. See FD&C Act section 201(I)(2) (21 U.S.C. 321(I)(2)).

FDA sees no reason why a reprocessed SUD that meets the other criteria for this exception should be excluded from the scope of the exception.

J. General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for a Custom Device Within the Meaning of § 812.3(b)—§ 801.30(a)(5)

FDA received approximately four comments on this proposed exception. One comment opposed this exception. Three comments recommended this exception be extended to specific devices: Cranial remolding orthoses, prescription eyewear, and contact lenses.

These are types of devices and do not categorically qualify as custom devices within the meaning of § 812.3(b). We note that single-use contact lenses, however, would be subject to the exemption from the need to be individually labeled with a UDI under § 801.30(a)(3). Concerning the other devices, FDA does not agree that they should generally be excepted from UDI. In particular, FDA intends the custom use exception of the final rule to be available only for devices within the meaning of § 812.3(b), and we have adopted proposed § 801.30(a)(5) without any change.

K. General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for a Device Intended for Export from the United States—§ 801.30(a)(8)

FDA received two comments on this proposed exception. One comment opposed the exception, viewing it as inconsistent with a “truly harmonized global device identification system.” The other comment recommended that class I single-use devices intended for export should bear a UDI.

FDA does not agree with either comment. There is no assurance that a UDI that meets U.S. regulatory requirements would meet the requirements of the nation to which a device is exported, and it is possible that U.S. UDI requirements conflict with the requirements of the nation to which a device is exported. For these reasons, FDA has not accepted the recommendation of either comment, and we have adopted proposed § 801.30(a)(8) without any change.

L. General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for a Device Packaged Within the Immediate Container of a Combination Product or Convenience Kit—Similar Requirements Proposed at § 801.25; Revised Requirements at § 801.30(a)(11)

Proposed § 801.25 was titled, “Unique device identifiers for combination products, device constituent parts of a combination product, and devices packaged in a convenience kit.” Section 801.25 would have required the label of every combination product with a device constituent and the label of each device constituent part of a combination product to bear a UDI (with one narrow exception), and would have required the label of every convenience kit and the label of every device included in a convenience kit to bear a UDI. FDA received many comments (approximately 70) concerning proposed § 801.25. These comments addressed a wide variety of concerns. For example, one comment stated that the law does not require UDIs for combination products, and that FDA therefore has “full latitude” in adapting UDI to combination products. Some comments suggested a single UDI would be sufficient for a combination product or a convenience kit, while other comments stated it was prudent to require a UDI for both a combination product and its device constituent parts. A comment suggested that FDA should require a UDI on any combination product with a device constituent part, regardless of its primary mode of action, while other comments stated it is “. . . NOT . . . appropriate to require each device constituent part of [a] combination product to bear its own UDI when the primary mode of action is not that of a device” or suggested combination products should be labeled with a UDI or an NDC according to the primary mode of action of the product. Some comments wanted to introduce additional nuances, such as requiring a UDI for the device constituents of combination products only if “they are already labeled and packaged individually” and another comment expressed the view that any device constituent that “may be used more than once (whether or not intended for a single use)” should be labeled with a UDI. One comment recommended that the final rule should “remove all references to convenience kits. . . . [T]hey are very difficult to define,” while another comment recommended, “FDA should require all devices in a convenience kit to be labeled.”

These and other comments convinced FDA that we need to simplify our requirements regarding combination products and convenience kits. The final rule provides a much simpler approach by removing proposed § 801.25 and providing two new exceptions—

- Section 801.30(a)(11) provides that if a device is packaged within the immediate container of a combination product or convenience kit, the label of that device will not be required to bear a UDI, provided that the label of the combination product or convenience kit bears a UDI.

- Section 801.30(b) addresses situations where a combination product properly bears an NDC number. The NDC database is a system that, while different from the GUDID, permits tracking and identification. Crafting this exception for products with an NDC number avoids potentially redundant requirements. Section 801.30(b)(1) makes clear that a combination product that properly bears an NDC number on its label is not required to bear a UDI. As provided in § 801.30(b)(2), the device constituent of a combination product described by § 3.2(e)(1) (such a product is often informally referred to as a “single-entity” combination product) that properly bears an NDC number on its label is not subject to UDI labeling requirements. Section 801.30(b)(3) makes clear that the device constituent of a combination product described by § 3.2(e)(2) (such a product is often informally referred to as “co-packaged” combination product) that properly bears an NDC number on its label must also bear a UDI on its label, unless it is exempt under § 801.30(a)(11).

We believe this simplified approach is far more likely to be understood and correctly applied and minimizes the changes labelers need to make to current practices to be in compliance with the rule.

M. Medical Procedure Kits and Trays

We received comments that were concerned with how UDI requirements would apply to medical procedure kits and trays. A medical procedure kit typically consists of one or more medical devices, packaged together with one or more combination products, drugs, or biologics, to facilitate a single surgical or medical procedure. The medical procedure kit is typically packaged upon or within a medical procedure tray and is packaged so as to maintain sterility or to facilitate sterilization. The devices within a medical procedure kit are not necessarily individually packaged, so as to be ready to use immediately upon

opening the medical procedure kit. A medical procedure tray is a tray or other container upon or within which the components of a medical procedure kit are arranged to facilitate a surgical or medical procedure. Orthopedic procedure kits are a well-known example of a medical procedure kit. These comments were primarily concerned that the rule would require changes in the way medical procedure kits are assembled and packaged, which could interfere with sterilization processes and the use of the medical procedure kit.

A medical procedure kit is either a convenience kit, if it contains only medical devices, or a combination product, if it contains both a device and a drug or biologic. The final rule excepts a device packaged within the immediate container of any convenience kit or within the immediate container of a combination product from bearing a UDI on its label provided, as long as the kit or combination product is labeled with a UDI in accordance with § 801.30(a)(11). Where a combination product properly bears an NDC and does not bear a UDI on its label, the device constituent part must bear a UDI on its label. We believe this approach addresses the concerns raised regarding medical procedure kits.

N. General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier—Exception for a Device Held by the Strategic National Stockpile and Granted an Exception or Alternative Under § 801.128(f)(2)—§ 801.30(a)(9)

FDA received two comments that opposed this exception, which would provide the Strategic National Stockpile (SNS) the same latitude with regard to UDI labeling as is provided for other labeling requirements. The commenters believe that proper SNS management requires expiration dates on devices and the removal of recalled devices.

FDA declines to remove this exception, which runs parallel with other exceptions or alternatives granted under § 801.128(f). The UDI final rule does not require the use of expiration dates or the removal of recalled devices. By the same token, the § 801.30(a)(9) exception does not restrict the use of expiration dates for SNS devices or applicability of recalls. We believe it is highly unlikely that such an exception or alternative will ever need to be granted, but it is essential to provide flexibility to respond to any unforeseen set of circumstances involving operation of the Strategic National Stockpile.

O. General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier. The Unique Device Identifier of a Class I Device Is Not Required to Include a Production Identifier—§ 801.30(c)

FDA received approximately seven comments on this exception. Three comments supported the exception or recommended expansion of the exception. For example, a comment suggested FDA should extend the exception to all devices sold at retail (this could include some class II and some class III devices). Four comments recommended that production identifiers be required for all class I devices, or at least for certain class I devices. For example, two comments recommended that the UDIs of electrically powered devices should include production identifiers, and another comment recommended that production identifiers be required for surgical instruments.

FDA does not agree that this exception should be modified. We agree that production identifiers are important, but we have provided this limited exception to avoid imposing significant burdens on lower risk devices, where the public health need for precise identification is less urgent than for moderate- and high-risk devices. The final rule adopts the proposed exception without any change.

P. Requests for Additional General Exceptions From the Requirement for the Label of a Device To Bear a Unique Device Identifier

Several comments suggested that the final rule should provide additional exceptions to § 801.30, excepting additional types of devices from UDI labeling and GUDID reporting requirements or providing for alternative placement of UDIs on some device labels; the following examples illustrate the scope of these suggestions:

- A comment recommended “HCT/Ps . . . be exempted from the UDI Final Rule.”
- A comment suggested that analyte-specific reagents that can, by regulation, be sold only to certain entities and which “are not directly used in any health care setting” should be exempted from UDI requirements.
- A comment suggested that an orthopedic procedure tray should not be treated as a medical device, but as a type of shipping container, as the contents vary with every shipment “due to patient needs.”
- A comment suggested that an exception should be provided for sterile convenience kits sold with a “standard

configuration of devices” and that UDIs should not be required for “non-sterile trays, such as orthopedic trays.”

- A comment suggested there should be an exception for durable medical equipment.

- A comment requested an exception for medical and dental x-ray film, because the film business is converting to digital media and will be commercially obsolete in 5 years.

- A comment suggested that FDA should provide an exception for certain devices that involve the generation, measurement, and use of medical gases, calibration gases, and gases that might be regulated as medical devices because, the comment states, they are low risk, have limited space for labeling, would require multiple UDIs on assemblies, already have traceable numbers, and it would be costly to make them compliant.

- A comment requested an exception for class II medical device gases and container closure systems, because, the comment states, they are subject to Department of Transportation, ISO, and Compressed Gas Association standards, are already traceable, have relatively small batch size, and high cost to implement UDI relative to the improvement afforded by UDI.

- A comment requested an exception for “flat pack” cases in which rigid gas-permeable contact lenses are initially shipped by the manufacturer, “because they are commonly discarded in favor of larger storage or disinfecting cases” and consequently a “requirement that the flat pack bear a UDI would be pointless.”

- A comment requested an exception from UDI labeling for diagnostic/trial contact lenses that are otherwise fully labeled, but which are not intended for commercial sale.

- A comment requested an exception for a nurse call system (characterized by the comment as a type of powered environmental control system under § 890.3725).

- A comment suggested that the implementation timeframe for class III contact lenses is “unrealistic” and that class II and class III contact lenses should be subject to the same implementation timeframe.

FDA is not providing a narrowly targeted exception for any of these devices in the final rule for two reasons. First, the final rule includes significant changes to § 801.30, which provides certain categorical exceptions from the requirement for the label of a device to bear a UDI, and to other provisions that may be relevant to the concerns expressed in the comments that request additional exceptions. Second, the

information provided by these requests and comments varied considerably in scope and detail, and none provided sufficient information to justify an FDA decision to except a category of devices from any UDI requirement. FDA believes it is more appropriate for all requests involving an exception or alternative to UDI requirements that do not fit into the categorical exceptions of the final rule to be evaluated through the revised process provided by § 801.55 of the final rule. Section 801.55 of the final rule builds on proposed § 801.35, but has been revised and has expanded the circumstances under which an exception from or an alternative to a UDI requirement may be requested or granted. If after reviewing the changes made in the final rule a person who requested an exception or alternative in a comment on the proposed rule still believes that some type of exception or alternative is required, we invite that person to submit a request under § 801.55, and to ensure that the request provides the information required by § 801.55(a).

A comment suggested FDA should add an exception to make clear that UDI requirements do not apply to a device constituent being shipped for further processing as part of a combination product.

FDA disagrees. Such shipments are already generally governed by § 801.150 (Medical devices; processing labeling, or repacking), and should be evaluated under that framework.

Q. Request for Modification of Unique Device Identifier Labeling Requirements for Devices That Have Small Labels

Some comments suggested the rule should provide an exception from UDI labeling requirements “where the label is too small” to accommodate both human readable and AIDC information, “provided that the UDI appears on the next higher level of packaging.” A similar comment suggested that if a device with a small label is included in a convenience kit, a UDI should be required only on the label of the convenience kit.

FDA believes that some of the concerns underlying these requests have been resolved by the revisions made to § 801.30, which provides general exceptions from the requirement for the label of a device to bear a UDI. For example, under the final rule, except for implantable devices, we have extended to all classes the exception for individual single-use devices, all of a single version or model, that are distributed together in a single device package, and which are not intended for individual commercial distribution (see

§ 801.30(a)(3)), and a UDI is not required on the label of the device constituents of combination products and the contents of convenience kits as long as the label of the combination product or convenience kit bears a UDI (see § 801.30(a)(11)).

FDA does not agree that any additional exception should be provided in the final rule based only on the size of the device label. First, the comments we received did not provide sufficient information to allow FDA to establish objective criteria to guide labelers in deciding when a device label or package would be “small enough” to qualify for any exception we might provide. Second, none of the comments we received provided sufficient information to evaluate the reach of an exception based on size. For these reasons, we believe it is preferable that requests for an exception or alternative to UDI requirements based on label size be evaluated through the process provided by § 801.55 of the final rule; this provision is explained in the section II.BB “Request for an Exception from or Alternative to a Unique Device Identifier Requirement—Proposed § 801–35; § 801.55 of the Final Rule.” Accordingly, we are not making any special provision concerning the labeling of small devices, and we expect the labels of devices of all sizes to bear a UDI as required by the final rule.

R. Voluntary Labeling of a Device With a Unique Device Identifier—Proposed § 801.40; Revised Requirements at § 801.35

FDA received two comments on this provision.

One comment stated voluntary UDI labeling will cause confusion, as most exempt devices will already bear a UPC.

FDA does not agree with this comment. We do not believe that any confusion will result from such labeling, as the formats of a UPC and a UDI will differ. The final rule permits, but does not require, a device to bear both a UDI and a UPC.

The other comment stated that if there are no categorical UDI exceptions, there would be no reason to allow voluntary UDI labeling.

Because FDA has determined that the final rule will provide a number of categorical exceptions, as explained previously, we cannot agree with this comment. The final rule does, however, make a change to this provision. In paragraph (b), we have deleted language that would have limited the use of UPCs to instances where a device “is sold at retail.” We do not believe that restriction is necessary to the objectives of the final rule, and its removal makes

clear that a class I device that bears a UPC on its label will be deemed to meet of the requirements of § 801.20(a).

S. Form of a Unique Device Identifier—Technical Requirements—Proposed § 801.45(a); § 801.40(a) of the Final Rule

FDA received many comments (approximately 25) on these requirements. Several of these comments simply voiced agreement with the proposal, or agreed that the requirement for an easily readable plain-text form of the UDI is clear.

Several comments suggested the rule should be more prescriptive. Many of these comments suggested FDA should designate a single issuing agency to operate the UDI system; that we should require the UDI system to conform to standards in addition to those that are incorporated by reference in part 830; that we should require use of one particular form of AIDC, such as particular versions of 2D or 3D barcodes or particular technologies to read and record those barcodes; that we should require the system to be designed so as to be compatible with systems used by certain other governmental agencies. Other comments took an opposing view, and urged FDA to remain technologically neutral, and not to require use of a particular form of AIDC; to allow the health care community to adapt to new technologies and process improvements; to recognize that labelers need the greatest amount of flexibility to handle changes in technology as they arise; and to allow flexibility in the use of AIDC technology to encourage innovation.

We believe that choosing a single issuing agency would limit the health care community's ability to develop and use appropriate device identification systems. Labelers currently use more than one system, each of which creates a globally unique identifier, and these systems can be used simultaneously to support different device types.

FDA does not agree that the UDI rule should be highly prescriptive with regards to AIDC technologies or standards. Requiring adherence to a particular AIDC technical standard would be detrimental to innovation concerning AIDC technologies, and would, we believe, do long-term harm by slowing the adoption of new technologies. There is nothing in section 519(f) of the FD&C Act that suggests FDA must, or should, impose a highly prescriptive UDI system. FDA agrees with comments that recommend that FDA not require the use of specific forms of AIDC or specific AIDC technologies.

A comment stated that permitting labelers to use a barcode or RFID as its AIDC would force purchasers to incur increased costs in order to read these differing forms of AIDC.

Though this rule does not impose any requirement on the purchaser or users of a device, we recognize the potential need for end users to acquire different technologies to read multiple forms of AIDC technologies. This potential concern, however, must be balanced against the concerns discussed in this document about prescribing a single AIDC technology, which FDA believes could also incur costs for certain purchasers as well as for labelers. As elsewhere in this rule, we have chosen the approach that retains flexibility for those subject to the regulation rather than prescribing a new requirement in the absence of a justification or uniform support.

The final rule makes no changes to the language of proposed § 801.45(a), now at § 801.40(a) of the final rule.

T. Form of a Unique Device Identifier—Unique Device Identifier To Include Device Identifier and Production Identifier—Proposed § 801.45(b); Revised Requirements at § 801.40(b) of the Final Rule

FDA received a few comments (approximately four) on these requirements.

Three comments suggested that if HCT/Ps regulated as devices are subject to the rule, the distinct identification code required in § 1271.290(c) should be added to the list of production identifiers that are used as part of an HCT/P's UDI.

FDA agrees with this view, and we have added “the distinct identification code required by § 1271.290(c) to the list of production identifiers included in the definition of *unique device identifier (UDI)*. Labelers are required to report to the GUDID only the type of production identifiers that appear on the label of the device, and not individual production identifiers. For example, if a serial number is provided on a device label, the labeler would have to report that fact to the GUDID, but would not have to report each individual serial number to FDA. Production identifiers such as distinct identification code required by § 1271.290(c) to appear on device labels will not have to be submitted to FDA and will not be included in the GUDID.

One comment raised a concern about how production identifiers would apply to laboratory-developed tests (LDTs). Another comment claimed that LDTs are services, do not fall within the definition of “device” at section 201(h)

of the FD&C Act, and that FDA therefore lacks statutory authority to impose UDI requirements on LDTs.

As this rule does not make changes to what qualifies as a “device” under section 201(h) of the FD&C Act, this comment is beyond the scope of this final rule.

U. Form of a Unique Device Identifier—Proposed Symbol To Indicate the Presence of Automatic Identification and Capture Technology—Proposed § 801.45(c); Revised Requirements at § 801.40(c) of the Final Rule

Proposed § 801.45(c) would have required a device label or device package to bear a symbol indicating the presence of AIDC technology whenever the AIDC “is not evident upon visual examination of the label or device package.” The proposed language identified the types of symbols that could be used. Among the types of symbols permitted was an FDA-proposed generic symbol.

We received many comments (approximately 40) on this proposal. None of these comments expressed support for the FDA-proposed generic symbol. Many suggested that only specific internationally recognized symbols should be permitted, and some suggested each issuing agency should specify the symbols that would be used. Some comments went further, and objected to the provision in its entirety; these comments were primarily concerned that an AIDC symbol would crowd label space and lead to confusion, particularly if the provision permitted different labelers to choose different symbols.

In response to these comments, FDA has simplified this provision, now at § 801.40(c), so that it requires that the label or device package disclose the presence of AIDC technology without specifying how. We deleted the authorized use of an FDA-proposed generic symbol. We believe this approach addresses the concerns of device users that the FDA symbol will crowd label space and be confusing or conflict with other expectations of the issuing agency, while providing labelers greater flexibility and reduced burdens.

V. Form of a Unique Device Identifier—Effect of Labeling a Class I Device With a Universal Product Code—New § 801.40(d) of the Final Rule

FDA has added this provision to explain that a class I device that bears a UPC on its label and device packages is deemed to meet all requirements of subpart B of this part; these devices will not have to bear a UDI on their label or device packages and will not be subject

to direct marking requirements. The UPC will serve as the UDI required by § 801.20. The labeler of such a device is still required to submit data concerning the device to the GUDID, unless the UPC device also qualifies for the exemption under § 801.30(a)(2) as a Class I GMP-exempt device. Such devices are wholly exempt from UDI requirements, including the requirement to submit data to the GUDID.

W. Changes to Codified Text in Response to Comments on Requirements Proposed in § 801.50—Devices That Must Be Directly Marked With a Unique Device Identifier

Requirements proposed in § 801.50, concerning devices that must be directly marked with a UDI, have been reorganized, modified, or withdrawn, as follows:

- §§ 801.50(a)(1) and (g)—Withdrawn.
- §§ 801.50(a)(2), and (b) through (f)—Now at § 801.45 of the final rule, which concerns devices that must be directly marked with a UDI.

- § 801.50(a)(3)—Now at § 801.50 of the final rule, which provides special requirements for stand-alone software.

Because of these changes, comments submitted concerning proposed § 801.50 are discussed under the following four topics.

X. Devices That Must Be Directly Marked With a Unique Device Identifier—Proposed Requirement for an Implantable Device To Bear a Permanent Marking Providing the Unique Device Identifier on the Device Itself—Proposed § 801.50(a)(1)

We received many comments (approximately 47) on this proposed requirement, which would have required an implantable device to bear a permanent marking providing its UDI on the device itself.

Nine comments expressed support for the proposal; eight of these comments expressed general support for the requirement; one other comment recommended a more rigorous requirement, suggesting all devices “that will be implanted for 24 hours or more” should be subject to direct marking (the definition of *implantable device* means a device intended to remain implanted for at least 30 days). The remaining comments opposed this requirement, identified obstacles that might undermine the proposal, requested an exception, or suggested an alternative that would have significantly limited the scope of the provision. For example, one comment stated, “direct marking of implantable medical devices is a waste of both industry and FDA

resources” and should not be part of the UDI rule. Other comments stated, “Direct labeling of implantable HCT/P devices . . . could impact the safety of the device”; that small implants cannot be directly marked without interfering with functionality; that direct marking of an implant would be useful only if the device was explanted; that the proposal is “substantially redundant in effect” with FDA’s Medical Device Tracking Requirements, 21 CFR part 821; and that a patient’s electronic health records will identify any implant. One comment summarized these objections by stating, FDA should “eliminate the direct marking requirement for implantable devices,” because there are no “discernible benefits to direct marking implantable devices above and beyond those expected from the entire UDI system, while the costs would be substantial.”

FDA finds these comments opposing direct marking for implants to be persuasive, and we are withdrawing the proposal for direct marking of implantable devices. We believe that the UDI label and package requirements will provide for adequate identification of an implantable device up to the point where it is implanted. We also acknowledge the common practice of recording information about implanted devices both in the patient’s health record, and on a card provided to the patient, and we expect health care providers will incorporate UDIs into both of these types of records. Further, we expect the use of EHRs and PHRs will facilitate the documentation of implantation. Direct marking would generally serve no purpose as long as the device remains implanted, as there would be no way to read the direct marking except in those instances where RFID technology could be built into the device. We believe that the move to electronic health records, as well as any records maintained under part 821 (device tracking), will provide adequate alternative sources of information concerning any implanted device, and any device that is explanted.

A comment that presented policy reasons for removing the direct marking requirement for implantable devices from the rule (which has been removed from the final rule as discussed elsewhere in this preamble) also argued that the FD&C Act does not provide FDA authority to require direct marking of devices.

FDA disagrees with this comment. As explained in the preamble to the amended proposed rule, the direct marking of devices will enable FDA to more efficiently and effectively respond to a reported device problem by using

its regulatory tools, such as notification or mandatory recall under section 518 of the FD&C Act, tracking under section 519(e), ensuring the adequacy of a voluntary recall with the assistance of reports of corrections and removals as required by section 519(g), or seizing a device that is adulterated under section 501 and/or misbranded under section 502. Thus, the provisions of the final rule requiring direct marking certain reusable devices are issued in aid of FDA’s authority under all of these sections of the FD&C Act, as well as under the Agency’s broad authority to issue enforcement regulations under section 701(a) and its specific authority to implement UDI requirements to identify devices “through distribution and use” of the device under section 519(f) (77 FR 69393 at 69395). The only devices subject to direct marking in the final rule are devices intended for more than one use and intended to be reprocessed before each use. Though stand-alone software has been removed from the direct marking provision of the final rule, the requirement that packaged stand-alone software must bear a UDI on its label and device packages as well as on a start-up screen or through a menu command has been retained at § 801.50(b). As discussed elsewhere in this preamble, both of these categories of devices are intended to be used long after they typically become separated from their label, making it particularly important for the efficient enforcement of the provisions outlined previously that these devices are directly marked with a UDI.

Y. Revision of Direct Marking Requirements—Proposed § 801.50; § 801.45 of the Final Rule

The proposed rule would have required a device that is intended to be used more than once, and intended to be sterilized before each use, to bear a permanent marking providing its UDI on the device itself. (See proposed § 801.50(a)(2).) This provision and the provisions in proposed § 801.50(b) through (f) have been moved to § 801.45 of the final rule, with certain modifications. All comments that pertain to the requirements now included in § 801.45 and to direct marking requirements in general are discussed here.

We broadened the scope of proposed § 801.50(a)(2) to apply to devices intended to be used more than once and intended to undergo any form of reprocessing before each use; the proposed rule was limited to devices intended to be reused and sterilized before each use. We made this change because we see no reason for this

provision to be limited to sterilization; the same objectives served by the proposed provision are applicable and will be served with respect to all reprocessed devices. These devices are intended to be used for months or years, sometimes many years. Because such a device is intended to be reprocessed and reused, it will inevitably be separated from its original label and device package. Direct marking is the only way to ensure the adequate identification of such a device.

A comment recommended that direct markings need to be “as permanent as the normal life expectancy” of the device, and need to be “capable of withstanding the normal usage and cleaning procedures” specified for the device.

FDA agrees that this is a reasonable approach, but we do not believe it is appropriate to specify any particular approach in the rule, because it would be difficult to define “normal” usage or “normal” cleaning procedures for all devices, and technological advancements may change what constitutes normal usage and appropriate cleaning procedures.

A comment stated that direct marking is “appropriate” for single-use sterilized devices, as well as for all devices intended for more than one use.

FDA disagrees that reprocessed single-use devices should be directly marked because, by definition, the device is originally intended only for a single-use. Direct marking is necessary to be able to identify and locate devices subject to reprocessing in case of problems with the reprocessing.

A comment stated, “to the extent practical, direct marking of reusable devices should occur” but also noted, that there “may be some products where size would prohibit direct marking with a UDI.” Another comment suggested that direct marking may interfere with sterilization of small devices.

FDA has not been presented with any data that shows a correlation between the size of a device marked with a UDI or similar mark and ineffective sterilization or reprocessing. Accordingly, FDA is taking no action in response to this comment. If a labeler can show that any direct marking of a device would interfere with sterilization or disinfection of the device, then the exception provided by § 801.45(e)(1), “Any type of direct marking would interfere with the safety or effectiveness of the device,” would apply.

A comment suggested that direct marking be required for all devices tracked under part 821, without exception.

FDA disagrees. A device tracked under part 821 is subject to controls that are specifically designed to take into account the particular characteristics and uses of that device, and the tracking requirements that apply to that device will ensure adequate identification of the device throughout its distribution and use.

A comment suggested that a reprocessor of a single-use device should not be permitted to display any form of the original UDI.

FDA disagrees. Section 830.60 requires that a relabeled device have a new UDI; therefore it would not be permissible to display the original UDI on the label or device package of the reprocessed device. FDA does not believe it is appropriate to require physical modification of a device in order to remove or obscure a UDI directly marked on the device by the original manufacturer, as any such action could compromise the physical characteristics of the device and might leave imperfections that would make it more difficult to effectively sterilize or disinfect the device.

A comment suggested that the rule require direct marking with “only one of the four production identifiers.”

FDA disagrees. The full UDI is necessary for precise identification of the device. For example, if a recall applies to only one lot or batch, it would not help if the direct marking omitted that information and instead provided only an expiration date that applies to several lots—it would not be possible to distinguish only devices subject to the recall from other devices that are not subject to the recall. Accordingly, a device required to be directly marked under § 801.45 must provide the full UDI, including all production identifiers that appear on the device label.

Z. Devices That Must Be Directly Marked With a Unique Device Identifier—Proposed Requirement for Submission of a Notice to FDA Upon Determining That an Exception Applies—Proposed § 801.50(g)

FDA received several comments (approximately 13) concerning this proposed requirement. These comments showed that the proposed requirement was unclear and unlikely to be useful. For example, a comment observed that FDA had not provided a way to inform the public concerning exceptions to direct marking documented under § 801.50(g). Some comments suggested FDA should acknowledge, and should approve or reject, each notice of the use of an exception, and that such notices should be called a “request” for

exception, since an FDA response would be required. Most comments appeared to be in agreement with a comment that stated the requirement for submission of a notice to FDA would be “burdensome and impractical.”

FDA agrees that this notice is not necessary. We do not require a notice to FDA in other contexts when a decision is made that no action is required; for example, FDA does not require a notice when a manufacturer decides that a change made to a device does not require submission of a 510(k) premarket notification. Accordingly, we have withdrawn proposed § 801.50(g), and a labeler will not have to provide a notice to FDA when it decides an exception provided by § 801.45(e) of the final rule applies. All such decisions must, however, be documented in the design history file; see § 801.45(f) of the final rule.

AA. Special Requirements for Stand-Alone Software—Final § 801.50

The proposed rule included stand-alone software among the types of devices that would have been subject to proposed § 801.50, requiring direct marking of certain devices; FDA moved the requirements for direct marking to § 801.45. Stand-alone software is not subject to direct marking requirements in the final rule, but is subject to requirements in new § 801.50 of the final rule, which provides special labeling requirements for stand-alone software.

A comment asked how the requirement for AIDC would apply to cloud software (software as a service), and the same question can be extended to any software that is not distributed in packaged form, for example, when downloaded from a Web site.

Under § 801.50(a) of the final rule, stand-alone software that is not distributed in packaged form (e.g., when downloaded from a Web site) is deemed to meet all UDI labeling requirements if the software provides its UDI in a manner specified by § 801.50(b), which requires a plain-text statement of the UDI to be displayed whenever the software is started, or a plain-text statement to be displayed through a menu command (e.g., an “About . . .” command). When these conditions are met, the use of AIDC is not required for stand-alone software that is not distributed in packaged form. When distributed in packaged form, § 801.50(a) will not apply, and the label and device package of stand-alone software must also include a UDI in plain-text and through AIDC; see § 801.40(a) of the final rule.

A related comment suggested FDA should clarify how direct marking, including production identifiers, applies to stand-alone software.

As with AIDC, this will depend on whether or not the stand-alone software is distributed in packaged form. If the stand-alone software is not distributed in packaged form (e.g., when downloaded from a Web site), it will be deemed to meet all UDI labeling requirements if the software provides its UDI in a manner specified by § 801.50(b). If distributed in packaged form, if the label provides 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; see § 801.40(b) of the final rule.

Some commenters were concerned that because software updates occur frequently, labelers would be faced with significant burdens of having to provide new UDIs, and to change direct markings to reflect the new UDI, with each update.

FDA believes that this concern is resolved by § 830.50 of the final rule. Under § 830.50, if a labeler makes a change to a device, including a change to stand-alone software, a new UDI would be required only if the change results in a new version or model. Section 830.50 is discussed in more detail later in this document.

Some comments suggested that software that does not have a user interface should be exempt from direct marking, and a similar comment suggested that FDA should provide guidance concerning when software is stand-alone software, and when it is a component of a device.

FDA believes these comments concern software that is a component of a device, rather than stand-alone software. The final rule does not provide any special requirements for a device that contains software as a component of the device, but does provide special labeling requirements for stand-alone software (see § 801.50). FDA has long defined standalone medical software as medical software that is itself a medical device and is not a component, part, or accessory of a medical device.

A comment stated, “We disagree with FDA regarding the proposed approach for UDI marking of stand-alone software. . . . FDA regulated software already requires software version information to be provided, which alone is sufficient of uniquely identifying software. . . . [S]tand-alone software could be exempted . . . without imposing undue risk on public safety.” This comment

went on to recommend that “if FDA insists upon including stand-alone software under the UDI rule,” FDA should provide requirements that “recognize the unique characteristics” of software.

FDA does not agree that stand-alone software should be excepted from UDI labeling requirements. There are no FDA regulations that require similar identification of stand-alone software and we know of no “special characteristics” that would justify excepting stand-alone software, and for the reasons discussed in section II.BB, “Requests for an Exception from or Alternative to a Unique Device Identifier Requirement—Proposed § 801.35; § 801.55 of the Final Rule,” FDA does agree that the final rule should provide exceptions that “recognize the unique characteristics” of software.

We have revised § 801.50 to focus on “Special labeling requirements for stand-alone software.” Section 801.50 of the final rule provides:

- An explanation of how stand-alone software can meet UDI labeling requirements when it is not distributed in packaged form (e.g., when it is downloaded from a labeler’s Web site); such software need comply only with § 801.50(b) and is excepted from all other UDI labeling requirements;
- A requirement for all stand-alone software to include a means of displaying its UDI; stand-alone software that is distributed in packaged form must display a UDI on its label, device package, and on screen either upon startup or through a menu command;
- An explanation that stand-alone software that is distributed in both packaged form and in a form that is not packaged (e.g., when downloaded from a Web site) may be identified with the same device identifier.

FDA believes that § 801.50 of the final rule provides appropriate and reasonable requirements concerning the labeling of stand-alone software, while taking into account the unique characteristics of such devices.

BB. Request for an Exception From or Alternative to a Unique Device Identifier Requirement—Proposed § 801.35; § 801.55 of the Final Rule

FDA received many comments (approximately 29) concerning this section. When proposed, this section was titled, “Request for an exception from or alternative to the requirement for a device to bear a unique device identifier.”

Most of the comments on this section were concerned with various aspects of the process outlined in the proposed

rule, and sought more clarity concerning the process, including timeframes, feedback, decisions, and appeals. A typical comment stated, “The procedure should include: Upon receipt and approval of an exemption request, FDA should notify the requester of the result, grant an exemption for the entire PROCEDURE . . . where appropriate, and post all exemption requests and results on an FDA managed Web site for public review. Additionally, the burden of estimating the number of labelers and the number of devices that would be affected by the exemption/alternative should be deleted.” Several comments suggested FDA provide categorical exceptions to avoid the need to request an exception or alternative.

FDA agrees that some categorical exceptions are useful, and the final rule provides several; see § 801.30 of the final rule and the discussion of that section earlier in this document.

A few comments suggested FDA should acknowledge the receipt of each request, and other comments suggested FDA decisions should be made public.

FDA agrees. We intend to make each FDA decision available to the public, along with the request or requests that prompted the decision.

One comment suggested a request should be “deemed” accepted if FDA does not provide a formal response within a specified timeframe.

FDA disagrees. There may be many valid reasons why FDA might not be able to respond to a particular request within the standard timeframe. The final rule does not include such a provision.

Two comments asked that a trade association be permitted to file a request for an exception or alternative.

FDA believes it is preferable for each request to be initiated by a labeler, but we have no objection if a trade association submits its views at the request of that labeler. The final rule has not been modified to permit a trade association to initiate a request.

FDA has made other important changes to this provision and the way FDA will implement the provision. Later in this document, we explain that FDA may, on its own initiative or upon the written request of the labeler of a class III device or a device licensed under the PHS Act, grant a 1-year extension of the compliance date applicable to § 801.20 when FDA determines that the extension would be in the best interest of the public health. Section 801.35(c) has been revised to require all requests for an exception or alternative to be submitted via email, and we have provided email addresses for requests concerning products

regulated by the Center for Biologics Evaluation and Research (CBER), and for all other products. Section 801.35(d) now makes clear that any labeler may make use of an exception or alternative granted under this section, provided that such use satisfies all safeguards or conditions that are part of the exception or alternative. Section 801.35(e) explains that FDA may initiate and grant an exception or alternative if we determine that the exception or alternative is in the best interest of the public health, and explains that any such exception or alternative will remain in effect only so long as there remains a public health need for the exception or alternative. Section 801.55(e) provides that the Center Director may also rescind an exception or alternative granted under this section if, after providing an opportunity for an informal hearing, the Center Director determines that the exception or alternative no longer satisfies the required criteria or that any safeguard or condition required concerning the device has not been met.

CC. Discontinuation of Legacy Identification Numbers Assigned to Devices (National Drug Code and National Health-Related Item Code Numbers)—§ 801.57

FDA received several comments (approximately 12).

Three comments recommended a transition period for depletion of devices with legacy identifier that exist in the current supply chain.

FDA believes these comments are adequately addressed by § 801.30(a)(1) of the final rule, which provides a limited exception period for existing inventories of finished devices; this is discussed earlier in this document.

Three comments urged FDA not to re-issue any NDC or NHRIC numbers that were previously assigned, because use of a reassigned code could result in confusion in patient records.

Five comments urged FDA to permit labelers to continue using FDA labeler codes that have been assigned to them. These comments explained that many device manufacturers use the FDA labeler code as their GS1 Company Prefix, “the basis for all GS1 product identification numbers.” (GS1 operates an existing, widely used system to identify medical devices and other products, and has expressed interest in applying to become an FDA-accrediting issuing agency.) These comments went on to explain that if labelers are forced to discontinue use of the FDA labeler code, they would have to assign new product identifiers to their devices, create new labels and labeling, and that

“unnecessary cost and confusion” would result.

FDA agrees with these comments, and we have amended § 801.57 to include a new provision, paragraph (c), that will permit a labeler who has been assigned a legacy FDA labeler code to continue to use that labeler code under a system for the issuance of UDIs, provided that such use is consistent with the framework of the issuing agency that operates that system, and that the labeler submits, and obtains FDA approval of, a request for continued use of the assigned labeler code.

A few comments suggested FDA should permit continued use of legacy identifiers, or suggested an alternative implementation schedule.

FDA disagrees, as such changes would interfere with the objectives served by § 801.57. FDA has added 801.57(b) to clarify that ALL medical devices, whether subject to UDI or not, may no longer use legacy device identification systems after the applicable compliance date.

DD. Requests for Clarification Concerning Whether Compliance With Any Unique Device Identifier Requirement Will Require Submission of a 510(k) Premarket Notification or Premarket Approval Supplement

A comment suggested the final rule “should address when [premarket] submissions to FDA will be required.” This comment provided two examples of areas where uncertainty exists, concerning whether a submission will be required when direct marking of a device is required, and whether a submission will be required when a label is changed to include a UDI. Another comment stated that to provide MRI compatibility information to the GUDID would be inconsistent with existing FDA policies requiring the submission of a 510(k) premarket notification or PMA supplement before labeling can include such information, unless the GUDID provides an option to indicate that MRI compatibility has not been evaluated.

FDA agrees that these are important questions, and we are providing the following guidance:

- The addition of a UDI to a device label or device package is very unlikely to require the submission of a 510(k) premarket notification or a PMA supplement. The addition of a UDI to the label of a class III device should generally be reported in the next annual report concerning the PMA of that device.
- The GUDID will provide some means to indicate that MRI compatibility has not been evaluated.

The final rule does not require MRI-compatibility testing; it requires submission only of information regarding MRI compatibility that the labeler already possesses.

- Although we believe it is possible that directly marking a device might require a supplemental application in certain instances, we cannot provide a definitive statement concerning whether a 510(k) premarket notification or PMA supplement is required prior to implementing direct marking of any particular device, because of the wide variety of materials, manufacturing processes, intended uses, types of required sterilization or other reprocessing, and many other factors that vary from one device to another, even among devices of the same general type. Therefore, we encourage labelers to contact the relevant Center for Devices and Radiological Health (CDRH) or CBER review division to determine whether direct marking could affect the safety and effectiveness of the device in a way that triggers premarket review requirements.

EE. Human Cells, Tissues, or Cellular or Tissue-Based Products That Are Regulated as Devices—§§ 801.3 and 801.20(a)(1)

Several comments suggested FDA did not clearly explain how the UDI rule would apply to HCT/Ps that are regulated as devices.

FDA agrees. In particular, the final rule provides a definition for *HCT/P regulated as a device*, and the definition *unique device identifier (UDI)* has been modified to take into account the special characteristics of HCT/Ps. (See §§ 801.3, 803.3, 806.2, 810.2, 814.3, 820.3, 821.3, 822.3, and 830.3.) A particularly important change is the inclusion of an additional production identifier that will capture, for HCT/Ps regulated as devices only, the distinct identification code required by § 1271.290(c). Requiring this code to be included in the production identifier when it appears on the label of a device will ensure that the UDI system is consistent with existing regulatory requirements, and existing identification and tracking systems for HCT/Ps.

FF. Technical Standards Applicable to Part 830—§ 830.10

FDA received four comments on this provision, which incorporates by reference the technical standards essential to the UDI system.

Two comments suggested FDA should require the UDI system to conform to additional technical standards. A comment recommended FDA reduce the

allowable technical standards and formats to as few as possible, and eliminate many options that were available under the proposed rule, such as the freedom to choose among different issuing agencies, AIDC technologies, options for production identifiers, and make other choices concerning how best to comply with the requirements of the UDI system.

These same (or very similar) comments and issues are discussed earlier in this document; see section II. S. “Form of a Unique Device Identifier—Technical Requirements—Proposed § 801.45(a); § 801.40(a) of the Final Rule.” As explained earlier, FDA is not accepting these suggestions.

A comment suggested FDA remove the publication dates of the standards listed in this section, so that a standard incorporated by reference would automatically update to the current standard whenever a change is made to that standard.

FDA declines to accept this suggestion as doing so would impermissibly allow the standards organizations to change regulatory requirements without going through notice-and-comment rulemaking.

GG. Requirements for a Unique Device Identifier—§ 830.20

FDA received six comments on this section.

Three comments recommended that FDA designate a single issuing agency, and require the UDI system to conform to additional standards.

These comments repeat comments discussed earlier in this document; see section II. S., “Form of a Unique Device Identifier—Technical Requirements—Proposed § 801.45(a); § 801.40(a) of the Final Rule.” FDA seeks to preserve existing flexibility concerning the choice of issuing agency and notes requiring use of a single issuing agency would disrupt current practices for many labelers that currently use UDIs.

As explained in section II. S., FDA does not agree with these suggestions.

One comment suggested that UDI “codes” should be standardized by device type, and not be “randomly assigned.” A similar comment stated, “The database would be more useful if specific field lengths were reserved for specific fields. Specifically we mean, reserve (for example) the first 12 characters for the ‘Device Identifier’ and characters 13–24 (for example) for the [Production Identifier]. Consider also dividing that number out into space for batch, date, etc.”

FDA does not agree with either of these comments. Under the system provided by this rule, each FDA-

accredited issuing agency will be permitted to design and operate its device identification system in any manner that conforms with the technical standards incorporated by reference in part 830. FDA believes that a high degree of freedom and flexibility is needed to ensure that the UDI system keeps pace with technological change; we also believe that the system as a whole will benefit from the options provided to labelers to choose among differing systems and technologies. For those reasons, the final rule adopts the language of the July 10, 2012, proposed rule without change.

HH. Use and Discontinuation of a Device Identifier—§ 830.40

FDA received six comments on this provision.

One comment stated that there should not be any consequences to the labeler of a device if the accreditation of the issuing agency is relinquished or revoked, and that the availability of GUDID data to patients and providers needs to be ensured.

FDA agrees. Section 830.40(d) addresses the concern regarding accreditation of the issuing agency; a labeler may continue to use a previously issued UDI on the label and packages of its device. FDA intends to make the data submitted to the GUDID generally available on our Web site indefinitely.

A comment inquired as to whether a labeler who applies UDIs from two issuing agencies to its device must report all data to the GUDID twice, once for each UDI.

FDA plans to design the GUDID data entry system so that such a labeler will have to report GUDID data only once, and will be able to add a UDI from an additional issuing agency to existing data concerning a version or model.

II. Changes That Require Use of a New Device Identifier—§ 830.50

When proposed, this section was titled, “Changes that result in a new version or model.” FDA received many comments (approximately 56) concerning these requirements.

Although a few comments expressed support for certain requirements, such as requiring a new UDI when adding a new device package, or when changing to or from a sterile package, most comments viewed the proposed requirements as “too broad,” or “substantially and unnecessarily overbroad” because they would require new device identifiers to be assigned “when relatively minor changes are made to the manufacture or specifications of a device.” Many comments suggested the need for

clarification of various aspects of the proposed language or suggested guidance would be required to understand the proposed requirements. A comment recommended that the requirement for a new UDI not be tied to changes that result in a new version or model, because the device industry uses the terms version and model for many different purposes, and “it often makes sense to retain [existing device] identifiers even after changes have been made. How these terms are used . . . will vary by company. There is no standard . . . and no consistency within the industry. . . .” A similar comment stated, “there are many situations in which a change to specifications, performance, or composition should not require a new device identifier . . . even if a supporting . . . 10(k) or PMA Amendment . . . were required,” and other comments added that requiring a new UDI whenever any change is made to a device, even a change that would not be noticeable by a user, would be overly burdensome. Other comments suggested that in order to avoid confusion, the requirement for a new UDI should be tied to a labeler’s decision to use a new version or model number.

FDA agrees that the proposed language was too broad. We also agree with the comments that suggested that in many instances the proposed requirement to consider a changed device a new version or model would conflict with common industry practice and that the rule should take into account those common practices. The final rule simplifies the requirement by assigning greater flexibility, and greater responsibility, to the labeler. If the labeler makes a change to a device that is required to bear a UDI on its label, and determines that the change results in a new version or model, the labeler must assign a new device identifier to that device and to all associated device packages. FDA believes this approach provides adequate flexibility and still ensures the adequate identification of devices through the UDI system. We have also retitled § 830.50 as, *Changes that require use of a new device identifier* to reflect the change in emphasis.

JJ. FDA Accreditation of an Issuing Agency—§ 830.100

FDA received many comments (approximately 41) on this provision.

Some comments supported FDA’s decision to leave the door open for multiple issuing agencies to apply for accreditation, stating that multiple issuing agencies would foster competition. Several other comments

suggested FDA require conformance to additional standards, that FDA should designate only one issuing agency, or should limit the number of issuing agencies.

These comments are the same as, or similar to, comments discussed earlier in this document; see section II. S., “Form of a Unique Device Identifier—Technical Requirements—Proposed § 801.45(a); § 801.40(a) of the Final Rule.” FDA does not agree with these comments, for the reasons stated in the earlier discussion.

In the proposed rule, we would have required an issuing agency to be either a private nonprofit organization or a State agency, in order to minimize potential conflicts of interest. We requested comment on the question, “Are there compelling reasons to permit a for-profit organization to be accredited as an issuing agency?” 77 FR 40736 at 40767 (Specific Question #26). Eight comments favored the requirement in proposed § 830.100(a) that only a nonprofit organization can apply to become an issuing agency. Only two comments recommended that we permit for-profit organizations to apply for accreditation as an issuing agency, and another comment suggested we allow any interested party to “bid” for the privilege of becoming an issuing agency.

We do not agree with the recommendation of the last commenter. We believe an application process with transparent criteria is preferable to a “bidding” process. We do not find the comments to be persuasive on either side of the question of accrediting for-profit organizations as issuing agencies.

We note that the international standard addressing conflicts of interest for accreditation bodies does not draw distinctions based on profit or non-profit status. ISO/IEC 17011:2004, clause 4.3.4 (Ref. 16) requires accreditation bodies to ensure that personnel and committees that could influence the accreditation process act objectively and are free from any undue commercial pressures that could compromise impartiality. We believe the potential for conflicts, whether or not related to an applicant’s for-profit status, are best addressed through FDA’s oversight of the application process and accrediting body criteria such as required conformance to standards rather than establishing a blanket prohibition. In the proposed rule, we would have limited accreditation to organizations that are non-profit in part “to minimize potential conflicts.” In the final rule, we are allowing any private organization, for-profit or non-profit, to be accredited as an issuing agency, as long as there is protection against

conflicts of interest. We have added protections against conflicts of interest to §§ 830.100(b) (Accreditation criteria), 830.110(a) (Application for initial accreditation), and 830.130 (Suspension or revocation of the accreditation of an issuing agency). See 78 FR 45782 (July 29, 2013) (Proposed rule for accreditation of foreign food safety auditors). We also specifically prohibit an issuing agency from engaging in anticompetitive activities in restraint of trade.

A few comments suggested that FDA serve as an issuing agency, or as the only issuing agency.

FDA does not agree and notes the suggested approach could require labelers that have voluntarily labeled their devices with UDIs to assign new UDIs to comply with the rule. We believe the UDI system will be best served if qualified private organizations that have relevant experience operate the day-to-day technical aspects of the UDI system. In addition, we have removed the provision that would have allowed a State agency to serve as an issuing agency. Although FDA may act as an issuing agency if it is necessary or appropriate for us to do so (see § 830.200 of the final rule), we believe that FDA’s expertise and resources are best applied to other functions.

One comment suggested that FDA address the constitutionality of the requirement that companies contract with third-party non-government companies or agencies that may impose their own requirements on a manufacturer that may exceed FDA’s regulatory authority, such as fees for service. This comment stated that, constitutionally, the government may not assign a government function to non-governmental entities. This comment appears to be directed at the requirement at § 830.20 that UDIs be issued under a system operated by FDA or an FDA-accredited issuing agency and conform to certain international standards regarding issuing agencies.

While FDA recognizes the constitutional limitations regarding the delegation of functions to private entities, FDA has not impermissibly delegated any governmental authority to issuing agencies or any other entities in this rule. Rather, the role that this rule creates for issuing agencies to serve in the unique device identification system is one that is ministerial and completely subordinate to FDA’s ultimate authority over the compliance of unique device identifiers with the FD&C Act, these regulations, and the international standards incorporated by reference in the regulations. (See, e.g., *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S.

381, 399 (1940) (upholding Congressional delegation of function to private entity because “members of the [private entity] functioned subordinately to the [public agency],” which had “authority and surveillance” over the private entity); *Pittston Co. v. United States*, 368 F.3d 385, 395 (4th Cir. 2004) (“Congress may employ private entities for ministerial or advisory roles, but it may not give these entities governmental power over others.” (citing *Sunshine Anthracite*, 310 U.S. at 399, *United States v. Frame*, 885 F.2d 1119, 1129 (3d Cir. 1989), *cert. denied*, 493 U.S. 1094 (1990))). Issuing agencies will be performing the ministerial function of issuing unique labeler codes for device identifiers and operating a system of identifier creation and maintenance focused on ensuring the uniqueness of alphanumeric codes, as the entities currently in existence already do. No UDI provides any advantage over any other UDI. FDA retains a high degree of control over the issuing agencies through the requirements providing that issuing agencies must be accredited by FDA, that FDA may suspend or revoke of an issuing agency’s accreditation, and that FDA may act as issuing agency if necessary or appropriate. (See subparts C and D of part 830 of the final rule.)

One comment suggested that FDA adopt far more detailed criteria for the accreditation of issuing agencies (other comments stated the criteria are appropriate) and that FDA should assign the task of accrediting issuing agencies to the private sector by designating a “board of providers . . . to run the selection process” in a manner that would ensure the needs of providers are met.

FDA disagrees with these suggestions. We have specified the criteria we believe are appropriate for our review of applications for accreditation as an issuing agency, and we are not persuaded that the UDI system needs, or would benefit from, more detailed accreditation criteria. As discussed in the response to the previous comment, FDA oversight of issuing agencies through accreditation is important from a legal standpoint, and we will not consider transferring this responsibility to a nongovernmental body.

Having considered the comments submitted concerning § 830.100, the final rule adopts the language proposed in our July 10, 2012, proposed rule without any change.

KK. Information Required for Unique Device Identification—§ 830.310

FDA received many comments (approximately 125) concerning these requirements.

Several comments we received requested a greater level of detail than we believe appropriate for this rule; nonetheless, many of these comments we expect to address in guidance on various aspects of the UDI system. Several comments asked for information or guidance concerning how to submit data to, and how to locate data in, the GUDID, or inquired about various technical aspects of the GUDID, such as security processes or whether or how the GUDID will be linked to other data systems.

Our general approach has been to regard a comment that did not suggest the need for a change to the regulatory language of this section as being a request for guidance. We will consider all such comments as we develop guidance concerning the final rule and the GUDID, and we plan to provide information concerning functions of the GUDID.

A comment asked whether the GUDID will accommodate reporting data concerning a device that has been assigned device identifiers under more than one issuing agency's system to assign UDIs.

The GUDID is being designed to accept data from multiple systems when necessary.

A comment suggested that each labeler should be allowed the flexibility to determine "what information will be reflected in the . . . GUDID." Some comments expressed concern that the publicly available GUDID may reveal proprietary information such as the number of devices manufactured.

FDA disagrees. Labelers are required to report only the type of production identifiers that appear on the label of the device to the GUDID, which would not reveal the number of devices manufactured. FDA does not believe any of the information required to be reported to the GUDID, most of which appears on the label of the device, would constitute trade secret or confidential commercial information.

A comment suggested the GUDID should not include company contact data, because it is typically a corporate officer whose contact information is not public. To serve as its point of contact with FDA on GUDID matters under § 830.32(a), the labeler of a device might designate a senior officer whose contact information is not otherwise publicly known. Unlike the other GUDID data that will help identify devices through

distribution and use by having it included in the public GUDID, FDA intends to use the contact person data submitted under § 830.310(a)(2) solely for internal purposes in managing the GUDID. The public side of the GUDID database will not otherwise contain any individual contact information, except for optional customer-service information if the submitting company chooses to provide individual contact information for that purpose. FDA plans to address in guidance the privacy aspects of how contact-person information will be handled, as well as other issues associated with the public availability of GUDID information.

A comment suggested that the GUDID data requirement should be harmonized with what is collected for other device repositories globally.

Although FDA appreciates the goal of global harmonization and has structured this regulation to further those goals in many ways, FDA does not fully agree with this comment. We have designed the GUDID to meet the needs of the UDI system established by this rule, and we have carefully specified the data we believe are essential to the success of the system. The sponsors of other systems may have other objectives and may make different decisions.

LL. Information Required for Unique Device Identification—Information Concerning Each Version or Model of a Device—§ 830.310(b)

FDA received many comments concerning the specific information required under § 830.310(b). Two comments voiced support for inclusion of GMDN codes in the GUDID.

Most of the comments concerned the requirement to submit the GMDN code of a device to the GUDID, and the majority of those comments opposed collection of GMDN codes for the following reasons: At the time the proposed rule was published, the GMDN Agency required a license fee to be paid to obtain GMDN codes; comments expressed concern regarding whether the GMDN system has codes for HCT/Ps regulated as devices; and comments expressed a preference that additional nomenclature systems be utilized, such as the Universal Medical Device Nomenclature System (UMDNS) and the United Nations Standard Products and Services Code (UNSPSC). One comment suggested FDA allow GMDN codes to be voluntarily submitted as ancillary data under § 830.340.

FDA believes the bases for most objections to the requirement concerning GMDN codes have been eliminated. In the preamble to our July

10, 2012, proposed rule, FDA stated that the GMDN code would not be required unless GMDN codes were made freely available. The GMDN Agency has agreed to provide free access to GMDN nomenclature within the context of the GUDID data submission process. A labeler who reports data to the GUDID will be able to enter a GMDN code if the labeler knows it, or may use a module integrated in the GUDID reporting system to search for and select the correct GMDN term, including for HCT/Ps regulated as devices. Because of these actions and FDA's belief that the use of GMDN nomenclature will add precision and consistency to the identification of medical devices, FDA is including the requirement for submission of GMDN codes in the final rule.

One comment argued that requiring submission of GMDN information is "anti-competitive" and would allow the GMDN Agency to skirt the Sherman Antitrust Act.

FDA disagrees. Permitting the submission of device terms from more than one nomenclature system would undermine the purposes of this provision: Consistent terminology for the identification of devices. FDA does not believe reliance upon the GMDN classification system for this program will foreclose the use of alternative classification systems in other contexts. Accordingly, competition among classification systems should not be adversely affected. We also note that FDA as an agency of the Federal Government, FDA is immune from antitrust liability. See *United States Postal Service v. Flamingo Indus., Ltd.*, 540 U.S. 736, 748 (2004); *Name, Space, Inc. v. Network Solutions, Inc.*, 202 F.3d 573, 581 (2d Cir. 2000) (National Science Foundation has "absolute immunity from the antitrust laws").

A comment suggested that the requirement for submission of the proprietary, trade, or brand name of the device as it appears on the label of the device be expanded to permit the submission of "other names, if applicable."

FDA does not understand how "other names" would contribute towards improved identification of devices, and we have not added "other names" to the GUDID's requirements.

Approximately 16 comments recommended adding MRI compatibility information to the GUDID, while 2 comments specifically opposed inclusion of MRI compatibility information, and another 8 comments expressed general opposition to including any additional data element beyond those proposed in the July 19, 2012, proposed rule.

FDA agrees with the comments that suggest FDA should require submission of MRI compatibility information to the GUDID to the extent it is otherwise available. Because identification of devices that are MRI compatible and ones that are not can be critical to the safety of patients, we have included a requirement for MRI compatibility information at § 830.310(b)(8) of the final rule. See second bullet point of section II.DD of this document. This final rule does not alter the criteria for when MRI compatibility must be determined.

One comment opposed inclusion of information in the GUDID concerning latex and whether the device is labeled as sterile, because GUDID is an “incomplete surrogate for appropriate and complete instructions for use” and these elements might discourage providers from reading the full labeling.

FDA believes this concern is misplaced, as we do not intend, and do not expect, the GUDID to be used in lieu of instructions for use provided on a device label or patient package insert. We have retained the requirements.

Several comments recommended significant expansion of GUDID reporting requirements to include additional data, including an indication that a device is either a prescription device or an over-the-counter device; the Healthcare Common Procedural Coding System Level II code; indications that a device is mercury free, Di(2-ethylhexyl)phthalate free, and thimerosal free; information on recalls, storage and handling conditions, hazardous warnings, radioactive isotopes data, and whether there is a Material Safety Data Sheets notice; an indication that hazardous materials and radioactive isotopes are present; “clinical attributes of the devices for meaningful post-market surveillance and research”; previously used NDC/NHRC codes, the Systematized Nomenclature of Medicine Clinical Terms (SNOMED) CT identifier, and the Logical Observation Identifiers Names and Codes (LOINC) code for tests; all package-insert information submitted in structured product labeling (SPL) format or as a stable link; storage and handling conditions; and more. Most of these proposals appeared only in a single comment.

At this time, FDA is not convinced that adding any of these proposed requirements would contribute towards the objectives of the UDI system in a way that outweighs the costs of including them in the system, and therefore we have not included any of these proposals in the final rule.

MM. Enforcement Authority

One comment stated that the proposed rule does not articulate the enforcement actions for noncompliance and asked FDA to detail its enforcement authority as it relates to the UDI system.

As explained in the legal authority section of the proposed rule, failure or refusal to furnish any material or information required by or under section 519 of the FD&C Act causes a device to be misbranded under section 502(t)(2) and is a prohibited act under section 301(q)(1)(B) of the FD&C Act (21 U.S.C. 331(q)(1)(B)). Potential enforcement actions for violations of UDI requirements include seizure, injunction, and civil and criminal penalties.

NN. Questions and Comments Suggesting the Need for Additional Guidance

We received many comments that requested guidance or suggested a need for guidance on various aspects of the rule. We also received comments asking how the rule would apply to specific medical devices.

FDA will develop guidance to help labelers understand and apply the requirements of this final rule as necessary, and comments requesting guidance will be carefully considered to ensure our guidance will address their principal concerns. We plan to provide one or more draft guidance documents for comment in the next year.

OO. Requests for Additional Opportunity for Comment Prior To Issuing a Final Rule

A few comments requested FDA take extraordinary steps to provide additional opportunities for comment before issuing a final rule. One comment suggested FDA should hold a public workshop to get feedback specifically concerning convenience kits.

FDA does not agree that any additional opportunities for comments are necessary. The July 10, 2012, proposed rule provided a liberal comment period ending November 7, 2012, and the November 19, 2012, amended proposed rule provided an additional comment period ending December 19, 2012. Furthermore, section 519(f) of the FD&C Act, as amended by FDASIA, requires FDA to “finalize the proposed regulations not later than 6 months after the close of the comment period” and FDA has no authority to extend that deadline. For changes making the final rule less burdensome for convenience kits, see section II.L (Exception for a Device Packaged Within the Immediate

Container of a Combination Product or Convenience Kit).

III. Legal Authority for the Final Rule

Section 226 of the Food and Drug Administration Amendments Act (Pub. L. 110–85) (2007), amended the FD&C Act by adding a new section 519(f). This section authorizes FDA to issue regulations establishing a unique device identification system for medical devices. In addition, section 510(e) of the FD&C Act 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 rule establishing a unique device identification system under sections 510(e), 519(f), and 701(a) 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 of the FD&C Act respecting the device are misbranded under section 502(t)(2) of the FD&C Act. 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.

Section 701(a) of the FD&C Act gives FDA the authority to issue regulations for the efficient enforcement of the FD&C Act. By requiring a UDI to appear on the label of devices, and by establishing the GUDID, the 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, in certain cases directly marked on the device itself, 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, 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 and/or misbranded under section 502 of the FD&C Act. Thus,

these provisions of the rule are issued under the authority of these sections in addition to the broad authority of section 519(f) of the FD&C Act.

The information required to be submitted to the GUDID under § 830.310 is necessary for UDIs to adequately identify devices through distribution and use, as required by section 519(f) of the FD&C Act. Collection of this information is further authorized by section 510(j) of the FD&C Act, which 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)). Most of the information required to be submitted to the GUDID 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).

The provisions of the rule that would require UDIs to be included in various FDA records and reports to FDA, 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 rule that would amend the Quality System Regulation 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) (21 U.S.C. 360j(f)) and 701(a) of the FD&C Act.

The provisions of the 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.

The provision of the 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. 360j), and 701(a) of the FD&C Act.

The changes in compliance dates for devices that are implantable, life-saving, and life sustaining, are under the changes to section 519(f) of the FD&C Act made by section 614 of FDASIA.

The provision in the rule requiring dates on device labels intended to be brought to the attention of the user to

appear in a particular format is issued under the authority of sections 502(a), 502(c), and 701(a) of the FD&C Act. The requirement for a uniform date format will ensure dates on device labels intended to be brought to the attention of the user are not misleading, and to the extent these dates are required to appear on the label, ensure that they are likely to be understood by the ordinary individual under customary conditions of use.

IV. Analysis of Impacts

FDA has examined the impacts of the final 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 (Pub. L. 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 finds that this final rule is an economically 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. FDA has examined the impacts of this rule as required by the Regulatory Flexibility Act. FDA finds that the potential impact of the final rule on some small entities may be significant. This Regulatory Impact Analysis and other sections of the preamble to the final rule constitute FDA'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 \$141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. The estimated costs of this final rule will result in a 1-year expenditure that exceeds this amount.

This final rule requires the label and packages of medical devices to bear a

UDI and provides for alternative placement and exceptions for certain devices. In addition, this final rule requires certain devices to be directly marked with a UDI, with exceptions. Medical device records throughout the required device recordkeeping and reporting systems will need to be modified to include the UDI. Under this final rule, FDA will establish the GUDID, a public database containing information about devices labeled with a UDI. The final rule requires labelers of medical devices to submit information concerning each device to the GUDID. In addition, the final rule establishes accreditation requirements for agencies that may operate a system for the issuance of UDIs and establishes the conditions for when FDA might act as an issuing agency.

A. Summary of Impacts

1. Summary of Costs

The full discussion of the Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis (Ref. 17) is available in docket FDA–2011–N–0090 and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm309815.htm>.

The detailed data for this cost analysis were developed by Eastern Research Group, Inc. (ERG) under contract to FDA and are presented in the full report "Unique Device Identification (UDI) for Medical Devices: Economic Analysis of the Final Rule," 2013 (cited in Ref. 17). The final ERG report updates the 2012 ERG cost analysis used to support the FDA's Preliminary Regulatory Impact Analysis of the proposed rule. The Preliminary Regulatory Impact Analysis and the 2012 ERG report are available at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm309815.htm>.

Table 2 of this document presents for each affected sector a summary of the estimated present value and the annualized domestic costs of this final rule over 10 years using discount rates of 7 percent and 3 percent. Over 10 years, the estimated present value of the total domestic costs is \$642.2 million using a 7 percent discount rate and \$737.7 million using a 3 percent rate, and the annualized costs are \$85.7 million using a 7 percent discount rate and \$84.1 million using a 3 percent discount rate.

TABLE 2—SUMMARY OF THE ESTIMATED DOMESTIC REGULATORY COSTS OF THE FINAL RULE (2012 DOLLARS)

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 ¹	\$713.2	\$620.4	\$81.2	\$82.6
Issuing Agencies	1.4	1.3	0.2	0.2
FDA	23.1	20.5	2.7	2.9
Total Domestic Cost of the Final Rule	737.7	642.2	84.1	85.7

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

2. Costs to Domestic Labelers

The majority of the costs of this final rule will be incurred by labelers of medical devices. Labelers include manufacturers, reproprocessors, 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 is \$620.4 million at a 7 percent discount rate and \$713.2 million at 3 percent. Over 10 years, the annualized costs for domestic labelers are \$82.6 million at a 7 percent discount rate and \$81.2 million at 3 percent. The largest components of one-time costs include planning and administration and the costs to integrate the UDI into existing information systems; to install, test, and validate barcode printing software; and to train employees. Other significant components of one-time costs include costs to redesign labels of devices to incorporate the barcode and date format, and to purchase and install equipment needed to print and verify the UDI on labels. In addition, labelers will incur one-time costs for recordkeeping and reporting requirements, 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.

3. Costs To Issuing Agencies

Three existing organizations now perform functions similar to those of an issuing agency under the final rule; the estimated present value of costs over 10 years for these three to apply for FDA accreditation and comply with the final reporting requirements is \$1.3 million at a 7 percent discount rate and \$1.4 million at 3 percent. The annualized costs over 10 years are be \$0.2 million at both 7 percent and 3 percent discount rates. There may be other organizations that might apply to FDA to become an

issuing agency. In such cases, the estimated application preparation, legal, and reporting costs apply to other organizations.

4. 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 is \$20.5 million at a 7 percent discount rate and \$23.1 million at 3 percent. The annualized costs over 10 years are \$2.9 million at 7 percent and \$2.7 million at 3 percent.

5. Costs to Foreign Labelers

Although we excluded foreign costs from our initial regulatory analysis, in our final regulatory impact analysis we include an estimate of the costs to foreign labelers. From Agency device registration and listing data we find that foreign labelers exporting devices to the United States are located in about 90 countries. Because there can be substantial variability in the labor and capital costs labelers face in different countries, we divide foreign labelers into four groups, apply different assumptions to each group, and estimate costs for each group. Over 10 years, the annualized present value for all foreign labelers equals about \$75 million with both a 7 and 3 percent discount rate. The present value of the total costs of the final rule for foreign labelers equals about \$561 million with a 7 percent discount rate.

6. Uncertainty

We computed uncertainty ranges based on the percentage relationship between the lower and upper bounds surrounding the central estimate of the costs to domestic labelers. The lower bound is about 57 percent lower and the upper bound about 43 percent higher than the central estimate. Applying a similar range of uncertainty to the total costs of the final rule to domestic labelers, issuing agencies, and FDA, over 10 years the total annualized domestic costs range from \$48.8 million

to \$122.5 million at 7 percent and \$47.9 million to \$120.2 million at 3 percent.

7. Alternatives

For the final rule, we compare two alternatives to the final rule. We estimate costs for a full coverage UDI requirement that does not allow reduced requirements for class I devices and for devices that FDA has by regulation exempted from the GMP requirements. The second alternative varies the content of the UDI and requires only the establishment and the device identifier to be included in the barcode across all device classes.

Over 10 years at 7 percent, the annualized present value of the highest cost alternative is about \$108.0 million. This alternative applies the UDI requirements to class I, II, and III devices, as well as unclassified devices, unless excepted by § 801.30(a)(3) through (11). Under the lower cost alternative labelers do not incur costs in certain categories such as purchasing and installing printing equipment and software. The annualized present value of this alternative is about \$20 million.

B. Summary of Regulatory Flexibility Analysis

FDA conducted a regulatory flexibility analysis of the impact of the final rule on small entities. About 96 percent of domestic labelers are small firms according to Small Business Administration size standards. The average annualized costs of compliance for domestic labelers as a percentage of annual receipts exceed 1 percent for about 32 firms with fewer than 19 employees that label multiple-use devices subject to the direct marking requirements. Without direct marking, the impact on small firms does not exceed 1 percent of average annual receipts.

C. Summary of Benefits

The public health benefits from the UDI are related to reductions in medical device-related patient injuries and deaths. The final rule is expected to

improve medical device event reporting by providing a standardized, reliable and unique identifier with which to report a problem device. With more reliable identification of devices associated with an adverse medical event, FDA would be able to improve postmarket surveillance of medical devices and detect problem devices more rapidly. FDA expects that more accurate and prompt identification of problems would lead to a reduced incidence of adverse events. Public

health safety alerts, for example, could be more accurate and timely. Similarly, FDA expects that recall actions could more effectively target a problem device. We expect that the increased accuracy of adverse medical device reporting and improved recalls would reduce the total number of adverse medical device events, although we are unable to quantify that reduction. In addition, a standardized UDI will 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; such benefits are beyond the scope of this rule. The ROCIS (Regulatory Information Service Center and Office of Information and Regulatory Affairs Combined Information System) accounting information is shown in table 3 of this document.

TABLE 3—ECONOMIC DATA: COSTS AND BENEFITS ACCOUNTING STATEMENT
[2012 dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Benefits:							
Annualized Monetized \$millions/year	7	
Annualized Quantified	3	
Qualitative	More accurate and prompt identification of device related adverse events should 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	\$85.7	\$48.8	\$122.5	2012	7	10 years	Costs to foreign labelers are not included.
Annualized Quantified	3	
Qualitative	7	
Transfers:	3	
Federal Annualized Monetized \$millions/year.	7	
From/To	From			To			
Other Annualized Monetized \$millions/year.	7	
From/To	From:			To:			
Effects: State, Local or Tribal Government: No effect Small Business: The final rule may have a significant economic impact on a substantial number of small entities that label medical devices. Wages: No effect Growth: No effect							

V. Information Collection Requirements

This final rule contains information collection requirements (OMB control 0910-0720) that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (the PRA). The title, description, and

respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data

sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. 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.

Title: Unique Device Identification System

Description: In accordance with the collection of information entitled “Unique Device Identification System (UDI),” medical device labelers, unless excepted, are required to design and use medical device labels and device packages that bear a UDI, present dates on labels in a particular format, and submit data concerning each version or model of a device to the GUDID no later than the date the label of the device must bear a UDI. Once a device becomes subject to UDI requirements, respondents will be required to update the information reported whenever the information changes. Respondents required to submit data to the Agency under certain other information collections are required to include the UDI for the device that is the subject of such information collection.

Section 801.18 requires that whenever a labeler 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 labeler must present the date on the label in a format that meets the requirements of this section. Section 801.20 requires every medical device label and package to bear a UDI. Under § 801.35, any labeler of a device that is not required to bear a UDI on its label may include a UDI on the label of that device and utilize the GUDID. Under § 801.45, any device that has to be labeled with a UDI also has to bear a permanent marking providing the UDI on the device itself if the device is intended for more than one use and intended to be reprocessed before each use. Section 801.50 requires stand-alone software to comply with specific labeling requirements that identify the software. Section 801.55 authorizes additional, case-by-case, labeling exceptions and alternatives to standard UDI labeling requirements. If a labeler relabels or modifies a label of a device that is required to bear a UDI, under § 830.60 it has to keep a record showing

the relationship of the original device identifier to the new device identifier.

Section 830.110 requires an applicant seeking initial FDA accreditation as a UDI-issuing agency to furnish to FDA an application containing certain information, materials, and supporting documentation. Under § 830.120, an FDA-accredited issuing agency is required to disclose information concerning its system for the assignment of UDIs; maintain a list of labelers that use its system for the assignment of UDIs and provide FDA a copy of such list; and upon request, provide FDA with information concerning a labeler that is employing the issuing agency’s system for assignment of UDIs. Sections 830.310 and 830.320 require the labeler to provide certain information to the GUDID concerning the labeler and each version or model of a device required to be labeled with a UDI, unless the labeler obtains a waiver. Section 830.360 requires each labeler to retain records showing all UDIs used to identify devices that must be labeled with a UDI and the particular version or model associated with each device identifier, until 3 years after it ceases to market a version or model of a device.

To require the use of UDIs to identify devices referenced in other information collections, the rule makes conforming amendments to part 803 (Medical Device Reporting), part 806 (Medical Devices; Reports of Corrections and Removals), part 814 (Premarket Approval of Medical Devices), part 820 (Quality System Regulation), part 821 (Medical Device Tracking Requirements), and part 822 (Postmarket Surveillance).

Description of Respondents: The recordkeeping, reporting, and third-party disclosure requirements referenced in this document 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 commercially distributed without any subsequent replacement or modification of the label. In most instances, the labeler would be the device manufacturer, but other types of labelers

include a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler. Respondents may also include any private organization 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. § 801.18 Format of dates provided on a medical device label.
2. § 801.20 Label to bear a unique device identifier.
3. § 801.35 Voluntary labeling of a device with a unique device identifier.
4. § 801.45 Devices that must be directly marked with a unique device identifier.
5. § 801.50 Labeling requirements for stand-alone software.
6. § 801.55 Request for an exception from or alternative to a unique device identifier.
7. § 830.60 Relabeling of a device that is required to bear a unique device identifier.
8. § 830.110 Application for accreditation as an issuing agency.
9. § 830.120 Responsibilities of an FDA-accredited issuing agency.
10. § 830.310 Information required for unique device identification.
11. § 830.320 Submission of unique device identification information.
12. § 830.360 Records to be maintained by the labeler.
13. Conforming amendments to Part 803—Medical Device Reporting
14. Conforming amendments to Part 806—Medical Devices; Reports of Corrections and Removals.
15. Conforming amendments to Part 814—Premarket Approval of Medical Devices
16. Conforming amendments to Part 820—Quality System Regulation
17. Conforming amendments to Part 821—Medical Device Tracking Requirements
18. Conforming amendments to Part 822—Postmarket Surveillance

TABLE 4—FIRST YEAR ESTIMATED BURDENS ¹

	Number of respondents ²	Number of responses per respondent ³	Total annual responses ⁴	Average burden per response 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 Disclosure (Date Format)	6,199	102	632,298	1 hour	632,298

¹ Table 4 shows the burden to labelers affected in the first year.

² Maximum number of respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.
³ Maximum number 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 reflect a more precise, non-rounded average burden per response. An approximate (non-rounded) conversion to minutes is shown in parentheses.
⁶ Total hours are based on a more precise burden per response than the rounded value shown in these tables.

TABLE 5—ONGOING ESTIMATED ANNUAL BURDENS

	Number of respondents ¹	Number of responses per respondent ²	Total annual responses ³	Average burden per response 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 number of respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.
² Maximum number 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 reflect a more precise, non-rounded average burden per response. An approximate (non-rounded) conversion to minutes is shown in parentheses.
⁵ Total hours are based on a more precise burden per response than the rounded value shown in these tables.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the PRA.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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. Effective Dates

A. Effective Dates. This rule is effective on December 23, 2013, except the following provisions are effective October 24, 2013—

- § 801.55—Request for an exception from or alternative to a unique device identifier requirement.
- § 830.10—Incorporation by reference.
- §§ 830.100, 830.110, 830.120, and 830.130—Provisions regarding FDA accreditation of issuing agencies.

B. Compliance Dates. FDA is establishing compliance dates for the following provisions of this final rule in

order to provide labelers, FDA, and the health care community adequate time to build and test the systems and infrastructure required to implement the final rule's requirements, and to spread the costs and burdens of implementation over a period of years. FDA believes this approach will help ensure the efficient and effective implementation of the final rule.

Compliance dates for: § 801.18—Format of dates provided on a medical device label; § 801.20—Label to bear a unique device identifier; § 801.50—Special labeling requirements for stand-alone software; and § 830.300—Devices subject to device identification data submission requirements.

FDA is establishing compliance dates for §§ 801.18, 801.20, 801.50, and 830.300 as follows for any device that its labeler puts in commercial distribution after the applicable date indicated below:

1. For a class III medical device or a device licensed under the Public Health Service Act, September 24, 2014. FDA may, on its own initiative, or upon a written request made under § 801.55 by the labeler of device, grant a 1-year extension of this compliance date when FDA determines that the extension would be in the best interest of the public health. A written request for such an extension must:

- a. Identify the device or devices that would be subject to the extension;
- b. Provide, if known, the number of labelers and the number of devices that would be affected if we grant the extension;

c. Explain why such an extension would be in the best interest of the public health;

d. Provide other requested information that the Center Director needs to clarify the scope and effects of the requested extension; and

e. Be submitted no later than June 23, 2014.

2. For an implantable, life-supporting, or life-sustaining device that is not covered by paragraph 1., September 24, 2015.

3. For a class II medical device that is not covered by paragraph 2., September 24, 2016.

4. For a class I medical device that is not covered by paragraph 2., September 24, 2018.

5. For a convenience kit that is not classified into class I, II, or III, the earliest compliance date that would apply to any device in the convenience kit if distributed separately from the convenience kit.

6. For a device that is not classified into class I, II, or III, September 24, 2018.

Compliance dates for § 801.45—Devices that must be directly marked with a unique device identifier. FDA is establishing compliance dates for § 801.45 as follows—

- 1. For a device that is a life-supporting or life-sustaining device, September 24, 2015.
- 2. For any other device, 2 years after the compliance date that applies to the requirements of §§ 801.18, 801.20, 801.50, and 830.300.

TABLE 6—SUMMARY OF COMPLIANCE DATES FOR THE FINAL RULE

Compliance date	Requirement
1 year after publication of the final rule (September 24, 2014).	The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Data for these devices must be submitted to the GUDID database. § 830.300. A 1-year extension of this compliance date may be requested under § 801.55; such a request must be submitted no later than June 23, 2014. Class III stand-alone software must provide its UDI as required by § 801.50(b).
2 years after publication of the final rule (September 24, 2015).	The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. A device that is a life-supporting or life-sustaining device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. § 801.45. Stand-alone software that is a life-supporting or life-sustaining device must provide its UDI as required by § 801.50(b). Data for implantable, life-supporting, and life-sustaining devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
3 years after publication of the final rule (September 24, 2016).	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 a device intended to be used more than once and intended to be reprocessed before each use. § 801.45. The labels and packages of class II medical devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Class II stand-alone software must provide its UDI as required by § 801.50(b). Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
5 years after publication of the final rule (September 24, 2018).	A class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45. The labels and packages 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. Dates on the labels of all devices, including devices that have been excepted from UDI labeling requirements, must be formatted as required by § 801.18. 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. § 830.300. Class I stand-alone software must provide its UDI as required by § 801.50(b).
7 years after publication of the final rule (September 24, 2020).	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 bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.

Compliance dates for all other provisions of the final rule. Except for the provisions listed in this table, FDA requires full compliance with the final rule as of the effective date that applies to the provision.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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 concludes that the 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. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (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/publication/view_supplier-labeling-standard/.
4. “Automatic Identification of Medical Devices,” ECRI Institute, August 17, 2005.
 5. See record and public comments related to the October 25, 2006 public meeting, 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, M.D., 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; available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM310427.pdf>.
11. Supporting Statement for Unique Device Identification (UDI) System, 21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830, OMB Control Number 0910-0720.
12. List of medical devices, by product code, that FDA classifies as implantable, life-saving, and life-sustaining devices for purposes of section 614 of FDASIA amending section 519(f) of the FD&C Act, September 2013.
13. Addendum to the Preliminary Regulatory Impact Analysis of the Proposed Rule to Require a Unique Device Identification System, Docket No. FDA-2011-N-0090.
14. "Healthcare GTIN Allocation Rules, GS1 Global Healthcare User Group," ¶ 5.1.6., GS1, June 2013 (Issue 8).
15. See: International Standards ISO/IEC 15459-2:2006(E): Information Technology—Unique Identifiers—Part 2: Registration Procedures, ¶ 3.1.1, and ISO/IEC 15459-3:2006(E): Information Technology—Unique Identifiers—Part 3: Common Rules for Unique Identifiers, ¶ 4, nn. 2 and 3, listed at http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=45332.
16. See International Standard ISO/IEC 17077:2004(E) Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies, listed at http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=45332.
17. Unique Device Identification System; Final Rule: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis; available at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm309815.htm>.

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, Incorporation by reference, 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, chapter I of title 21 is amended to read as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 21 CFR 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 21 CFR part 801 continues to read as follows:

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

Subpart A—[Amended]

■ 4a. Add new § 801.3 to read as follows:

§ 801.3 Definitions.

As used in this part:

Automatic identification and data capture (AIDC) means any technology that conveys the unique device identifier 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 medical devices packaged together for the convenience of the user.

Device package means a package that contains a fixed quantity of a particular version or model of a device.

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.

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

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.

Human cells, tissues, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

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 commercially distributed without any intended subsequent replacement or modification of the label; and

(2) Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the

purposes of determining whether a person is a labeler.

Lot or batch means one *finished device* 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.

Shipping container means a container used during the shipment or transportation of devices, 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;

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

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

Version or model means all devices that have specifications, performance, size, and composition, within limits set by the labeler.

■ 4b. Add new § 801.18 to subpart A to read as follows:

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

(a) *In general.* Whenever the label of a medical device includes a printed expiration date, date of manufacture, or any other date intended to be brought to the attention of the user of the device, the date must be presented in the following format: The year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens. For example, January 2, 2014, must be presented as 2014-01-02.

(b) *Exceptions.* (1) A combination product that properly bears a National Drug Code (NDC) number is not subject to the requirements of paragraph (a) of this section.

(2) If the device is an electronic product to which a standard is applicable under subchapter J of this chapter, Radiological Health, the date of manufacture shall be presented as required by § 1010.3(a)(2)(ii) of this chapter.

■ 5a. Effective October 24, 2013, add subpart B consisting of § 801.55 to read as follows:

Subpart B—Labeling Requirements for Unique Device Identification

§ 801.55 Request for an exception from or alternative to a unique device identifier requirement.

(a) A labeler may submit a request for an exception from or alternative to the requirement of § 801.20 or any other 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 or devices 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, if known, 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 written request for an exception or alternative must be submitted by sending it:

(1) If the device is regulated by the Center for Biologics Evaluation and Research (CBER), by email to: cberudirequests@fda.hhs.gov or by correspondence to: Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448.

(2) In all other cases, by email to: udi@fda.hhs.gov, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

(c) The Center Director may grant 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. Any labeler may make use of an exception or alternative granted under this section, provided that such use satisfies all safeguards or conditions that are part of the exception or alternative.

(d) FDA may initiate and grant an exception or alternative if we determine that the exception or alternative is in the best interest of the public health. Any such exception or alternative will remain in effect only so long as there remains a public health need for the exception or alternative.

(e) The Center Director may rescind an exception or alternative granted under this section if, after providing an opportunity for an informal hearing as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act and under part 16 of this chapter, the Center Director determines that the exception or alternative no longer satisfies the criteria described in this paragraph (e) or that any safeguard or condition required under this paragraph (e) has not been met.

■ 5b. Effective December 23, 2013, add §§ 801.20, 801.30, 801.35, 801.40, 801.45, and 801.50 to subpart B to read as follows:

Sec.

801.20 Label to bear a unique device identifier.

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

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

801.40 Form of a unique device identifier.

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

801.50 Labeling requirements for stand-alone software.

§ 801.20 Label to bear a unique device identifier.

(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 of this chapter.

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

(b) *Exceptions.* Exceptions to the general rule of paragraph (a) of this section are provided by §§ 801.30, 801.45, and 801.128(f)(2), and § 801.55 provides a means to request an exception or alternative not provided by those provisions.

§ 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 finished device manufactured and labeled prior to the compliance date established by FDA for § 801.20 regarding the device. This exception expires with regard to a particular device 3 years after the compliance date established by FDA for the device.

(2) A class I device that FDA has by regulation exempted from the good manufacturing practice requirements of part 820 of this chapter, exclusive of any continuing requirement for recordkeeping under §§ 820.180 and 820.198.

(3) Individual single-use devices, all of a single version or model, that are distributed together in a single device package, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution. This exception is not available for any implantable device. The device package containing these individual devices is not excepted 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) of this chapter.

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

(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 packaged within the immediate container of a combination product or convenience kit, *provided that* the label of the combination product or convenience kit bears a UDI.

(b) *National Drug Code (NDC) Numbers.* If a combination product properly bears an NDC number on its label—

(1) The combination product is not subject to the requirements of § 801.20.

(2) A device constituent of such a combination product whose components are physically, chemically, or otherwise combined or mixed and produced as a single entity as described by § 3.2(e)(1) of this chapter is not subject to the requirements of § 801.20.

(3) Each device constituent of such a combination product, other than one described by § 3.2(e)(1) of this chapter, must bear a UDI on its label unless paragraph (a)(11) of this section applies.

(c) *Exception for shipping containers.* This rule does not require a UDI to be placed on any shipping container.

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

§ 801.35 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 of this chapter.

(b) A device may bear both a Universal Product Code (UPC) and a UDI on its label and packages.

§ 801.40 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 label includes a lot or batch number, a serial number, a manufacturing date, an expiration date, or for a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device, a distinct identification code as required by § 1271.290(c) of this chapter, 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 disclose the presence of AIDC technology.

(d) A class I device that bears a Universal Product Code (UPC) on its label and device packages is deemed to meet all requirements of subpart B of this part. The UPC will serve as the unique device identifier required by § 801.20.

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

(a) *In general.* A device that must bear a unique device identifier (UDI) on its label must also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

(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 of the device, or

(2) A different UDI used to distinguish the unpackaged device from any device 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 may be provided through either or both of the following:

(1) Easily readable plain-text;

(2) Automatic identification and data capture (AIDC) technology, or any alternative technology, that will provide the UDI of the device on demand.

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

(1) Any type of 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 a single-use device and is subjected to additional processing and manufacturing for the purpose of an additional single use.

(4) The device has been previously marked under paragraph (a) of this section.

(e) *Exception to be noted in design history file.* A labeler that decides to make use of an exception under paragraph (d of this section) must document the basis of that decision in the design history file required by § 820.30(j) of this chapter.

§ 801.50 Labeling requirements for stand-alone software.

(a) Stand-alone software that is not distributed in packaged form (e.g., when downloaded from a Web site) is deemed to meet the UDI labeling requirements of this subpart if it complies with the requirements of paragraph (b) of this section and conveys the version number in its production identifier.

(b) Regardless of whether it is or is not distributed in packaged form, stand-alone software regulated as a medical device must provide its unique device identifier through either or both of the following:

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

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

(c) Stand-alone software that is distributed in both packaged form and in a form that is not packaged (e.g., when downloaded from a Web site) may be identified with the same device identifier.

■ 5c. Effective December 23, 2013, add § 801.57 to subpart B to read as follows:

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

(a) On the date your device must bear a unique device identifier (UDI) on its label, 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.

(b) If your device is not required to bear a UDI on its label, any NHRIC or NDC number assigned to that device is rescinded as of September 24, 2018, and beginning on that date, you may no longer provide an NHRIC or NDC number of the label of your device or on any device package.

(c) A labeler who has been assigned an FDA labeler code to facilitate use of NHRIC or NDC numbers may continue to use that labeler code under a system for the issuance of UDIs, *provided that—*

(1) Such use is consistent with the framework of the issuing agency that operates that system; and

(2) No later than September 24, 2014, the labeler submits, and obtains FDA

approval of, a request for continued use of the assigned labeler code. A request for continued use of an assigned labeler code must be submitted by email to: *udi@fda.hhs.gov*, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002.

(d) Each request for continued use of an assigned labeler code must provide—

(1) The name, mailing address, email address, and phone number of the labeler who is currently using the labeler code;

(2) The owner/operator account identification used by the labeler to submit registration and listing information using FDA’s Unified Registration and Listing System (FURLS).

(3) The FDA labeler code that the labeler wants to continue using.

■ 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 paragraphs (f)(3) through (f)(8), respectively, 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 of this chapter in its entirety;

* * * * *

PART 803—MEDICAL DEVICE REPORTING

■ 8. The authority citation for 21 CFR 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 following definitions to read as follows:

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

* * * * *

Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated

as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

* * * * *

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.

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

* * * * *

■ 10. Amend § 803.32 by redesignating paragraphs (c)(6) through (c)(10) as paragraphs (c)(7) through (c)(11), respectively, 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), respectively, 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), respectively, 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), respectively, 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 21 CFR part 806 continues to read as follows:

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

■ 15. Amend § 806.2 by redesignating paragraphs (f) through (l) as paragraphs (g) through (m), respectively, and by adding paragraphs (f) and (n) to read as follows:

§ 806.2 Definitions.

* * * * *

(f) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

* * * * *

(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 UDI 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.

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

■ 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 21 CFR 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 redesignating paragraphs (h) through (k) as paragraphs (i) through (l), respectively, and by adding paragraphs (h) and (m) to read as follows:

§ 810.2 Definitions.

* * * * *

(h) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

* * * * *

(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.

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

■ 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 21 CFR part 814 continues to read as follows:

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

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

§ 814.3 Definitions.

* * * * *

(p) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

(q) *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.
- (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.
- (r) *Universal product code (UPC)* means the product identifier used to identify an item sold at retail in the United States.

■ 23. Amend § 814.84 by adding new 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 December 23, 2013.

PART 820—QUALITY SYSTEM REGULATION

■ 24. The authority citation for 21 CFR 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 new paragraphs (bb), (cc), and (dd) to read as follows:

§ 820.3 Definitions.

* * * * *

(bb) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

(cc) *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.
- (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

(dd) *Universal product code (UPC)* means the product identifier used to identify 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 21 CFR 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 new paragraphs (n) and (o) to read as follows:

§ 821.3 Definitions.

* * * * *

(n) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

(o) *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.

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

■ 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 21 CFR part 822 continues to read as follows:

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

■ 35. Amend § 822.3 by redesignating paragraphs (e) through (m) as paragraphs (f) through (n), respectively, and by adding new paragraphs (e) and (o) to read as follows:

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

* * * * *

(e) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

* * * * *

(o) *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 UDI 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 label 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.

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

■ 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;

* * * * *

■ 37a. Effective October 24, 2013, add new part 830 to read as follows:

PART 830—UNIQUE DEVICE IDENTIFICATION

Subpart A—[Reserved]

Subpart B—Requirements for a Unique Device Identifier

Sec.

830.10 Incorporation by reference.

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—[Reserved]

Subpart E—[Reserved]

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

Subpart A—[Reserved]

Subpart B—Requirements for a Unique Device Identifier

§ 830.10 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Food and Drug Administration must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860, and is available from the source listed in paragraph (b) of this section.

Copies are also available for purchase from the American National Standards Institute (ANSI), mailing address: ANSI, Attn: Customer Service Department, 25 West 43rd St., 4th floor, New York, NY 10036, phone: 212-642-4980, and may be ordered online at <http://webstore.ansi.org/>. The material is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) International Organization for Standardization (ISO), mailing address: ISO, Attn: ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, Switzerland, phone (dialing from the United States): 011-41-22-749-0111, and may be ordered online at <http://www.standardsinfo.net>.

(1) ISO/IEC 646:1991(E), Information technology—ISO 7-bit coded character set for information interchange (third edition; December 15, 1991), into §§ 830.20(c) and 830.100(b);

(2) ISO/IEC 15459-2:2006(E), Information technology—Unique identifiers—Part 2: Registration procedures (second edition; March 1, 2006), into §§ 830.20(b) and 830.100(b);

(3) ISO/IEC 15459-4:2008(E), Information technology—Unique identifiers—Part 4: Individual items (second edition; July 15, 2008), into §§ 830.20(b) and 830.100(b);

(4) ISO/IEC 15459-6:2007(E), Information technology—Unique identifiers—Part 6: Unique identifier for product groupings (first edition; June 15, 2007), into §§ 830.20(b) and 830.100(b).

Subpart C—FDA Accreditation of an Issuing Agency

§ 830.100 FDA accreditation of an issuing agency.

(a) *Eligibility.* A private organization 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 each of the following international standards:

(i) ISO/IEC 15459-2, which is incorporated by reference at § 830.10;

(ii) ISO/IEC 15459-4, which is incorporated by reference at § 830.10;

(iii) ISO/IEC 15459-6, which is incorporated by reference at § 830.10.

(3) Uses only characters and numbers from the invariant character set of ISO/IEC 646, which is incorporated by reference at § 830.10.

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

(5) Will protect against conflicts of interest between the issuing agency (and its officers, employees, and other agents) and labelers (and their officers, employees, and other agents) seeking to use UDIs that may impede the applicant's ability to independently operate a fair and neutral identifier system.

§ 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 by email to udi@fda.hhs.gov, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

(2) 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 provided in paragraph (a)(1) of this section, an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant;

(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 decisionmaking 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 UDIs;

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

(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;

(vii) Detailed information regarding any financial or other relationship between the applicant and any labeler(s) or governmental entity(ies); and

(viii) 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 UDIs 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 (UDIs) that meets the requirements of § 830.20;

(b) Make available information concerning its system for the assignment of UDIs;

(c) Maintain a list of labelers that use its system for the assignment of UDIs 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 UDIs; 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 officer, employee, or other agent of the issuing agency:

(a) Has been guilty of misrepresentation or failure to disclose required information in obtaining accreditation;

(b) Has failed to fulfill the responsibilities outlined in § 830.120;

(c) Has failed to protect against conflicts of interest that may impede the issuing agency's ability to independently operate a fair and neutral identifier system;

(d) In the operation of the issuing agency, has engaged in any anticompetitive activity to restrain trade; or

(e) 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.

Subpart D—[Reserved]

Subpart E—[Reserved]

■ 37b. Effective December 23, 2013, add subpart A to part 830 to read as follows:

Subpart A—General Provisions

§ 830.3 Definitions.

As used in this part:

Automatic identification and data capture (AIDC) means any technology that conveys the unique device identifier 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 a particular version or model of a device.

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.

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

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.

Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

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 commercially distributed without any subsequent replacement or modification of the label; and

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

Lot or batch means one *finished device* 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.

Shipping container means a container used during the shipment or transportation of devices, 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 UDI 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.

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

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

Version or model means all devices that have specifications, performance, size, and composition, within limits set by the labeler.

■ 37c. Effective December 23, 2013, add §§ 830.20, 830.40, 830.50, and 830.60 to subpart B to read as follows:

Sec.

830.20 Requirements for a unique device identifier.

830.40 Use and discontinuation of a device identifier.

830.50 Changes that require use of a new device identifier.

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

§ 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 each of the following international standards:

(1) ISO/IEC 15459–2, which is incorporated by reference at § 830.10;

(2) ISO/IEC 15459–4, which is incorporated by reference at § 830.10; and

(3) ISO/IEC 15459–6, which is incorporated by reference at § 830.10.

(c) Use only characters and numbers from the invariant character set of ISO/IEC 646, which is incorporated by reference at § 830.10.

§ 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 (UDIs) may be used to identify a particular version or model of a device. A particular version or model may be identified by 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 use a previously issued UDI until such time as § 830.50 requires you to assign a new device identifier.

§ 830.50 Changes that require use of a new device identifier.

(a) Whenever you make a change to a device that is required to bear a unique device identifier (UDI) on its label, and the change results in a new version or model, you must assign a new device identifier to the new version or model.

(b) Whenever you create a new device package, you must assign a new device identifier to the new device package.

§ 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:

(a) Assign a new device identifier to the device, and

(b) Keep a record showing the relationship of the prior device identifier to your new device identifier.

■ 37d. Effective December 23, 2013, add subparts D and E to part 830 to read as follows:

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 Correction of information submitted to the Global Unique Device Identification Database.

830.360 Records to be maintained by the labeler.

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 § 801.55 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 bear a unique device identifier (UDI).

(b) *Voluntary submission of information.* If a labeler voluntarily includes a UDI on the label of a device under § 801.40, the labeler may also voluntarily submit information concerning that device under this part.

(c) *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, licensure, 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 designated under § 830.320(a) shall provide FDA with the following information concerning each version or model of a device required to bear a unique device identifier (UDI) on its label:

(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 UDIs used by the labeler.

(b) *Concerning each version or model of a device with a UDI on its label:*

(1) The device identifier portion of the UDI 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 § 801.45 of this chapter requires the device to bear a UDI as a permanent marking on the device itself, either:

(i) 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

(ii) The device identifier portion of the UDI 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) Whether a patient may be safely exposed to magnetic resonance imaging, nuclear magnetic resonance imaging, or magnetic resonance tomography while using the device, or while the device is implanted in patient.

(9) 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;

(10) The type of production identifiers that appear on the label of the device;

(11) 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;

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

(13) The Global Medical Device Nomenclature (GMDN) term or code for the device;

(14) 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 request by email to: udi@fda.hhs.gov, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

(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: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

§ 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 announce any change on the FDA Web site at <http://www.fda.gov/udi/> at least 60 days before making the change.

§ 830.350 Correction of information submitted to the Global Unique Device Identification Database.

(a) If FDA becomes aware that any information submitted to the Global Unique Device Identification Database (GUDID) appears to be incorrect or potentially misleading, we may notify the labeler of the specific information that appears to be incorrect, and request that the labeler provide corrected information or explain why the information is correct. The labeler must provide corrected information or provide a satisfactory explanation of why the information is correct within 30 days of receipt of FDA's notification.

(b) If the labeler does not respond to FDA's notification within 30 days of receipt, or if FDA determines, at any time, that any information in the GUDID is incorrect or could be misleading, we may delete or correct the information. Any action taken by FDA under this paragraph does not relieve the labeler of its responsibility under paragraph (a) of this section to provide corrected information or an explanation of why the information previously submitted is correct.

§ 830.360 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 bear a UDI on their label, 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: September 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-23059 Filed 9-20-13; 8:45 am]

BILLING CODE 4160-01-P