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:

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*);

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,

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

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

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 PROCODE . . . 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

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.

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, reprocessors, specification developers, repackagers and relabelers that cause a label to be applied to a medical device. The estimated present value of the costs for domestic labelers over 10 years 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

[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.

(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:

§ 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 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.

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.

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

Subpart E Global Unique Device Identification Database

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.

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