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

Proposed Rule (as amended)	Final Rule
The proposed rule would have required a combination product *for which the primary mode of action is that of a medical device* to bear a UDI on its label. Proposed § 801.25(a).	The final rule also makes clear that the device constituent of a combination product whose components are physically, chemically, or otherwise combined or mixed and produced as a single entity as described by § 3.2(e)(1) (21 CFR 3.2(e)(1)) is not subject to the requirements of § 801.20 if the combination product properly bears a National Drug Code (NDC) number. See § 801.30(b)(2). The final rule provides that a combination product that properly bears a National Drug Code (NDC) number is not required to bear a UDI. See § 801.30(b)(1). However, the final rule also makes clear that each device constituent of a combination product, other than one described by § 3.2(e)(1), that properly bears an NDC on its label must also bear a UDI on its label unless the combination product bears a UDI on its label. See § 801.30(b)(3).
The proposed rule would have provided an exception for a device that is packaged in a convenience kit, *provided that* the device is intended for a single use. Proposed § 801.30(a)(12).	The final rule broadens and simplifies this exception, and extends it to the label of *any* device that is packaged in a convenience kit as long as the label of the convenience kit bears a UDI. See § 801.30(a)(11).
The proposed rule would have required use of a symbol to indicate the presence of AIDC technology, and provided a generic symbol that could have been used in lieu of any other symbol. Proposed § 801.45(c).	The final rule renumbers proposed § 801.45 as § 801.40. The final rule does not require use of a symbol to indicate the presence of AIDC technology, no longer provides for use of a generic symbol, and instead requires only that a label ''disclose'' the presence of AIDC technology. See § 801.40(c).
The proposed rule would have required an implantable device required to bear a UDI on its label to also bear a permanent marking providing the UDI. See proposed § 801.50(a)(1).	This provision has been removed; an implantable device will *not* be required to be directly marked with a UDI.
The proposed rule would have required a device required to bear a UDI on its label to also bear a permanent marking providing the UDI if the device is intended for more than one use and must be sterilized before each use. See proposed § 801.50(a)(1).	The final rule renumbers proposed § 801.50 as § 801.45. The final rule changes this provision to apply to devices that are ''reprocessed'' before each use; this broadens the scope of the provision. See § 801.45(a)(1).
The proposed rule did not fully explain how UDI labeling requirements would apply to stand-alone software regulated as a medical device. Proposed § 801.50, concerning direct marking, was the only provision that specifically addressed stand-alone software.	The final rule includes a new section that provides special labeling requirements for stand-alone software regulated as a medical device, including: • An explanation of how stand-alone software can meet UDI labeling requirements when it is not distributed in package form (e.g., when it is downloaded from a labeler's Web site); • a requirement for all stand-alone software to include means of displaying its UDI; and • an explanation that stand-alone software that is distributed in both packaged form and in a form that is not packaged (e.g., when downloaded from a Web site) may be identified with the same device identifier. See § 801.50.
The proposed rule was not clear regarding the process for requesting an exception or alternative to some UDI labeling requirements, and provided one process for requests that concern the use of UDIs on a device label and device package, proposed § 801.35, and an entirely different process concerning direct marking of medical devices, proposed § 801.50.	The final rule provides a single process for all types of requests, and provides a more comprehensive process. See § 801.55. The final rule adds these provisions: • FDA may grant a 1-year extension of the compliance date applicable to class III devices and devices licensed under the Public Health Service Act; see § 801.55(b), discussed previously; • FDA may initiate and grant an exception or alternative if we determine that the exception or alternative is in the best interest of the public health; see § 801.55(e); • FDA may rescind an exception or alternative; see § 801.55(e); • any labeler may make use of an exception or alternative that FDA has granted (FDA plans to make all decisions available to the public on FDA's Web site); see § 801.55(d).
The proposed rule was unclear whether the discontinuation of legacy FDA identifiers for devices (National Health-Related Item Code (NHRIC) and NDC numbers) would apply to devices that are exempted from UDI labeling requirements. Proposed § 801.57.	The final rule explains that *every* NHRIC and NDC number assigned to *any* device (even a device that is not required to bear a UDI) will be rescinded *no later than* September 24, 2018. See § 801.57.
The proposed rule did not explain how the discontinuation of legacy FDA identifiers would affect FDA-issued labeler codes that are already in use in the private sector and whose use might be permitted under an FDA-accredited system for the issuance of UDIs.	The final rule will permit continued use of an FDA-issued labeler code under an FDA-accredited system for the issuance of UDIs, provided that such use is permitted by the issuing agency that administers that system, and provided the labeler submits a request for continued use of a labeler code; FDA must receive the request *no later than* September 24, 2014. See § 801.57(c).
The proposed rule more prescriptively defined the types of changes that resulted in a new version or model, and which therefore required a new device identifier to be used to identify the changed device. See proposed § 830.50, which was then titled ''Changes that result in a new version or model.''.	The final rule gives labelers more flexibility to determine when a change to a device will require use of a new UDI. § 830.50 is now entitled ''Changes that require use of a new device identifier.''

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

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

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

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

GG. Requirements for a Unique Device Identifier—§ 830.20

FDA received six comments on this section.

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

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

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

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

FDA does not agree with either of these comments. Under the system provided by this rule, each FDA-accredited issuing agency will be permitted to design and operate its device identification system in any manner that conforms with the technical standards incorporated by reference in part 830. FDA believes that a high degree of freedom and flexibility is needed to ensure that the UDI system keeps pace with technological change; we also believe that the system as a whole will benefit from the options provided to labelers to choose among differing systems and technologies. For those reasons, the final rule adopts the language of the July 10, 2012, proposed rule without change.

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

FDA received six comments on this provision.

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

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

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

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

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

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

Although a few comments expressed support for certain requirements, such as requiring a new UDI when adding a new device package, or when changing to or from a sterile package, most comments viewed the proposed requirements as ''too broad,'' or ''substantially and unnecessarily overbroad'' because they would require new device identifiers to be assigned ''when relatively minor changes are made to the manufacture or specifications of a device.'' Many comments suggested the need for clarification of various aspects of the proposed language or suggested guidance would be required to understand the proposed requirements. A comment recommended that the requirement for a new UDI not be tied to changes that result in a new version or model, because the device industry uses the terms version and model for many different purposes, and ''it often makes sense to retain [existing device] identifiers even after changes have been made. How these terms are used . . . will vary by company. There is no standard . . . and no consistency within the industry. . . .'' A similar comment stated, ''there are many situations in which a change to specifications, performance, or composition should not require a new device identifier . . . even if a supporting . . . 10(k) or PMA Amendment . . . were required,'' and other comments added that requiring a new UDI whenever any change is made to a device, even a change that would not be noticeable by a user, would be overly burdensome. Other comments suggested that in order to avoid confusion, the requirement for a new UDI should be tied to a labeler's decision to use a new version or model number.

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

JJ. FDA Accreditation of an Issuing Agency—§ 830.100

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

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