Department of Health and Human Services
Food and Drug Administration
Unique Device Identification System
Proposed Rule

Executive summary

On Tuesday, July 10, 2012 the Food and Drug Administration issued a proposed rule to establish a unique device identification system. This proposed regulation would implement the requirement found in Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which directs the FDA to add new section 519(f) to the Federal Food, Drug, and Cosmetic Act (FD&C).

The system established by this rule would require the label of medical devices and device packages to include a unique device identifier (UDI). Each UDI would have to be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. In addition, the rule standardizes the human readable format of dates. The rule would require the submission of information concerning each device to a database that the FDA intends to make public, to ensure that the UDI can be used to adequately identify the device through its distribution and use.

The GS1 System and services (GTIN, GLN and GDSN) can be used to comply with this rule.

Electronic or written comments are due by September 10, 2012 for comments on information collection activities, and November 7, 2012 for comments on all other content. There are 35 questions that the FDA specifically asked to be addressed in the comments. It is expected that the final rule will be published in May 2013 after review of the comments.

BACKGROUND

Purpose of Regulation

1. Reduce medical errors by reducing confusion over what the device is and its proper use, speeding up the reporting of adverse events and increase the efficiency of recalls.
2. Simplify the integration of device use information into data systems by using UDIs for rapid and accurate data collection, recording, and retrieval.
3. Provide for more rapid identification of medical devices with adverse events by increasing the efficiency of precise and accurate reporting.
4. Provide more rapid development of solutions to reported problems
5. Provide for more rapid and more efficient resolution of device recalls
6. Provide better focused and more effective FDA safety communication
7. Provide easily-accessible source of definitive device identification
8. Ease confusion by standardizing the format for dates provided on device label or package
9. Additional benefits, such as enhancing management of the Strategic National Stockpile, ease inventory management, encouraging useful patient electronic records, and helping to identify similar devices in the case of a shortage.

Basic Requirements

1. A UDI, both in plain-text format and a format that can be read by a bar code scanner or some other AIDC technology, must appear on the label and packaging of a device
2. Certain devices must also have a UDI marked directly on the product. These include implantable devices, devices intended to be used more than once, and stand-alone software.
3. The regulation will create a new database known as the Global Unique Device Identification Database (GUDID).
4. The format of all human readable dates on packages will be standardized
5. The rule specifies what must be included on the labels: the specific version or model and the labeler of the device, the device's control mechanism (lot/batch number, serial number, expiration date, and/or date of manufacture).
6. All UDIs will be issued by an FDA-accredited issuing agency. The FDA will explain its reasons for accreditation, evaluating applications, and suspension or revocation of accreditation.
7. Whenever a device must be identified with a UDI the labeler of that device would be required to submit information concerning the device to the FDA to make public and be included in the GUDID.

The full benefits of the UDI recommend that hospitals and other healthcare facilities adopt information technology in order to identify medical devices throughout distribution and use.

Although many scanners are already in place they should be adopted universally, and it is important that standard procedures are implemented to link patient information to the information provided about particular devices.

Principles that guided the development of the proposed rule

1. The UDI system should generally include all classes of devices, with appropriate exceptions.
2. The UDI system should be based on existing, broadly-accepted standards
3. The UDI system should recognize that the private sector has already implemented device identification systems, and, wherever possible, the rule should not require significant alteration of these systems. GS1 uses a Global Trade Item Number (GTIN). These commercial systems are designed for uses that go beyond the FDA's responsibilities and jurisdiction, such as enabling inventory management and commercial transactions, and because of their diverse purposes the FDA believes it would be counterproductive to try to replace these systems with one designed by the FDA. It would be better to simply require these existing systems to seek accreditation from the FDA.
4. "Burdens should be minimized."
5. The UDI system should be open to all technological advances. The system would permit use of any type of bar code, RFID tag, near-field communication, or other technology, whether existing or developed in the future.
6. The UDI system should be designed to integrate smoothly with other FDA systems, such as registration and listing, post-market surveillance, and adverse event reporting. Overlap with other regulatory requirements has been minimized and the proposed rule is streamlined in the FDA's regulatory process.

7. Requirements should be phased in over several years to ensure smooth and effective implementation.
8. The UDI system should foster innovation by, and competition among, issuing agencies.
9. There will be effective FDA oversight of issuing agencies.
10. The UDI system should provide for appropriate regulatory flexibility, including exceptions and alternatives.
11. Safeguards should be provided to protect small businesses, first by allowing small businesses to choose any system provided by an accredited issuing agency and second by allowing the FDA to act as an issuing agency if they find that a significant number of small businesses will be substantially harmed by the fees accessed by all accredited issuing agencies.
12. The establishment of a publicly accessible GUDID database is a critical component of an effective UDI system. The identification number must serve as a reference number, for the real value of the identifier is the information it can be connected to and the other devices it allows the device to be compared with. The GUDID system must be open and available to all.

Prior consultation with the healthcare community and industry

When various entities asked that the FDA revisit the question of bar codes the FDA met with various stakeholders, including device manufacturers and distributors, hospital associations, and other Federal agencies to solicit information and comments about employing a uniform system for the unique identification of medical devices. The proposed rule was based off information shared from these stakeholders and the collective support for an identification system.

Description of the Rule

Overview

- Proposed §801.18 provides for standardized formatting of dates of medical device labels
- The labeler of each device would be responsible for meeting labeling and data submission requirements. The labeler would, in most cases, be the manufacturer of the device
- Unless the device is excepted, the label of a medical device, and a device package, marketed in the United States would be required to bear a UDI; this requirement would be phased in over five years
- The UDI would have to be provided in two forms: easy readable plain text and AIDC technology
- The proposed rule provides several categorical exceptions, proposed in §801.30, as well as case-by-case exceptions and alternatives, proposed in §801.35 and §801.128(f)(2).
- Direct marking would be required for certain categories of devices, with exceptions. For each device subject to direct marking, this requirement would go into effect two years after the base UDI labeling requirement for that device
- Whenever a device must be labeled with a UDI, the labeler would have to submit data concerning that device to the GUDID database
- UDI labeling requirements would also apply to certain combination products, to the device constituent parts, to convenience kits, and a device included in a convenience kit, except for a single use device

- UDIs would be issued under systems operation by FDA-accredited issuing agencies and conform to certain international standards. A different UDI would be required for each version or model of a device
- The FDA proposes to phase in these requirements

UDI Labeling Requirements

- Part 830 looks to replace Part 801 to make it clear that all UDI labeling requirements apply to in vitro diagnostic devices
- Definitions: The UDI regulation would not change the meaning of any term currently defined in Part 801, which includes definitions of: *Automatic identification and data capture (AIDA) technology, Center Director, Combination product, Convenience kit, Device packaging, Finished devices, FDA, GUDID, Label, Labeler, Lot or Batch, Shipping container, Specification, UDI, Universal Product Code (UPC),* and *Version or model.* (page 40747-40748)
- When would the requirement for UDI labeling go into effect, and where would the UDI have to appear? On the individual device package, on the box, and on the carton of boxes, which reflects standards used in GS1. Class III devices will require labeling 1 year after the published final rule, 3 years after for Class II and 5 years for Class I and other devices. Data requirements go into effect at the same time as labeling requirements.
- How would UDI labeling requirements apply to a combination production and a device constituent part of a combination product? All combination products will require a UDI regardless of which FDA Center has been designated as having primary jurisdiction for the premarket review and regulation of the product.
- How would UDI labeling apply to a convenience kit? The FDA would require a UDI on the label of and device package of each convenience kit.
- A request for case-by-case exception would have to identify the device, identify labeling requirement for exception, explain why labeling is not technologically feasible, describe alternative if applicable, and provide an estimate for the number of devices and labels that would be affected.
- May a device that is exempt from UDI labeling requirements nevertheless be labeled with a UDI? Yes.
- How would a UDI have to appear on a device label and on a device package? In plain text form and in AIDC technology form
- When would a device have to be directly market with a UDI? If the device is an implantable device, a device that is intended to be used more than once, or stand-alone software that is a 'device' under §201(h) of the FD&C Act. If direct marking is not technologically feasible or would interfere with the safe use of the device, if the device is intended to remain implanted for less than 30 days, the device has been previously marked, if the device bears a UPC code, or if the device is software that is not stand-alone software, direct marking would not be required.
- After the requirement for UDI labeling goes into effect, may I continue to identify my device with the National Health-Related Code (NHRIC) or National Drug Code (NDC) number assigned to it? No.
- Formatting of dates provided on medical device labels: Month, Day, Year, with the month shown as a three-letter abbreviation (E.g. SEP 30, 2012)

Requirements Relating to Issuing Agencies and Submission of Data to the GUDID (part 830)

- Definitions of: *AIDC, device package, expiration date, FDA, labeler, lot or batch, specification, shipping container, UDI, U.P.C., version or model, issuing agency, GUDID, premarket submission,* and *small business.*
- What would be the requirements for the composition and issuance of a valid UDI? Every UDI must be issued under a system operated by FDA or by an FDA-accredited issuing agency. It must conform to the international standards that would be incorporated by reference to §830.10. UDIs would be compose only of characters from a single character set defined by one of these incorporated standards
- Use and discontinuation of a device identifier: one UDI per version or model of a device, one device per UDI.
- What changes would require a new UDI? Each distinct model or version needs a new UDI. Any change that could affect the safety or effectiveness of a device, a change from non-sterile to sterile packaging, a change in the quantity of devices per package, or a relabeling of a device that previously held a UDI from another labeler requires a new UDI.
- How would FDA accredit an issuing agency? An issuing agency would be an FDA-accredited private nonprofit organization or a State agency that operated a system for the assignment of UDIs pursuant to this rule. The system must be available to all users. Within 60 days of receipt of any application, FDA will notify the applicant of any deficiencies and will request correction of those within 60 days.
- What would be the responsibilities of an FDA-accredited issuing agency? Operating a system for assignment of UDIs that meets the requirements of proposed §830.20 and the standards incorporated by reference at proposed §830.10, making information available concerning its system for the assignment of UDIs, maintaining a list of labelers that use its system for assigning UDIs and providing FDA with a copy each year, upon request providing FDA with information concerning a labeler that is employing the issuing agency's system, and remaining in compliance with the eligibility and accreditation criteria set forth in proposed §830.100.
- How would an issuing agency relinquish its accreditation, and how would FDA suspend or revoke an issuing agencies accreditation? The agency could relinquish its accreditation by submitting a letter stating its intent to the FDA, and the FDA could suspend or revoke if the issuing agency has been guilty of misrepresentation in obtaining accreditation, failed to fulfill responsibilities, or violated or aided and abetted in the violation of any regulation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- When would FDA act as an issuing agency? During any period where there is no accredited issuing agency or if small businesses would be substantially and adversely affected by the fees required by all accredited issuing agencies. If FDA did act as an issuing agency it would not assess a fee for its services.
- What devices would be subject to GUDID data submission requirements? Any device that would have to be labeled with a UDI
- Would FDA ever reject data submitted to the GUDID or remove data from the GUDID? Only for the purpose of increasing accuracy, and not for removing historical data.
- What device identification data would I have to submit to the GUDID? The device identifier portion of the UDI associated with the device version or model, any UDI previously associated with the device, a statement that the UDI that appears in marking is identical to the UDI assigned to the

model or version of the device, the proprietary, trade, or brand name of the device as it appears on the label of the device, any version or model number on the label of the device, if the device is labeled sterile, a statement to that effect, if the device is labeled containing natural rubber latex that contacts humans, a statement to that effect, if the device is available in multiple sizes, the size of the version or model, the type of production identifiers that appear on the label, the FDA Product Code, the FDA premarket submission number, the FDA listing number, the GMDN code, and the number of individual devices contain in each device package.

- How would I have to submit device identification data to the GUDID? Each labeler would have to designate an individual to serve as a point of contact with the FDA on matter relating to the identification of medical devices marketed by the labeler. The rule requires electronic submission unless it is not technologically feasible. Data could either be entered as part of a structured product label (SPL) or through a secured internet site. Manufacturers on Global Data Synchronization Network (GDSN) can utilize their data pools to send messages to the GUDID.
- When would I have to submit device identification data to the GUDID? No later than the date the label of the device must be identified with the UDI, and any time updated information is required.
- Would I be permitted to submit information to the GUDID that is not required by the FDA? No, except where the FDA allows specific additional information to be submitted to the GUDID as ancillary information.
- What records would a labeler be required to maintain concerning its UDIs? All records linking the UDI to the associated version or model, retained for three years after the date the labeler ceases to market the version or model.
- Who would have access to the information I submit to the GUDID? Everyone has free, easy and unlimited access to the GUDID is essential for identifying devices.

Exceptions

1. Non-prescription sold at retail establishments or when delivered directly to a hospitals and other health care facilities
2. Class I devices that FDA has by regulation exempted from the good manufacturing practice requirements of part 820 of the Quality Systems Regulation
3. Production identifier would not be required for Class I devices
4. Device used solely for research, teaching, or chemical analysis, and not intended for any clinical use
5. Custom device intended only for use by an individual patient and not generally available for sale
6. Veterinary medical device not intended for use in the diagnosis of disease or other conditions in man
7. Investigational devices (subject to a variety of requirements under part 812)
8. Single use devices included in a convenience kit
9. Combination product device constituent part that can be used only exclusively as part of the use of the combination product
10. Shipping containers
11. Device held by the Strategic National Stockpile and granted an exception or alternative under § 801.128(f)(2)
12. Device intended for export from the United States
13. Device for which FDA has established a standard pursuant to section 514(b) of the FD&C Act and has provided therein an exception from the requirement of proposed § 801.20, or for which FDA

has recognized all or part of a standard pursuant to section 514(c) of the FD&C Act and has included an exception from the requirement of proposed § 801.20 within the scope of that recognition

14. Software that is an integrated component of a device, such as software embedded in a chip
15. DPM that
    a. Would Interfere with safe and effective use
    b. Is not technologically feasible (E.g. Amorphous state; costly compared to revenue or by risk analysis)
    c. Is implanted continuously for a period of less than 30 days
    d. Is previously directly marked
    e. Is sold at retail and bears a Universal Product Code
    f. Is software that is not stand-alone software, but is a component of a medical device
16. Date format: electronic products to which a standard is applicable under subchapter J, Radiologic Health

GS1 Healthcare / GS1 Healthcare US

GS1 and GS1 US formed a workgroup (WG) to provide comments to this proposed regulation. The WG will meet weekly to develop comments and to review comments from other organizations posted on the Federal government website www.regulations.gov.

To learn more about participating in this workgroup and how GS1 Standards-- including the GTIN and the GS1 Global Data Synchronization Network™ (GDSN®), a single, synchronized data source for product information – will foster UDI regulation compliance across the industry, visit www.gs1us.org/healthcare.

Disclaimer

GS1 US, its members, officers, directors, employees, or agents shall not be liable for any injury, loss, damages, financial or otherwise, arising from, related to, or caused by the use of this document. Use of said document does not guarantee compliance with applicable state and/or federal laws. User is responsible for the interpretation of and compliance with applicable laws. The use of said document shall constitute your express consent to the foregoing disclaimer.

###