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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. FDA-2008-N-0661]

Unique Device Identification System; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: "Unique Device Identification System." The purpose of the public workshop is to obtain information to help us better understand the issues involved in the establishment of a unique device identification system (UDI system) and request comments on this topic.

Dates and Time: The public workshop will be held on, February 12, 2009, from 9 a.m. to 5 p.m. See section V of this document for additional dates associated with registration and participation in the workshop.

Location: The public workshop will be held at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878, 301-590-0044.

Contact Person: Jay Crowley, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-500), 1350 Piccard Dr., Rockville, MD 20852, 240-276-2389, or Stephen Ripley, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

Registration: Register electronically at <http://www.fda.gov/cdrh/ocd/udi/index.html> by January 30, 2009. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Jay Crowley (see *Contact Person*) by January 30, 2009.

Comments: Regardless of attendance at the public workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The deadline for submitting comments regarding this public workshop is February 27, 2009. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

A. What Does Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) Require?

On September 27, 2007, President George W. Bush signed into law FDAAA (Public Law 110-85). Section 226 of FDAAA amended the Federal Food, Drug, and Cosmetic Act (the act) by requiring the establishment of a UDI system. Specifically, section 226(a) of FDAAA created a new section 519(f) of the act

(21 U.S.C. 360i(f)) stating that “The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.”

A UDI system may provide for early detection of the warning signs of a defective device and facilitate device recalls (Ref. 1) and other possible benefits of a UDI system have been suggested.

B. Why Are We Holding a Public Workshop?

The enactment of section 519(f) of the act has raised many questions for our consideration. For example, the statute requires the UDI to go on the device’s label, but it also allows for “alternative placement” and for exceptions. Thus, what circumstances would justify alternative placement of the UDI, and which devices should receive an exception from a UDI requirement? Consequently, we are issuing this notice to announce that we will hold a public workshop to discuss and to invite comment on the questions set out in section II. B of this document.

II. Issues to Be Considered

A. Organization and Basic Instructions

We invite comments on the questions presented in this section. We intend to discuss these same questions at the public workshop. If you wish to comment in writing on a particular question, please identify the question that you are addressing before providing your response to the question. For example, your comment could take the following format:

“Question 1—[Quote the question].”

“Response—[Insert your response].”

You do not have to address each question. Additionally, for those questions pertaining to economic issues or the prevalence of a particular problem or action, please provide data and/or references so that we may understand the basis for your comment, figures, and any assumptions that you used.

As this workshop will only take place over the course of a single day, in order to most effectively use this time and obtain as much information from as many different points of view as possible, the public workshop will be divided into sessions that focus on each of the main topic areas. Each session will begin with an invited presentation to describe the issue. This will be followed by a moderated question and comment session. Following this discussion, the moderator will open up the discussion to questions and comments on the topic from the audience. Though limited, at the end of the day there will be time for other presentations.

Because of the workshop’s format, we will only have a short time for additional presentations. We encourage attendees to raise their issues and concerns during the discussion portion of the main topic areas. We also encourage persons and groups having similar interests to consolidate their information and present it through a single representative.

Additionally, through this public workshop, we hope to gain greater understanding of various automatic identification technologies. Therefore, we invite manufacturers and organizations that market or have in development automatic identification technologies, which could be used with medical devices, to display these technologies. Questions about whether your product

or technology would fall within the scope of this vendor display should be directed to the contact persons listed at the beginning of this notice.

You may register to present at the public workshop or participate in the vendor display at <http://www.fda.gov/cdrh/ocd/udi/index.html>. Because of time constraints, vendors may register either to present at the public workshop or participate in the vendor display. You may not register for both. If you choose to participate in the vendor display, you will have the opportunity to share information about your products with FDA and other attendees when they visit your display.

B. Questions Pertaining to the UDI System

1. Which types of devices or particular devices should be subject to the requirements of a UDI system? Which types of devices or particular devices should be excepted?

Section 519(f) of the act states that the Secretary of Health and Human Services may provide “an exception for a particular device or type of device.” However, the statute does not specify any criteria for an exception, nor does it describe the scope of an exception.

a. Should all devices be subject to the requirements of a UDI system?

Please explain your reasoning.

b. Are there types of devices or particular devices that should receive an exception from the requirements of a UDI system? If so, what types of devices or particular devices should receive an exception and why?

2. What are the characteristics or aspects necessary to uniquely identify a device?

Section 519(f) of the act states that the UDI “shall adequately identify the device through distribution and use, and may include information on the lot or serial number.” The statutory language does not describe the characteristics or features that make a device “unique” or that “adequately identify the device through distribution and use.”

a. What characteristics are needed to uniquely identify a device?

b. What core attributes, elements, or characteristics of a device should constitute a minimum data set for a device identifier?

c. What changes to an attribute, element, or characteristic associated with the unique identification of a device change should result in a new UDI?

d. Should the UDI include a component that represents package size or packaging level?

e. To what extent would or should the list of unique device characteristics vary depending on the type of device?

3. What should be the UDI’s components?

a. Could existing standards, such as the standards used by GS1, Health Industry Business Communications Council (HIBCC), or others be used as a model for the UDI system? What are the advantages and disadvantages of these existing organizations and standards?

b. Some identification systems currently in use employ a combination of a device identifier (meaning information that identifies the manufacturer, make, and/or model of the device) and a production identifier (meaning information that relates to the lot or serial number). What should the device “identifier” component of the UDI cover or contain?

c. With respect to the production identifier, we note that the statute says that the UDI may include information on the device's lot or serial number. When should lot or serial number information be required for a device? Are there particular devices for which serial numbers should be required? If yes, what particular devices should be labeled with a serial number? Please explain your reasoning.

d. How might we ensure that UDIs, regardless of the manufacturers or devices associated with those UDIs, are uniform or standardized in their structure or composition? For example, the NDC (National Drug Code) number is always 10 digits long and always presents the labeler code first, followed by the product code and then the package code. Should we limit the number of ways that the UDI can be created or the standards to be used?

e. How should the UDI be created to ensure that UDIs are unique?

4. Where should the UDI be placed? What should be the criteria for alternative placement of the UDI?

The statute requires the label of devices to bear a unique identifier, unless we require an "alternative placement" or provide an exception. Section 201(k) of the act defines "label" "as a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

a. Should we specify where on the label the UDI must appear? If so, where should the UDI appear on the label? Please explain your reasoning.

i. Should we allow the components of the UDI to be placed separately on the same package or on different levels of packaging? For example, if the UDI consists of a device identifier component and a production identifier component, should we allow the device identifier component of the UDI to be placed in one location and allow the production identifier component to be placed elsewhere on the label or on the device? Please explain your reasoning.

As another example, some devices are packaged individually and then packaged again in a larger container (such as a “shelf pack”). We are aware that some manufacturers would prefer placing both the device identifier component of the UDI and the production identifier component of the UDI on the larger container and placing only the device identifier component of the UDI on the individual packages. Separating UDI components or allowing part (rather than all) of the UDI on package labels may provide for flexibility in product labeling, but also generate confusion as to which UDI to read or scan (if the UDI components are separated) or limit the usefulness of the UDI if a component of the UDI is not present.

ii. For barcodes (whether linear or two-dimensional (2D)), should we require the UDI to be expressed in a concatenated manner (whereby the components of the UDI are expressed on the same line adjacent to each other) or in a stacked manner (whereby one component of the UDI rests atop the other component)?

b. Are there devices where we should require the UDI to appear on the device itself (direct part marking)? For example, it might be beneficial to put the UDI on the device itself if the device is re-processed because this might help firms identify or record how many times a particular device has been

reprocessed. Similarly, certain single use devices (SUDs) sometimes are reprocessed, so a UDI on the device itself could facilitate the mandatory and voluntary MedWatch reporting relating to such reprocessed devices or facilitate other activities (such as documenting sterilization reprocessing of SUDs and validation studies) associated with SUDs. Conversely, are there devices where the UDI cannot or should not go on the device itself? If so, please describe those devices and explain why the UDI cannot or should not go on the device.

c. If we allow for “alternative placement” of the UDI for some particular devices or types of devices, what should be the general criteria for requiring “alternative placement” of the UDI, e.g., such as on the device itself or other location that is not on the label?

d. What specific challenges or limitations exist regarding “alternative placement?” For example, placing a UDI in an automatic identification form on an implantable device may present issues as to whether the automatic identification technology affects the device’s integrity or function. As another example, certain devices, such as software, may pose particular challenges for how to label with a UDI.

5. How should the UDI be presented?

We are aware of several automatic identification technologies in use, such as linear bar codes, 2D bar codes, and radio frequency identification. We also note that various FDA regulations and initiatives have required or recommended one or more automatic identification technologies (see 21 CFR 201.25 (bar code label requirement for human drug products); 21 CFR 610.67 (bar code label requirement for biological products); Ref. 2; and section 505D of the act (21 U.S.C. 355e) (regarding “pharmaceutical security” and specifying “promising technologies” such as RFID (radio-frequency identification),

nanotechnology, encryption technologies, and other “track-and-trace or authentication technologies”)). Therefore:

a. Should we require human-readable UDIs or automatic identification of UDIs or both? Are there devices where it would be sufficient to have human-readable UDIs alone? Please explain your reasoning. For example, devices used in a home care setting might not need an automatic identification UDI because the home might not be equipped to read the automatic identifier. Are there situations where we should require both human-readable and automatic identification UDIs? Please explain your reasoning.

b. Should we specify a particular type of automatic identification technology or should we allow the automatic identification technology to vary depending on the type of device? Should we identify automatic identification standards (as opposed to specific technologies) that can be used? Please explain your reasoning. Specifying a particular type of automatic identification technology would enable hospitals and other parties who might read or use a UDI to make specific investments in scanning or reading equipment, but the technology chosen might not be easily applied to all devices (if we require the UDI to be placed somewhere other than the label.) For this question, we are particularly interested in hearing from parties who might use UDIs as well as entities that may have already adopted or installed device identification systems.

c. Should we allow the use of different automatic identification technologies to express different parts of the UDI? For example, the device identifier component might be expressed in a linear bar code and the production identifier component might be expressed in a 2D bar code.

Allowing the use of different technologies for different components of the UDI

may enable manufacturers to make more efficient use of label space or space on the device itself, but it also could generate confusion as to which identifier to read or scan and could necessitate the purchase of several types of reading and scanning equipment.

d. Are there existing standards or systems we should consider in establishing the requirements for how the UDI must be presented? For example, we are aware of various standards organizations, such as GS1 and the HIBCC, that exist and have specific formats or specifications for automatic identifiers for products. Should we allow any or all of these standards to be used?

6. How should the UDI Database be developed and maintained?

For parties to benefit from UDI information, it would seem necessary for those parties to know, at a minimum, the UDIs that exist, the specific device associated with each UDI, and the information associated with each UDI. It might be efficient for one entity to collect the UDIs, associate those UDIs with specific devices, and make the information associated with those UDIs publicly available. However, it is also conceivable (but perhaps less efficient or more costly) that the information could rest with individual manufacturers themselves (rather than FDA) or with a third party or third parties.

Consequently:

a. How and when should we require UDIs and associated information to be entered into a database? How frequently should we require changes to a UDI or to the information associated with or linked to a UDI to be reported?

b. Aside from information that is necessary to uniquely identify a device, what other information (if any) should be part of a UDI system database or otherwise linked to the UDIs?

c. If variable data (such as a lot or serial number) is necessary to uniquely identify a device, should such data be included in a UDI system database?

C. Questions Pertaining to Possible Impacts of a UDI System

Many production situations that might be affected by UDI requirements are complex. In its basic form, a device identifier is a series of digits and/or letters associated with a specific device. At a minimum, a system can be thought of as the set of procedures that allow stakeholders to use an identifier. Through public consultation, however, FDA has found that there are many different views as to the purpose of a UDI system and different opinions about how to describe and implement a UDI system. Because of the diversity of affected devices and manufacturing processes, we expect that affected entities might comply with UDI requirements in a variety of ways. If you respond to the following questions about the costs and benefits of a UDI system, we encourage you to provide as much detail and context as possible. For example, if you identify exceptional costs related to incorporating a UDI in certain production lines, we need to understand the production process details. In addition, we specifically invite small businesses to provide information about a UDI's potential impact.

1. What is the magnitude of the problem to be addressed by the establishment of a UDI system?

Please describe and provide qualitative or quantitative evidence of the incidence of deaths, injuries and illnesses associated with medical devices. What role would a UDI system play in helping to reduce the incidence of such deaths, injuries, and illnesses and how might the structure of a UDI system facilitate this role?

2. Questions for manufacturers

a. *Current practices.* Describe your current practices for applying standards to medical devices, marking identifiers on medical device labeling and managing medical device identifier data. For example, how do you currently use classification standards such as UNSPSC (United Nations Standard Products Service Code), nomenclature standards such as GMDN (Global Medical Device Nomenclature), and identification standards such as GS1 or HIBCC? What percent of your devices are not currently marked with a standardized identifier? Please describe any plans you have to change these practices in the near future.

b. *Changing current identifiers.* If you were to add a UDI or change the presentation of your current identifier, please describe your approximate expected capital and operating costs (including labor) to plan for, implement, and apply a UDI to product labeling. To provide context for your estimate, please explain your expected approach to adding a UDI, considering the possibility that a UDI might be a static number (e.g., a manufacturer/product code) or that it might include a variable number (e.g., manufacturer/product/lot code).

c. *Encoding variable data.* If you were to add a UDI bar code with variable data (such as lot or serial number) to medical device labeling, please describe how you would print the variable bar coded information. For example, do you foresee using on-line label printing, other in-house printing, or contract printers to add a UDI bar code?

d. *Production line impacts.* Considering your operations, are there products where adding a UDI (human readable or barcode; static or variable) to labeling would not be feasible without major capital investment or

overhauling production lines? If so, please describe the products and suggest alternatives or solutions.

e. *Small devices and small packages.* A UDI could present a challenge for some small packages. What percentage of your product line consists of devices whose small size could make placing a UDI on a label problematic? Of those devices identified, what “alternative placement” of the UDI would be feasible? Please explain your reasoning. Please describe the nature of the problems and costs to solve such problems. Please suggest alternatives or solutions.

3. Questions for hospitals, nursing homes, and clinics

a. *Using a UDI.* If UDIs were placed on at least some medical devices, what functions could a UDI serve in your institution?

b. *Expenses.* What expenses do you foresee in attempting to capture and use UDIs placed on medical devices? If you foresee using UDIs, how would you modify operations in your facility?

c. *Adverse event reporting and recalls.* How would capturing the UDI change your recall management or adverse event reporting? For recalls or adverse events involving the most serious device malfunctions or failures, how have problems in device identification impaired your recall management or adverse event reporting? Please describe the magnitude of the problems you have encountered.

III. References

The following references have been placed on display in the Division of Dockets Management (see *Comments*) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. 153 Cong. Rec. H10597 (daily ed., September 19, 2007) (statement of Rep. Hooley).

2. FDA, "FDA Counterfeit Drug Task Force Report: 2006 Update," p. 12, (http://www.fda.gov/oc/initiatives/counterfeit/report6_06.pdf) (advocating use of RFID).

IV. Where and When Will the Public Workshop Occur?

We will hold the public workshop on February 12, 2009, from 9 a.m. to 5 p.m., at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878.

V. Do You Have To Register To Attend a Public Workshop or To Make a Presentation?

If you wish to make a presentation at or to attend the public workshop, please register online at <http://www.fda.gov/cdrh/ocd/udi/index.html> by January 30, 2009. The online registration form will instruct you as to the information you should provide. Space may be limited, and we will close on-site registration when the maximum seating capacity is reached.

We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations will depend on the number of people who wish to speak on a given topic, and the public workshop schedule. Similarly, the time allotted to each topic may vary depending on the expressed interests of persons registering for the public workshop. To obtain updates on the public workshop, please visit <http://www.fda.gov/cdrh/ocd/udi/index.html>.

Additionally, regardless of whether you wish to make a presentation or simply attend the public workshop, if you need any special accommodations (such as wheelchair access or a sign language interpreter), please notify Jay Crowley (see *Contact Person*) by January 30, 2009.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System

(FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cdrh/ocd/udi.index.html>.

Dated: 1/6/09
January 6, 2009.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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1-8-09

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