on the nature of the requests made for presentations.

III. Will Meeting Transcripts Be Available?

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

IV. How Should You Send Comments on the Issues?

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 1, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–6867 Filed 8–8–06; 3:14 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0292]

Unique Device Identification; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to request comments to help the agency understand how the use of a unique device identification (UDI) system may improve patient safety, e.g., by reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting. We are also interested in understanding the issues associated with the use of various automatic identification technologies (e.g., bar code, radiofrequency identification). We invite comments about specific UDI issues for medical devices.

DATES: Submit written or electronic comments by November 9, 2006.

ADDRESSES: Submit written comments concerning this document 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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: David Racine or Jay Crowley, Center for Devices and Radiological Health (HFZ–500), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3400, e-mail: *CDRHUDI@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On February 26, 2004, we published a final rule (the ''bar code rule'') (69 FR 9120) requiring bar codes on certain human drug and biological products to help reduce medication errors in hospitals and other health care settings. The bar code is intended to enable health care professionals to use bar code scanning equipment in conjunction with computerized medication administration systems to verify that the right drug, in the right dose, is being given to the right patient at the right time. This rule (now codified at 21 CFR 201.25 and 610.67) requires that manufacturers encode the unique National Drug Code (NDC) number in a linear bar code on the product's label.

The bar code rule, however, does not apply to medical devices. In the bar code rule, we stated that, unlike drugs, medical devices do not have a standardized, unique identifying system comparable to the NDC number, and that the absence of such a system complicates efforts to put bar codes on medical devices for purposes of preventing medical errors (69 FR 9120 at 9132).

Since the issuance of the final bar code rule, various entities, including members of Congress and a consortium of hospital groups, have asked that we revisit the issue of bar coding medical devices to improve patient safety; improve quality of care; and encourage cost effectiveness, e.g., of health care by improving delivery and supply chain efficiency (Refs. 1 and 2).

A. Stakeholder Meetings

In response to the interest in revisiting the issue of bar coding medical devices, FDA met with various stakeholders, including device manufacturers and distributors, hospital associations, and other Federal agencies such as the Agency for Healthcare Research and Quality, Department of Defense, Department of Veterans Affairs, and Centers for Medicare and Medicaid Services to solicit information and comments about employing a uniform system for the unique identification of medical devices. (References 3 and 5 contain summaries of some of these meetings). We were interested in hearing views about the value of a uniform system of unique identifiers for medical devices, what efforts or initiatives are currently ongoing among stakeholders, and the use of various automatic identification technologies. We were also interested in FDA's role related to the establishment and use of a UDI system and whether FDA should consider a voluntary or a mandatory approach for such a system.

As a result of these meetings, FDA learned that the majority of stakeholders support the development of a uniform system of unique identifiers as a way to improve patient safety and recognized other ancillary benefits such as better management of the purchase, distribution, and use of medical devices. However, there were a variety of opinions and experiences about how best to implement such a system.

B. Report on Automatic and Unique Identification of Medical Devices

In addition to holding stakeholder meetings, we commissioned two reports from outside experts to provide: A general overview of some of the most prevalent technologies available to support automatic identification of medical devices, the current published positions and standards of various stakeholders, and highlights of some of the general applications reported in the literature involving the use of such systems for medical devices. (See Refs. 4 and 6 and *http://www.fda.gov/cdrh/ocd/udi/*). The reports identified several potential benefits to widespread use of UDI, such as reducing medical errors, facilitating recalls, improving medical device reporting, and identifying incompatibility with devices or potential allergic reactions. The reports further indicated that many issues have to be addressed prior to successful implementation of UDI for devices, including determining the technology needed to utilize UDI effectively, identifying the data needed for patient safety; development, maintenance, and validation of a central data repository; and harmonizing UDIs for the international marketplace.

II. UDI Development and Implementation

We are interested in receiving comment on the possible role that a unique device identification system could have on improving patient safety, for example, by reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting. In addition, we are interested

in receiving comments on the feasibility, benefits, and costs involved in the development and implementation of such a system and views on FDA's role in such a process.

A. Development of a Unique Device Identification System

The agency believes that unique device identification would entail creating a uniform, standard system of device attributes—which, when combined, would uniquely identify a particular device at the unit of use. The definition of ''unit of use'' would likely vary for different device types—for example, unit of use could be a box of examination gloves or an infusion pump. The device attributes or elements of a unique identifier could include:

- Manufacturer, make, and model;
- Unique attributes (e.g., size, length, quantity, software version); and
- Serial number, identifying lot number, manufacturing, or expiration date (depending on the device type).

We envision that a change to any of the above criteria would likely necessitate a new UDI. For example, different size or length catheters of the same type would need different (unique) UDIs. Then, taken together, for example—if the Acme Company manufactured different types and styles of examination gloves in various sizes and quantities—the elements of the UDI might include:

[1 - manufacturer] Acme (manufacturer number 12345)
[2 - make and model] Great Latex Examination Gloves (product number 6789)

[3 - size] Adult large (size number 012)
[4 - how packaged] Box of 50 (quantity number 50)
[5 - lot number] Lot number: 6789 (lot number 6789)

When these elements or attributes are combined together—the result is a number which would uniquely identify all lots of those specific gloves. The UDI might then look like:

[1] 12345 [2] 6789 [3] 012 [4] 50 [5] 6789

This UDI is human readable and could be listed on device labeling. The UDI could also be encoded in any of a number of different automatic identification technologies (e.g., barcode, radiofrequency identification (RFID))[1]—depending on the stakeholders' needs and uses. Though the number does not necessarily have any inherent meaning, it could be used to reference more information about the device.

B. Implementing Unique Device Identification

We believe that the UDI could be used in two broad ways. First, the UDI itself would represent a way to uniquely identify a specific device (or, for example, a lot of the same device). The UDI could be used to specifically identify a particular device—for example, to facilitate reporting an adverse event or locating a recalled device.

Second, the UDI may be used to convey information to promote safe device use. The UDI could interface with a computer database that could access an additional reference data set with information related to safe use (such as indications for use and accessories needed to operate the device). For example, a UDI could be used to convey any or all of the following information as part of a minimum data set:

- Manufacturer, make, and model;
- Unique attributes (e.g., size, length, quantity, software version); and
- Serial number, identifying lot number, manufacturing, or expiration date (depending on the device type).
- Product type (and identifying code, such as FDA procode[2]);
- Indications for use, contraindications, warning, precautions;
- The accessories needed to operate the device; and
- If the device is an accessory to another device, the specific device with which it operates.

This information could reside in a publicly available database, such as the National Library of Medicine's DailyMed (*http://dailymed.nlm.nih.gov/*)—which currently provides information about marketed drugs, including FDA approved labels. The information from this website is available electronically and is both easier for people to read and ''computer friendly.'' As such, it is intended to be the basis for populating computer systems and provide users up to date information. The agency requests comment on whether some or all of the information in the minimum data set, described previously, would improve patient safety, and if so, how. If not, why not?

C. The Use and Benefits of UDIs

We believe that the use of UDI could bring about a number of patient safety benefits, including reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting.

D. Reducing Medical Error

Device-related medical errors are a common and serious problem. The November 1999 Institute of Medicine report, ''To Err is Human—Building a Safer Health System,'' estimated that as many as 98,000 people die in any given year from medical errors that occur in hospitals. Incorrect medical device use represents a category of medical device related error. For example, while all implants are intended to be sterilized before use, some of these devices are shipped sterile and some are shipped nonsterile because the hospital plans to sterilize the implant itself prior to use. Shipping both sterile and nonsterile implants could lead to difficulties at the hospital due to errors in distinguishing between the sterile and nonsterile implants. UDI information and its associated labeling data could be automatically read and help users distinguish between sterile and nonsterile products. This could prevent the possibility that a patient would receive a nonsterile implant.

Another example is when devices, which are not designed or intended to be used together, are erroneously used together. The UDI system could be used to improve interoperability issues, such as identifying the specific accessories to be used with a medical device. A UDI could also identify compatibility issues—such as those devices which can be used safely with magnetic resonance imaging (MRI) systems.

E. Facilitating Device Recalls

An effective system of device identification could improve various postmarket efforts. Currently, locating all devices subject to a recall is a time and labor intensive process. Manufacturers, distributors and healthcare facilities often do not know exactly where all recalled devices are located. Consequently, the failure to identify recalled devices could result in the continued use of such devices on patients in a variety of settings (e.g. hospitals, long-term care facilities, homecare environments) and cause increased risk for patient harm. Moreover, it is usually not possible to associate the use of a device with a particular patient. The UDI could facilitate identifying patients who have

[1] RFID refers to a wireless communication technology that uses radio frequency signals to capture data from a tag that can identify and track objects.

[2] At the time that new medical devices are cleared or approved by FDA, the agency assigns them a product code (or ''procode''), which is a general classification scheme and is used for FDA listings of types of devices. Manufacturers are required to use this system for identifying devices on all MDR reports they send to FDA (including reports they forward from user facilities).

been exposed to or received the recalled device.

F. Improving Adverse Event Reporting

Present adverse event reporting systems do not usually capture the specific device used, or overall device use (referred to as ''denominator data''). UDI could facilitate identification of devices in adverse event reports, in the use of active surveillance systems, and provide better documentation of specific medical device use in electronic health records and health databases. This would allow us both to identify new problems and also establish a denominator of device use, so that the incidence of adverse events related to the overall device use can be better quantified.

G. Ancillary Benefits

In addition to improved patient safety from reducing medical errors, facilitating device recalls, and improving adverse event reporting, there may be secondary or ancillary benefits from the use of a UDI. These benefits include improved materials management and associated healthcare cost savings. UDIs could also facilitate the development of useful electronic health records by allowing providers to automatically capture important information about the device that has been used on a patient. UDIs could help identify similar devices or devices that are substantially equivalent if there were concerns that recalls or other problems with marketed devices might create a shortage. The use of UDIs could also reduce the potential for injury from counterfeit devices by offering a better way to track devices and detect counterfeit product.

III. Agency Request for Information

In light of the potential benefits highlighted previously, FDA is interested in gathering information about the feasibility, utility, benefits, and costs associated with the development and implementation of a UDI system for medical devices. We are also interested in understanding the issues associated with the use of various automatic identification technologies (e.g., bar code, RFID). Therefore, we invite comments and available data on the following questions:

Developing a System of Unique Device Identifiers

1. How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

2. What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?

3. What are the incentives for establishing a uniform, standardized system of unique device identifiers?

4. What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?

5. Have you implemented some form of UDI in your product line? Please describe the extent of implementation, type of technology used, and the data currently provided.

6. Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?

7. At what level of packaging (that is, unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?

8. What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system (e.g., solutions for packaging issues)?

Implementing Unique Device Identifiers

9. What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?

10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?

11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be ''compatible'' with those used for the drug bar code rule? If yes, why? If not, why not?

UDI Benefits and Costs

13. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.

14. From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation, and use of a UDI system? Please submit detailed data to support these cost estimates.

15. If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training, and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?

16. From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?

17. From your perspective, what are the obstacles to implementing or using a UDI system in your location?

18. For hospitals and other device user facilities considering technology investments, what would be the relative priority of developing UDI capabilities compared to other possible advancements, such as Electronic Health Records, bedside barcoding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities, and other possible advances?

19. What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes? How costly are these advancements?

20. Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class I) or next most serious (Class II) recalls would having access to and an ability to capture UDI information help you to respond?

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m.., Monday through Friday. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Letter from Pete Sessions, Mike Doyle, Tim Murphy, Michael Conaway, Bill Jenkins, Bob Inglis, George Radarovich, Members of

Congress to Lester M. Crawford, Acting Commissioner, Food and Drug Administration, dated May 24, 2005.

2. Letter from Margaret Reagan (Premiere, Inc.), Rick Pollack (American Hospital Association), Larry Gage (National Association of Public Hospitals and Health Systems), Charles Kahn (Federation of American Hospitals), Edward Goodman (Veterans Health Administration), Michael Rodgers (Catholic Health Association of the United States), Robert Dickler (Association of American Medical Colleges) to Lester Crawford, Acting Commissioner, Food and Drug Administration, dated May 9, 2005.

3. The Food and Drug Law Institute/CDRH Report on Meeting to Discuss Unique Device Identification, (*http://www.fda.gov/cdrh/ocd/uidevices061405.html*), April 14 and 15, 2005.

4. ECRI/FDA White Paper: Automatic Identification of Medical Devices, (*http://www.fda.gov/cdrh/ocd/ecritask4.html*), August 17, 2005.

5. The Food and Drug Law Institute/CDRH, ''Report on Meeting to Discuss Unique Device Identification,'' (*http://www.fda.gov/cdrh/ocd/uidevices011606.html*), October 27, 2005.

6. ''ERG Final Report: Unique Identification for Medical Devices,'' (*http://www.fda.gov/cdrh/ocd/udi/erg-report.html*), March 22, 2006.

7. ''Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Safety Program,'' (*http://www.fda.gov/cdrh/postmarket/mdpi-report.pdf*), January 18, 2006.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic copies or two paper copies of any mailed comments are to be submitted, 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–6870 Filed 8–9–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Assessment of the Engagement of Historically Black Colleges and Universities in Campus and Community-Based Activities to Eliminate Health Disparities (NEW)

The Health Resources and Services Administration (HRSA) plans to conduct a survey of 525 university administrators at Historically Black Colleges and Universities (HBCUs) to collect information not otherwise available about the extent to which HBCUs have engaged in health promoting activities on campus and in their surrounding communities that are designed to eliminate health disparities among African Americans. The results of this survey will be used by HRSA's Office of Minority Health and Health Disparities (OMHHD) to obtain information regarding the engagement of HBCUs in health disparities activities. The results of the survey will also permit OMHHD (1) to describe the origins, structure, content, and intensity of such activities, (2) to document the level of support for campus and community activities among administrative leaders at HBCUs, (3) to document the factors that facilitate or hinder the ability of HBCUs to engage in campus and community activities to eliminate health disparities, and (4) to determine whether there is a need among HBCUs for additional assistance that will allow them to expand their role and improve their effectiveness in addressing health disparities.

The survey process will include a web-based survey to be completed by targeted respondents. Follow-up telephone calls will be conducted with respondents who do not complete the online survey. Approximately 5 administrators will be surveyed at each of the 105 recognized HBCUs. The types of administrators to be surveyed include Presidents, Deans of Faculty, Deans of Students, and staff and/or faculty that are leaders for programs that are associated with eliminating health disparities.

The burden estimate for this project is as follows:

Form	No. of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Survey	525	1	525	.75	394

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 8, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–13217 Filed 8–10–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).