DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Neurological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 31, 2006, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Ballroom Salons C, D, and E, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512513. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on a premarket notification application for a device intended for the treatment of major depressive disorder. The committee will also hear and discuss the post approval study reports for two recently approved neurological device premarket approval applications. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panel* (click on Upcoming CDRH Advisory Panel/Committee Meetings).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 17, 2006. Oral presentations from the public will be scheduled for 30 minutes at the beginning of the committee deliberations and for 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 17, 2006.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301–827–7291, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 18, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. 06–8114 Filed 9–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2006N–0292]

Unique Device Identification; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and vendor display.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and vendor display to discuss the issues associated with the development, implementation, and use of a unique device identification (UDI) system and the use of various automatic identification technologies. We are inviting individuals, companies, organizations, and other stakeholders to attend this public meeting, which will focus on the development and implementation of a UDI system; the benefits and costs of a UDI system; the use of automatic identification technologies; and the development, maintenance, and use of a repository for UDI related information. We are also inviting vendors of automatic identification technologies to display their products for the educational benefits of FDA and other attendees.

DATES AND TIMES: The public meeting will be held on Wednesday, October 25, 2006, from 9 a.m. to 4 p.m. Registration to attend the meeting, to present at the meeting, and to participate in the vendor display must be received by October 10, 2006. Submit written comments by November 9, 2006.

You may register electronically at *www.fda.gov/cdrh/ocd/udi/index.html* (see **SUPPLEMENTARY INFORMATION**, section V of this document for information on registration.

ADDRESSES: The public meeting will be held at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878, 1–301–590–0044.

A block of rooms is being held for the evening of Tuesday, October 24, 2006. Please mention the ''FDA UDI Meeting'' when calling the hotel.

Submit written 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.fda.gov/dockets/ecomments*. All comments should be identified with the docket number found in brackets in the heading of this document.

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*

If you need special accommodations due to a disability, please contact Ann Marie Williams at 301–827–7291 at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of 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 have asked that we revisit the issue of bar coding medical devices to improve patient safety, improve quality of care, and encourage cost effectiveness of health care, e.g., by improving delivery and supply chain efficiency. In response to this, 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.

As a result of these meetings, FDA has learned that the majority of stakeholders support the development of a uniform system of unique identifiers as a way to improve patient safety and recognize 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. We therefore published a notice in the **Federal Register** of August 11, 2006 (71 FR 46233) (*http://www.fda.gov/OHRMS/DOCKETS/98fr/06-6870.pdf*) requesting comments by November 9, 2006, to help the agency understand how the use of a unique device identification system could improve patient safety, for example, by reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting. We are now announcing a public meeting to further discuss the issues around UDI and the use of various automatic identification technologies.

II. Meeting Format

The meeting will be divided into four sessions, each one focused on one of the four main topic areas (described in section III of this document (Scope of Discussion)). Each session will begin with an invited presentation to describe the issue and will be followed by a moderated discussion with an invited representative panel. 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.

III. Scope of Discussion

We will hold a public meeting on October 25, 2006, from 9 a.m. to 4 p.m. to discuss the development, implementation, and use of a unique device identification system. We anticipate discussions among an invited panel and other members of the public on these issues and we intend to focus on these main areas and the following specific questions:

A. The Benefits and Costs of a UDI System

1. What public health and patient safety benefits could be gained from having a standardized UDI system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error?

2. What are the setup costs measured in time and other resources associated with the development, implementation, and use of a UDI system? 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?

B. Design and Implementation of a System of UDI

1. How should a UDI system be developed? What attributes or elements of a device should be used to create the UDI? Should unique device identifiers be considered for all devices? At what unit of packaging (that is, unit of use) should UDIs be considered (for example, the unit of use could be a box of examination gloves or an infusion pump)? Should UDIs be considered for different levels of packaging?

2. What are the incentives for establishing a uniform, standardized system of UDIs? What are the barriers for establishing UDIs? What suggestions would you have for overcoming these barriers?

C. The Development, Maintenance, and Use of a Repository for UDI-related Information

1. What is the minimum data set that should be associated with a UDI? Would this minimum data set differ for different devices? What other data would improve patient safety?

2. 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?

D. The Use of Automatic Identification Technologies

1. Should the UDI be both human readable and encoded in an automatic identification technology? Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific?

2. If a bar code is recommended, is a specific type of symbology preferred? Should the bar code be ''compatible''' with those used for the drug bar code rule? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

IV. Vendor Display

There will be no fee for participating in the vendor display. For the purposes of this meeting, we are only interested in displays from vendors of automatic identification technologies that can be used to identify medical devices. At the time of registration, you will be asked to submit a short summary of your product. We can accommodate 15 vendors at this meeting. When vendor registration reaches this number, additional vendor display registrants will be placed on a wait-list. If you have been placed on the wait-list, we will notify you by e-mail or telephone if you become confirmed. There will be no onsite registration for vendors. Each vendor will be provided with a 6-foot tabletop space. Please note that Internet access will not be available.

One purpose of this meeting is to gain greater understanding of various automatic identification technologies. Therefore, we are inviting 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 (see **FOR FURTHER INFORMATION CONTACT**).

V. Registration

Registration is necessary if you would like to present at the meeting or participate in the vendor display. Registration is also necessary to attend the meeting and vendor display because space is limited.

You may register to present at the meeting or participate in the vendor display at *www.fda.gov/cdrh/ocd/udi/index.html*, no later than October 10, 2006. The registration form will instruct you as to the information you should

provide (such as name, address, telephone number, e-mail address, whether you wish to make a presentation or participate in the vendor display and how to provide FDA with a summary of your presentation or product).

You may register to attend the meeting at *www.fda.gov/cdrh/ocd/udi/index.html*. Seating is limited to 300 persons, and if capacity is reached, registration will close. If you register as a presenter or to participate in the vendor display, you do not need to also register as an attendee.

Because of time constraints, vendors may register either to present at the meeting 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 the FDA and other attendees when they visit your display.

Because of the format of the meeting, 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 four main topic areas. We also encourage persons and groups having similar interests to consolidate their information and present it through a single representative. By October 16, 2006, we will schedule each presentation and, by e-mail or telephone, notify each participant who will present of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. The time allotted for presentations may be between 5 to 15 minutes, depending on the number of people who wish to present. Confirmed presenters need to send final electronic presentations in Microsoft PowerPoint, Microsoft Word, or PDF by October 20, 2006 to *CDRHUDI@fda.hhs.gov*.

VI. Transcripts

The meeting will be transcribed and will be available on the Internet at *www.fda.gov/cdrh/ocd/udi/index.html*. You may also request a copy of the transcript by writing to our Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857. We anticipate that transcripts will be available approximately 10 days after the public meeting at a cost of 10 cents per page. The transcripts will also be available for public examination at the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–7969 Filed 9–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Stem Cell Therapeutic Outcomes Database—(New)

The Stem Cell Therapeutic and Research Act of 2005 provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. The Health Resources and Services Administration's (HRSA), Healthcare Systems Bureau (HSB), is establishing the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain record keeping and reporting requirements in order to perform the functions related to hematopoietic stem cell transplantation under contract to HHS. The Act requires the Secretary to contract for the collection and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. Data will be collected from transplant centers in a manner similar to the data collection activities conducted by The Center for International Blood and Marrow Transplant Research (CIBMTR) and will be used for ongoing analysis of transplant outcomes. HRSA will use the information in order to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation, and to provide the Secretary with an annual report of transplant center-specific survival data.

The estimate of burden is as follows:

Record keeping	Number of responses	Responses per respondent	Total responses	Hours per response	Total burden hours
Baseline Patient/Day of Transplant Data	250	40	8,000	2.25	18,000
Product Receipt/Analysis/Preparation Data	250	40	8,000	1	8,000
100-Day Post-Transplant Data	250	40	8,000	2.25	18,000
6-Month Post Transplant Data	250	28	5,538	2.25	12,460.5
12-Month Post-Transplant Data	250	22	4,308	2.25	9,693
Annual Post-Transplant Data (year two and beyond)	250	40	8,000	2.25	18,000
Death Information	250	25	4,923	0.5	2,461.5
Total	250		46,769		86,615