TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency perResponse	Total Annual Records	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.24(b)	1.2	1	1.2	30	36		
900.24(b)(1)	0.3	1	0.3	200	60		$26
900.24(b)(3)	0.15	1	0.15	100	15		$13
900.25(a)	0.2	1	0.2	16	3.2		
FDA Form 3422	700	1	700	0.25	175		
Total					3,072,138	$40,000	$14,612,872

[1] Refers to entities that are applying for the first time.
[2] Refers to accreditation bodies applying to accredit specific Full Field Digital Mammography units.
[3] Refers to the facility component of the burden for this requirement.
[4] Refers to the accreditation body component of the burden for this requirement.
[5] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record-keeper	Total Hours	Total Capital Costs	Total Oper-ating & Maintenance Costs
900.4(g)	6	1	6	1	6		
900.12(a)(1)(i)(B)(2)	89	1	89	8	712		
900.12(a)(4)	8,840	4	35,360	1	35,360		
900.12(c)(4)	8,840	1	8,840	1	8,840	$25,000	
900.12(e)(13)	8,840	52	459,680	0.083	38,154		
900.12(f)	8,840	1	8,840	16	141,440		
900.12(h)(2)	8,840	2	17,680	1	17,680		
900.22(a)	6	1	6	1	6		
900.22(d)	6	1	6	1	6		
900.22(e)	6	1	6	1	6		
900.22(f)	3	1	3	1	3		
900.22(g)	6	1	6	1	6		$60
900.25(b)	6	1	6	1	6		
Total					242,225	$25,000	$60

This request for OMB approval now serves to consolidate previously approved information collection, OMB Control Number 0910–0580 into 0910–0309. The hourly burden as well as the associated operating costs were increased to better represent the actual burden and costs on facilities and accreditation bodies.

The following regulations were not included in the above burden tables because they were considered usual and customary practice and were part of the standard of care prior to the implementation of the regulations. Therefore, they resulted in no additional reporting or recordkeeping burden: 21 CFR 900.12(c)(1), 900.12(c)(3), and 900.3(f)(1).

The following regulations were not included in the previously mentioned burden tables because they were not considered applicable during the information collection period or their burdens were reported under other regulatory requirements. Therefore, they resulted in no additional reporting or recordkeeping burden: 21 CFR 900.3(c), 900.11(b)(1), 900.11(b)(2), and 900.24(c).

Dated: September 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–8027 Filed 9–21–06; 8:45 am]

BILLING CODE 4160–01–S

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