This regulation also refers to previously approved collections of information found in FDA regulations. The collections of information under §§ 800.12(d) and 801.437(i) have been approved under OMB control number 0910–0183; the collections of information under § 800.12(e) have been approved under OMB control number 0910–0231; and the collections of information under § 801.435(g) have been approved under OMB control number 0910–0073.

Further, FDA concludes that labeling statements under §§ 801.63; 801.405(b)(2) and (b)(3); 801.420(c)(2) and (c)(3); 801.430(c) and(e)(1); 801.433; 801.437(d) through (g); 809.30(d)(2), (d)(3), and (e) do not constitute a ''collection of information'' under the PRA. Rather, these labeling statements are ''public disclosure'' of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

Reporting

These estimates are based on FDA's registration and listing database for medical device establishments, agency communications with industry, and FDA's knowledge of, and experience with device labeling.

Recordkeeping

These estimates are based on FDA's registration and listing database for medical device establishments, agency communications with industry, and FDA's knowledge of and experience with device labeling. In addition, the Vision Council of America provided the growth rate used to estimate the burden under § 801.410(e) and (f).

FDA is correcting its recordkeeping burden estimate for § 801.410(e) and (f). In the **Federal Register** of April 23, 2008, the recordkeeping burden estimate in Table 2 was overestimated as 11,935,028 hours. The corrected recordkeeping burden estimate for this proposed collection is 422,686 hours. The correction for the recordkeeping burden estimate was necessary due to two errors. First, FDA incorrectly gave an estimate of 0.25 hours per recordkeeper for § 801.410(e) and (f). The corrected estimate is 0.0008 hours per recordkeeper. Secondly, FDA inadvertently duplicated the recordkeeping burden for these sections.

This regulation also refers to previously approved collections of information found in FDA regulations. The collections of information under §§ 800.12(d) and 801.437(i) have been approved under OMB control number 0910–0183; and the collections of information under § 800.12(e) have been approved under OMB control number 0910–0231.

The information collection requirements under §§ 801.22, 801.63, 801.405(b)(2) and (b)(3), 801.420(c)(2) and (c)(3), 801.430(c) and (e)(1), 801.433, 801.437(d) through (g); 809.30(d)(2), (d)(3), and (e) are not considered information collection because the public information is originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

We have not estimated a burden for information that is disclosed to third parties, because it is a ''usual and customary'' part of a medical device manufacturer, distributor, or importer's normal business activities. Nor have we estimated a burden for time that is spent designing labels to improve the format or presentation.

Dated: June 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14658 Filed 6–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0168]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 28, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0303. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Records; Electronic Signatures—(OMB Control Number 0910–0303)—Extension

The FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the agency has stated its ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures; (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, State or local governments, Federal agencies, and nonprofit institutions.

In the **Federal Register** of March 26, 2008 (73 FR 16017), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11.100	4,500	1	4,500	1	4,500

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
11.10	2,500	1	2,500	20	50,000
11.30	2,500	1	2,500	20	50,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					280,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14659 Filed 6–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Core Instrumentation.

Date: July 14–15, 2008.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph D. Mosca, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 5158, MSC 7808, Bethesda, MD 20892, 301–435–2344, *moscajos@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Dermatology/Rheumatology Small Business, Special Emphasis Panel.

Date: July 18–22, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Daniel F. McDonald, PhD, Scientific Review Officer, Chief, MOSS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 435–1215, *mcdonald@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cancer Biology.

Date: July 18, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Denise R. Shaw, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301–435–0198, *shawkath@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Discovery of Novel Epigenetic Marks.

Date: July 25, 2008.

Time: 8 a.m. to 9 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Richard Panniers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1741, *pannierr@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Sharing Data and Tools and Data Ontologies.

Date: July 28, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alexander Gubin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 5144, MSC 7812, Bethesda, MD 20892, 301–435–2902, *gubina@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Drug Abuse Aspects of HIV/AIDS.