

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 2000N-1652]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 3, 2002 (67 FR 22367), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0530. The approval expires on November 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: December 9, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-30962 Filed 12-15-03; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 2003N-0142]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 23, 2003 (68 FR 43532), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0445. The approval expires on November 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: December 9, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-30963 Filed 12-15-03; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 2003N-0542]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification Submissions**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for premarket notification (510(k)) submissions.

**DATES:** Submit written and electronic comments on the collection of information by February 17, 2004.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance

of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Premarket Notification 510(k) Submissions—21 CFR Part 807 (OMB Control Number 0910-0120)—Extension**

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) requires a person who intends to market a medical device to submit a 510(k) submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. The definition of "person" has been expanded to include hospitals who re-use or re-manufacture single-use medical devices. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), added section 510(o) to the act to establish new regulatory requirements for reprocessed single-use devices (SUDs) (MDUFMA section 302(b), the act section 510(o)). MDUFMA was signed into law on October 26, 2002. Section 301(b) of MDUFMA adds new requirements for reprocessed SUDs to section 510 of the act. The estimated submissions below include those submitted by hospitals re-manufacturing single-use medical devices.

Section 510(k) of the act allows for exemptions to the 510(k) submissions, i.e., a 510(k) submission would not be required if FDA determines that

premarket notification is not necessary for the protection of the public health, and they are specifically exempted through the regulatory process. Under 21 CFR 807.85 "Exemption from premarket notification," a device is exempt from premarket notification if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling and advertising by the manufacturer, importer, or distributor for commercial distribution. In addition, the device must meet one of the following conditions: (1) It is intended for use by a patient or dentist (or other specially qualified persons), or (2) it is intended solely for use by a physician or dentist and is not generally available to other physicians or dentists.

A commercial distributor who places a device into commercial distribution for the first time under their own name and a repackager who places their own name on a device and does not change any other labeling or otherwise affect the device, shall be exempted from premarket notification if the device was legally in commercial distribution before May 28, 1976, or a premarket notification was submitted by another person.

One of MDUFMA's provisions requires the submission of validation data specified in the statute for certain reprocessed SUDs (as identified by FDA) such as cleaning and sterilization data, and functional performance data. FDA offers a guidance document to assist reproducers of single use devices in submitting MDUFMA mandated validation data for the devices.

MDUFMA requires that FDA review the types of reprocessed SUDs not subject to premarket notification requirements and identify which of these devices require the submission of validation data to ensure their substantial equivalence to predicate devices. MDUFMA also requires that

FDA review critical and semi-critical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require the submissions of 510(k)s to ensure their substantial equivalence to predicate devices. Under MDUFMA, FDA will use the validation data submitted for a reprocessed SUD to determine whether the device will remain substantially equivalent in terms of safety and effectiveness to its predicate after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

The information collected in a premarket notification is used by the medical, scientific, and engineering staffs of FDA in making determinations as to whether or not devices can be allowed to enter the U.S. market. The premarket notification review process allows for scientific and/or medical review of devices, subject to section 510(k) of the act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market. This information will allow FDA to collect data to ensure that the use of the device will not present an unreasonable risk for the subject's rights. The respondents to this information collection will primarily be medical device manufacturers and businesses.

FDA Form 3514 was developed to assist respondents in categorizing 510(k) data for submission to FDA. This form also assists respondents in organizing and submitting data for other FDA medical device programs such as premarket approval applications, investigational device exemptions, and humanitarian device exemptions.

FDA estimates the burden of this collection of information to be as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 807, Subpart E (807.81 and 807.87 (510(k)))		4,000	1	4,000	80	320,000
	FDA 3514	2,000	1	2,000	.5	1,000
Submission of validation data (2003)		20	5	100	40	28,000
Totals						349,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
807.93	2,000	10	20,000	0.5	10,000
Totals					10,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in tables 1 and 2 of this document.

The total burden for using voluntary FDA Form 3514 is estimated to be approximately 1,000 hours and has been included in this collection of information. Once this collection of information has been approved, the burden for FDA Form 3514 will be reported and approved in each of the following OMB information collections: (1) Investigational device exemption reports and records (OMB control number 0910-0078), (2) premarket approval of medical devices (OMB control number 0910-0231), and (3) medical devices, humanitarian devices (OMB control number 0910-0332).

Dated: December 9, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-30964 Filed 12-15-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

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 meeting.

The meeting 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Preparation of Radiolabeled Materials.

*Date:* December 19, 2003.

*Time:* 12 p.m. to 3 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* C. Michael Kerwin, Ph.D., MPH Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8057, MSC 8329, Bethesda, MD 20892-8329, 301-496-7421, [kerwinm@mail.nih.gov](mailto:kerwinm@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.

(Catalogue of Federal Domestic Assistant Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 10, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03-30981 Filed 12-15-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552(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 property.

*Name of Committee:* National Cancer Institute Initial Review Group, Subcommittee G—Education.

*Date:* February 9–11, 2004.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Wyndham Washington, DC, 1400 M Street, NW., Washington, DC 20005.

*Contact Person:* Ilda M. McKenna, Scientific Review Administrator, Research Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard Room 8111, Bethesda, MD 20892, 301-496-7481, [mckennai@mail.nih.gov](mailto:mckennai@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 10, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03-30982 Filed 12-15-03; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health Sciences; Notice of Closed Meeting

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 meeting.

The meeting 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