FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3602	3,000	1	3,000	1	3,000

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

FDA based these estimates on conversations with industry, trade association representatives, and from internal FDA estimates. This represents FDA's estimate on the number of small businesses that will submit a premarket notification, a premarket application, a premarket report, a panel track supplement, efficacy supplement, 180-day supplement, or a real time supplement to FDA during a single fiscal year from FY 2004 through 2007.

Dated: October 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25752 Filed 10–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0016]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; The FDA Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''The FDA Medical Products Reporting Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. 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 April 29, 2003 (FR 68 22716), 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 0910–0291.

As requested by the agency, in addition to the approval of the revised forms, the existing forms are approved for continued use for the next 6 months to allow for the industry to make necessary changes to their computerized systems. The approval expires on March 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: October 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25753 Filed 10–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0456]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prevention of Medical Gas Mixups at Health Care Facilities

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on measures taken by certain Health Care medical facilities that use medical oxygen to prevent mixups with other gases.

DATES: Submit written or electronic comments on the collection of information by December 9, 2003.

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: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482

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, 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.

Medical Oxygen Manufacturers and Fillers—21 CFR Parts 210 and 211

The Food and Drug Administration (FDA) has received four reports of medical gas mixups occurring during the past 5 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but who were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facility's oxygen supply system. In 2001, FDA published guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mixups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mixups, to determine if further steps are warranted to ensure the safety of patients.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
210 and 211	285	1	285	.25	71.25
Total	285	1	285	.25	71.25

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

Dated: October 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25754 Filed 10–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting; Interagency Autism Coordinating Committee

The National Institutes of Health (NIH) hereby announces a meeting of the Interagency Autism Coordinating Committee (IACC) to be held on November 21, 2003, on the NIH campus in Bethesda, Maryland.

The Children's Health Act of 2000 (Pub. L. 106–310), Title I, section 104, mandated the establishment of an Interagency Autism Coordinating Committee (IACC) to coordinate autism research and other efforts within the Department of Health and Human Services (DHHS). In April 2001, Secretary Tommy Thompson delegated the authority to establish the IACC to the National Institutes of Health (NIH). The National Institute of Mental Health (NIMH) at the NIH has been designated the lead for this activity.

The IACC meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: Interagency Autism Coordinating Committee.

Date: November 21, 2003.

Time: 10:30 a.m.–3:30 p.m.

Agenda: Discussion of autism activities across Federal agencies.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 10 (6th floor), Bethesda, Maryland 20892.

Contact Person: Ann Wagner, Ph.D., Division of Services and Intervention Research, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 7142, MSC 9633, Bethesda, Maryland 20892, E-mail: *awagner@mail.nih.gov,* Phone: (301) 443–4283.

Any member of the public interested in presenting oral comments to the committee may notify the contact person listed on this notice at least 5 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Presentations may be limited to 5 minutes; both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding his/her statement to the contact person listed on this notice. The statement should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

Information about the meeting and on-line registration forms are also available on-line on the NIMH homepage at *http://www.nimh.nih.gov/autismiacc/index.cfm.*

Dated: October 3, 2003.

Raynard Kington,

Deputy Director, National Institutes of Health.

[FR Doc. 03–25778 Filed 10–9–03; 8:45 am]

BILLING CODE 4140–01–P

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 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: National Cancer Institute Special Emphasis Panel, SPORES in Leukemia—Lymphoma.

Date: October 29–31, 2003.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Bratin K. Saha, Ph.D., Scientific Review Administrator, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Bethesda, MD 20892, (301) 402–0371, *sahab@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 Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention