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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					1,082

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

The following burden estimates are based on FDA's experience with voluntary recalls under 21 CFR part 7. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily.

Section 810.10(d)—FDA estimates that it will take approximately 8 hours for the person named in a cease distribution and notification order to gather and submit the information required by this section. The total estimated annual burden is 16 hours.

Section 810.11(a)—Based on experience in similar situations, FDA expects that there will be only one request for a regulatory hearing per year and that it will take approximately 8 hours to prepare this request.

Section 810.12(a) and (b)—Based on experience in similar situations, FDA expects that there will be only one written request for a review of a cease distribution and notification order per year and that it will take approximately 8 hours to prepare this request.

Section 810.14—Based upon its experience with voluntary recalls, FDA estimates that it will take approximately 16 hours to develop a strategy for complying with the order.

Section 810.15(a) through (d)—Based upon its experience with voluntary recalls, FDA estimates that it will take approximately 16 hours to notify each health professional, user facility, or individual of the order.

Section 810.15(e)—Based upon its experience with voluntary recalls, FDA estimates that there will be approximately 5 consignees per recall (10 per year) who will be required to notify their consignees of the order. FDA estimates that it will take them about 1 hour to do so.

Section 810.16—FDA estimates that it would take no more than 40 hours to assemble and prepare a written status report required by a recall. The status reports are prepared by manufacturers 6 to 12 times each year. Therefore, each manufacturer would spend no more than 480 hours each year preparing status reports. If there were two FDA invoked recalls each year, the total burden hours estimated would be 960 hours each year.

Section 810.17—Based on experience with similar procedures, FDA estimates that it would take 8 hours to draft a written request for termination of a cease distribution and notification or mandatory recall order.

Dated: August 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–17499 Filed 9–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products 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 September 29, 2005, from 8 a.m. to 5 p.m.

Location: Food and Drug Administration, conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Donald W. Jehn or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 29, 2005, the committee will discuss new drug application (NDA) 21–882 proposed trade name EXJADE (deferasirox) Tablets for Oral Suspension, Novartis Pharmaceutical Corp., proposed for the indication of the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Following this discussion, the committee will hear an overview of the research programs in the Laboratory of Hemostasis and the Laboratory of Plasma Derivatives, Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), and in closed session will discuss the report from the laboratory site visit of February 25, 2005.

Procedure: On September 29, 2005, from 8 a.m. to 4:15 p.m., the meeting is open to the public. 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 by September 22, 2005. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 12:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 22, 2005, 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.

Closed Committee Deliberations: On September 29, 2005, from approximately 4:15 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss a review of internal research programs in the Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research.

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 Donald Jehn or Pearline K. Muckelvene 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: August 26, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–17470 Filed 9–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request; Extension of OMB No. 0925–0417/exp. 08/31/05, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors—42 CFR Part 50, Subpart F

Summary: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director (OD), Office of Extramural Research (OER), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. Proposed information collection was previously published in the **Federal Register** on May 12, 2005, Volume 70, No. 91, page 25095 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors—42 CFR Part 50, Subpart F; *Type of Information Collection Request:* Extension, OMB 0925–0417, Expiration Date 8/31/05. *Need and Use of Information Collection:* This is a request for OMB approval for the information collection and recordkeeping requirements contained in the final rule 42 CFR Part 50 Subpart F and Responsible Contractors: 45 CFR Part 94. *Frequency of response:* On occasion. *Affected Public:* Individuals or households; business or other for-profit; not-for-profit institutions; and State, Local or Tribal Government. *Type of Respondents:* Any public or private entity or organization. The annual reporting burden is as follows: *Estimated Number of Respondents:* 42,800; *Estimated Number of Responses per Respondent:* 1.60; *Average Burden Hours Per Response:* 3.40; and *Estimated Total Annual Burden Hours Request:* 232,000.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIR. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Diane Dean, Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3525, 6705 Rockledge Drive, Bethesda, MD 20892–7974, or call non-toll-free number 301–435–0930, or E-mail your request, including your address to: *hahnm@od.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 25, 2005.

Charles Mackay,

Chief, Project Clearance Branch, OPERA, OER, National Institutes of Health.

[FR Doc. 05–17458 Filed 9–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: Selected Technologies From the NIH Cancer Therapeutics Portfolio

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting George G. Pipia, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852; telephone: 301/435–5560; fax: 301/402–0220; e-mail: *pipiag@mail.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Antitumor Macrocyclic Lactones

Michael R. Boyd (NCI).

U.S. Patent No. 6,353,019 issued 05 Mar 2002 (HHS Reference No. E–244–1997/0–US–07) and related foreign patent applications.

Vacuolar-Type (H+)-ATPase-Inhibiting Compounds and Uses Thereof

Michael R. Boyd (NCI).

U.S. Patent Application No. 09/914,708 filed 31 Aug 2001 (HHS Reference No. E–244–1997/3–US–06) and related foreign patent applications.

This technology covers a broad composition of matter which includes the salicylihalamides, lobatamides, and numerous other structurally related small molecules which have been shown to inhibit mammalian vacuolar ATPase at low nanomolar concentrations. The compounds are also potent inhibitors of cancer cell growth, with particular specificity for melanoma, osteosarcoma and selected lung, colon and CNS tumor cell lines. Experimental tumor and pharmacokinetic studies are underway