Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 23, 1999.

Dated: September 8, 1999.

Janet Woodcock

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–24720 Filed 9–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Workshop on Standards for Inactivation and Clearance of Infectious Agents in the Manufacture of Plasma Derivatives from Nonhuman Sources for Human Injectable Use; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Standards for Inactivation and Clearance of Infectious Agents in the Manufacture of Plasma Derivatives from Nonhuman Sources for Human Injectable Use.'' The purpose of the public workshop is to discuss whether infectious agent inactivation and clearance steps should become standard industry practice in the manufacture of human injectable products from nonhuman source plasma.

Date and Time: The public workshop will be held on Monday, October 25, 1999, from 9 a.m. to 3:30 p.m.

Location: The public workshop will be held at the National Institutes of Health (NIH), NIH Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Contact:

For information regarding the public workshop and registration: Therese Burke, Laurel Consulting Group, 1815 Fort Meyer Dr., suite 300, Arlington, VA 22209, 703–351–7676, FAX 703–528–0716, e-mail: tburke@lcgnet.com.

For information regarding this document: Nathaniel L. Geary, Center for Biologics Evaluation and Research (CBER) (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210, FAX 301–594–1944.

SUPPLEMENTARY INFORMATION:

FDA is considering the requirement of inclusion of steps for the inactivation and clearance of infectious agents in the manufacture of products from nonhuman source plasma. This is an effort to level the regulatory requirements for all plasma derivatives regardless of their source and to continue to ensure high levels of safety for injectable blood products.

Many plasma derivatives represent product lines that are of critical use to a limited number of patients. Some of these products are used chronically, some acutely. For those products that utilize human plasma as a raw material, standards have been set that require inactivation procedures to be included in the manufacturing process. The risk of plasma derivatives manufactured from nonhuman raw materials has been more difficult to define. With the development of gene therapy, somatic cell therapy, and xenotransplantation, concerns are growing regarding the effect of xenobiotics on patients. Concerns have also been expressed about the use of plasma derivatives manufactured from nonhuman source plasma.

In an effort to address the needs of patients to have safe and effective blood products and to set realistic requirements for blood derivative manufacturers, FDA is sponsoring a public workshop to discuss these issues. Specifically, blood products manufactured from equine (horse), lapine (rabbit), ovine (sheep), caprine (goat), and porcine (pig) plasma and formulated into injectable products will be discussed.

Registration: Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Therese Burke (address above) by Friday, October 8, 1999. Onsite registration will be done on a space available basis on the day of the public workshop, beginning at 7:30 a.m. There is no registration fee for the public workshop. Space is limited, therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Therese Burke at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The meeting transcript will be available on CBER's website at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: September 16, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–24721 Filed 9–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request the NIH Consultant Information File System

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Scientific Review (CSR), National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 24, 1999, page 28001 (Volume 64, Number 99) 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, and 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: The NIH Consultant Information File System.

Type of Information Collection Request: Extension.

Form Number: OMB 0925–0358 (expiration 10/31/99) NIH 2668–1; 2668–3.

Need and Use of Information Collection: This system directly supports the recruitment and appointment of scientific experts. These experts provide evaluative advice on the merit and program relevance of the research grant applications and research contract proposals submitted to the NIH. The primary objective of this system is to support the NIH Peer Review system, but other PHS review administrative staff use the system to identify experts to support their advisory committees.

Frequency of Response: Intake established record on file, candidate can

initiate the updating of their information at any time, formal information update requested every 24 months.

Affected Public: Individuals or household; Not-for-profit institutions; business or other for-profit; Federal Government.

Type of Respondents: Adult scientific professionals, Individuals or household.

The annual reporting burden is as follows:

Estimated Number of Respondents: 9,741;

Estimated Number of Responses per Respondent: 1;

Average Burden Hours Per Response: 0.308; and

Estimated Total Annual Burden Hours Requested: 2,998.

The estimated annualized cost to respondents is $148,665 (using a $55 physician/professor hourly wage rate). There are not Capital Costs, Operating Costs, or Maintenance Costs to report.

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 NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact CAPT Edward C. Farley, USPHS, Project Clearance Liaison Officer, CSR, NIH, Rockledge II Building, Room 2216, 6701 Rockledge Drive, Bethesda, MD 20892–7740, or call non-toll-free number (301) 435–0601 or E-mail your request, including your address to: farleye@csr.nih.gov

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before October 25, 1999.

Dated: September 15, 1999.

Chris Wisdom,

Executive Officer, CSR.

[FR Doc. 99–24723 Filed 9–22–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee on Research on Minority Health.

The 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: Advisory Committee on Research on Minority Health.

Date: September 24, 1999.

Time: 8:30 AM to adjournment.

Agenda: Agenda items include: (1) a report by the Associate Director, ORMH; (2) FY '99 minority health initiatives; (3) review of the ORMH research and training portfolio; and (4) other business of the Committee.

Place: Holiday Inn, Bethesda, Washington Room, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jean L. Flagg-Newton, PHD, Special Assistant to the Associate Director, Office of Research on Minority Health, National Institutes of Health, Building 1, Room 256, 9000 Rockville Pike, Bethesda, MD 20892, (301) 402–2518.

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. 93.14, Intramural Research Training Award; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds; 93.22, Clinical Research Loan Repayment Program from Individuals for Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936; NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 16, 1999.

LaVerne Y. Stringrield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–24735 Filed 9–22–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; 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 patnetable 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 Center for Complementary and Alternative Medicine Special Emphasis Panel.

Date: September 29–30, 1999.

Time: 8:30 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Bethesda Ramada, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: John C. Chah, PHD, Scientific Review Administrator, National Institues of Health, NCCAM, Building 31, Room 5B50, 9000 Rockville Pike, Bethesda, MD 20892, 301–402–4334, johnc@od.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.

Dated: September 16, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–24732 Filed 9–22–99; 8:45 am]

BILLING CODE 4140–01–M