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of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 23, 1999.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