knowledgeable in the daily operations of the Oakland, Richmond, and Berkeley facilities. As a result of these inspections and investigations, FDA determined that there were numerous deviations from the standards established in the license as well as the applicable Federal regulations.

The inspections and investigations indicate that Pasca repeatedly deviated from donor protection standards which are intended to assure a continuous and healthy donor population and to assure the continued safety, purity, potency, and quality of the products manufactured. Deviations at the Richmond and Berkeley facilities included, but were not limited to, the following: (1) At the Richmond facility, failure to assure the suitability of the donor would be determined by a qualified licensed physician on the day of collection from the donor as required by 21 CFR 640.63; (2) at the Richmond facility, failure to determine that donors were in good health on the day of donation as required by 21 CFR 640.63(c); (3) at the Richmond facility, failure to assure that a qualified licensed physician explained the hazards of the plasmapheresis procedure to the prospective donor as required by 21 CFR 640.61; (4) at the Richmond and Berkeley facilities, violation of general donor suitability standards as required by 21 CFR 640.63(d); and (5) at the Richmond and Berkeley facilities, failure to assure that the skin of the donor at the site of phlebotomy was prepared by a method that gives maximum assurance of a sterile container of blood as required by 21 CFR 640.64(e). Deviations identified at the Oakland facility included: (1) Failure to provide adequate space for private and accurate examinations to determine their suitability and good health as donors as required by 21 CFR 606.40(a)(1); (2) failure to assure that facilities are maintained in a clean and orderly manner as required by 21 CFR 606.40; and (3) failure to determine the suitability of a donor by means of medical history, tests and physical exam as required by 21 CFR 640.63(a) and (c).

FDA's inspections and investigations also revealed that Pasca's operations were not in compliance with Federal regulations governing establishment standards and current good manufacturing practices (CGMP's). Deviations included the following: (1) Pasca and its responsible head failed to properly train and ensure the competent performance of its employees as required by 21 CFR 600.10 and 21 CFR 606.20; (2) at least one employee at the Berkeley facility was not provided with the proper training needed to perform his assigned duties; (3) despite not having attended training programs or read the standard operating procedures (SOP's), employees at the Berkeley facility were required to sign training forms that indicated that they had read the SOP's or participated in training programs; and (4) management was aware that employees at the Berkley facility conferred with each other during a recent test to determine the correct answers. In addition, Pasca employees at the Berkeley facility seriously departed from CGMP's by routinely squeezing saline into the whole blood bags during collection, to shorten the collection time for a full bag, and directly reinfusing whole blood into donors from whom an excess of whole blood had been collected.

FDA's inspections and investigations also revealed that at both the Richmond and Berkeley facilities, Pasca violated general donor suitability standards defined in 21 CFR 640.63(d). Pasca's violations included the following: (1) Pasca employees routinely accepted donations from donors who appeared to be under the influence of alcohol; (2) Pasca failed to determine that donors were in good health on the day of donation as required by 21 CFR 640.63(c); and (3) Pasca failed to assure that the skin of the donor at the site of phlebotomy was prepared by a method that gives maximum assurance of a sterile container of blood as required by 21 CFR 640.64(e) in that Berkeley facility employees failed to routinely perform the arm scrub at the phlebotomy site for 30 seconds as required by the SOP, and, at the Richmond facility, a donor's arm was scrubbed for only 15 seconds which was inconsistent with the SOP that required a 30-second arm scrub to be performed in concentric circles.

Because these deviations represented a danger to health, FDA suspended Pasca's establishment and product licenses at the Oakland location by letter dated April 16, 1993, and at the Berkeley and Richmond locations by letter dated May 10, 1993. Subsequently, Pasca informed FDA that it was discontinuing the manufacture of products at all facilities. In a letter to FDA dated July 7, 1993, Pasca submitted its license for revocation.

FDA has placed copies of the letters discussed above on file under the docket number found in brackets in the heading of this notice with the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under 21 CFR 601.5, section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68) the establishment license (U.S. License No. 1015) and the product license for the manufacture of Source Plasma issued to Pasca at the Berkeley, Oakland, and Richmond locations were revoked, effective August 4, 1993.

This notice is issued and published under 21 CFR 601.8, and the authority delegated to the Director, Center for Biologics Evaluation and Research under 21 CFR 5.67.

Dated: August 28, 1996.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 96–23873 Filed 9–17–96; 8:45 am]

BILLING CODE 4160–01–F

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 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 June 11, 1996, page 29567 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 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:* Revision. *Form Number:* OMB 0925–0358 (approved through 9/30/96) NIH 2668–1; 2663–3, *Need and Use of Information Collection:* Directly support the recruitment and appointment of experts that provide scientic merit and program relevance evaluations 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 DHHS review administrative staff use the system to identify experts to support their advisory committees. *Frequency of Response:* Intake established record on file, participant can initiate the updating of their information at any time. Formal information update requested on the occasion of their appointment to an advisory committee and every 24 months. *Affected Public:* Individuals; Not-for-profit institutions; Business or other for-profit; Federal Government; State, Local or Tribal Government. *Type of Respondents:* Adult scientific professionals. The annual professionals. 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:* 0.305; and *Estimated Total Annual Burden Hours Requested:* 2,998. The estimated annualized cost to respondents is $164,876 (Using a $55 physician/professor hourly wage rate.) There are no Capital Costs to report. There are no Operating 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, D.C. 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 Officer, DRG, NIH, Rockledge II Building, Room 3032, 6701 Rockledge Drive, Bethesda, MD 20892–7762, or call non-toll-free number (301) 594–0601 or E-mail your request, including your address to: (efarley@nih.gov).

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before October 18, 1996.

Dated: September 11, 1996.

John H. Jones,

Acting Executive Officer, DRG.

[FR Doc. 96–23936 Filed 9–17–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Aging; Notice of Closed Meetings

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 meetings:

Name of Panel: National Institute on Aging Special Emphasis Panel.

Date of Meeting: October 21, 1996.

Time of Meeting: 10:00 a.m. to adjournment.

Place of Meeting: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Purpose/Agenda: To review grant applications.

Contact Person: William A. Kachadorian, Ph.D., Scientific Review Administrator, Gateway Building, Room 2C212, National Institute of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

Name of Panel: National Institute on Aging Special Emphasis Panel.

Dates of Meeting: October 24–25, 1996.

Times of Meeting: October 24—7:00 p.m. to recess, October 25—8:00 a.m. to adjournment.

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

Purpose/Agenda: To review proposed program project.

Contact Person: William A. Kachadorian, Ph.D., Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health.)

Dated: September 13, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–23931 Filed 9–17–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Notice of Closed Meetings

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 meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: October 10, 1996.

Time: 8:30 a.m.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Ave, Chevy Chase, MD 20815.

Contact Person: Phyllis L. Zusman, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1340.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: October 22, 1996.

Time: 8:30 a.m.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Ave, Chevy Chase, MD 20815.

Contact Person: W. Gregory Zimmerman, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1340.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: September 14, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–23932 Filed 9–17–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Environmental Health Sciences; Notice of Closed Meetings

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 National Institute of Environmental Health Sciences Special Emphasis Panel (SEP) meetings:

Name of SEP: Studies of Chemical Disposition in Mammals.