Center for Infectious Diseases in accomplishing the part of its mission related to preparing recommendations for the prevention and control of all types of viral hepatitis and their sequellae. In order to focus prevention efforts and resource allocation, a representative view of the overall burden of chronic liver disease, its natural history, and the relative contribution of viral hepatitis is needed. The total cost to respondents is estimated at $600.

Respondents	No. of respondents	No. of responses/ respondent	Average burden/ response (in hrs.)	Total burden (in hrs.)
All consenting adults with physician- diagnosed chronic liver disease residing in catchment area	120	1	0.50	60
Total				60

Dated: September 12, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–23863 Filed 9–17 –96; 8:45 am]

BILLING CODE 4163–18–P

Cabin Exposure Assessment for a Study of Reproductive Outcomes Among Female Flight Attendants; Meeting

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Cabin Exposure Assessment for a Study of Reproductive Outcomes Among Female Flight Attendants.

Time and Date: 9 a.m.–4 p.m., October 11, 1996.

Place: Alice Hamilton Laboratories, NIOSH, Conference Room C, 5555 Ridge Road, Cincinnati, Ohio 45213.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: Invited participants will provide NIOSH with their individual advice and comments regarding the technical and scientific aspects of the study, ''Cabin Exposure Assessment for a Study of Reproductive Outcomes Among Female Flight Attendants,'' being conducted at NIOSH. Participants on the peer review panel will review the study protocol and provide individual advice on the conduct of the study. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited.

Contact Person for Additional Information: Martha Waters, Ph.D., NIOSH, CDC, M/S R–14, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/841–4458.

Dated: September 11, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–23866 Filed 9–17–96; 8:45 am]

BILLING CODE 4160–19–M

Advisory Council for the Elimination of Tuberculosis: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following council meeting.

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Times and Dates: 8:30 a.m.–5 p.m., October 9, 1996, 8:30 a.m.-1 p.m., October 10, 1996.

Place: Corporate Square Office Park, Corporate Square Boulevard, Building 11, Room 1413, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters To Be Discussed: Agenda items will include an update on ACET's letter to the Secretary of the Department of Health and Human Services; discussion of interactions between rifamycins and protease inhibitors; a report on Isoniazid hepatitis; and a discussion on tuberculosis vaccine development.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Connie Granoff, Program Specialist, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, M/S E–07, Atlanta, Georgia 30333, telephone 404/639–8008.

Dated: September 11, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–23861 Filed 9–17–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 96N–0166]

Pasca Plasma Center, Inc.; Revocation of U.S. License No. 1015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 1015) and the product license issued to Pasca Plasma Center, Inc., (Pasca) for the manufacture of Source Plasma. Pasca has facilities in Berkeley, Oakland, and Richmond, CA. In a letter to FDA dated July 7, 1993, Pasca submitted U.S. license No. 1015 for revocation.

DATES: The revocation of the establishment license (U.S. License No. 1015) and the product license became effective on August 4, 1993.

FOR FURTHER INFORMATION CONTACT: Valerie A. Windsor, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA has revoked the establishment license (U.S. License No. 1015) and the product license issued to Pasca at the following locations for the manufacture of Source Plasma: (1) 1796 University Ave., Berkeley, CA 94703 (U.S. License 1015–003); (2) 650 E. 14th St., Oakland, CA 94606 (U.S. License 1015–001); and (3) 2316 MacDonald Ave., Richmond, CA 94804 (U.S. License 1015–002). Pasca's mailing address is: 650 E. 14th St., Oakland, CA 94606.

FDA inspected Pasca's Richmond facility from December 1, 1992 through December 11, 1992, and its Oakland facility from March 22, 1993, through April 2, 1993. In addition to the inspections, FDA conducted investigations which included interviews with individuals

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.