Dated: April 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–9412 Filed 4–14–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93N–0109]

Houston Apheresis, Inc.; Revocation of U.S. License No. 990

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. 990) and product licenses (the licenses) issued to Houston Apheresis, Inc., for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Fresh Frozen Plasma. Houston Apheresis, Inc., did not respond to a notice of opportunity for a hearing on a proposal to revoke its licenses.

DATES: The revocation of the establishment license (U.S. License No. 990) and product licenses is effective April 17, 1995.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is revoking the establishment license (U.S. License No. 990) and product licenses issued to Houston Apheresis, Inc., formerly located at 9265 Kirby Dr., Houston, TX 77054, for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Fresh Frozen Plasma.

An attempted onsite inspection by FDA on March 26, 1991, revealed that the facility was no longer in operation at the location listed on the license. A forwarding address, obtained from the post office for the facility, was the home address of the Responsible Head. An FDA investigator left messages for the Responsible Head requesting that the agency be contacted; however, the messages were not returned. Based on the inability of authorized FDA employees to conduct an inspection of the facility after reasonable efforts, FDA initiated proceedings for the revocation of the licenses under 21 CFR 601.5(b). FDA issued a certified letter, dated October 26, 1992, to the Responsible Head of the firm, providing notice of FDA's intent to revoke the licenses and its intent to offer an opportunity for a hearing on the proposed revocations.

Pursuant to 21 CFR 12.21(b), FDA published in the **Federal Register** of May 18, 1993 (58 FR 28982), a notice of opportunity for a hearing on a proposal to revoke the licenses of Houston Apheresis, Inc. In the notice, FDA explained that the proposed license revocation was based on the inability of authorized FDA employees to conduct an inspection of the facility, which was no longer in operation, and noted that documentation in support of the license revocation had been placed on file for public examination with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. The notice provided the firm with 30 days to submit a written request for a hearing and 60 days to submit any data and information justifying a hearing. The notice provided other interested persons with 60 days to submit written comments on the proposed revocation. The firm did not respond within the 30-day time period with a written request for a hearing. The 30-day time period, prescribed in the notice of opportunity for a hearing and in the regulations, may not be extended. No other interested persons submitted written comments on the proposed revocation within the 60-day time period.

Accordingly, under 21 CFR 12.38, 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), the establishment license (U.S. License No. 990) and the product licenses issued to Houston Apheresis, Inc., for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Fresh Frozen Plasma, are revoked, effective April 17, 1995.

This notice is issued and published under 21 CFR 601.8 and 12.38.

Dated: April 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–9410 Filed 4–14–95; 8:45 am]

BILLING CODE 4160–01–F

Regulatory Concerns in Biopharmaceutical Manufacturing; Notice of Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Office of the Pacific Region, Office of the Southwest Region, Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and Office of External Affairs) is announcing a series of three free public workshops to assist small companies that are developing and producing biopharmaceutical and biologic therapeutic products for clinical trials and product marketing approval. The workshops will address regulatory policy, licensing requirements, cooperative manufacturing arrangements, multi-product facilities, clinical trial design, and manufacturing requirements for clinical material.

DATES: The public workshops are scheduled as follows:

1. Monday, May 22, 1995, 8:30 a.m. to 5 p.m., Houston, TX.
2. Wednesday, May 24, 1995, 8:30 a.m. to 5 p.m., San Diego, CA.
3. Friday, May 26, 1995, 8:30 a.m. to 5 p.m., San Francisco, CA.

ADDRESSES: The public workshops will be held at the following locations:

1. Houston—Rice University, Sewall Hall, rm. 301, Houston, TX.
2. San Diego—Pan Pacific Hotel, 400 West Broadway, San Diego, CA.
3. San Francisco—Holiday Inn Golden Gateway, 1500 West Van Ness Ave., San Francisco, CA.

FOR FURTHER INFORMATION CONTACT: Regarding registration for the Houston TX, public workshop: Marie T. Falcone, Small Business Representative Southwest Region, Food and Drug Administration, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247, 214–655–8100, ext. 128 or FAX 214–655–8130. Regarding registration for the San Diego and San Francisco workshops: Mark S. Roh, Small Business Representative Pacific Region, Food and Drug Administration, Federal Office Bldg., 50 United Nations Plaza, San Francisco, CA 94102, 415–556–2263 or FAX 415–556–2822.

SUPPLEMENTARY INFORMATION: The public workshops are free of charge, however registration is required. Due to space limitations, early registration is recommended. To register please submit your name(s), affiliation, address, phone and fax numbers and any specific questions you want addressed at the workshop, to the contact person listed above.

The workshops are to further assist small companies that are developing and producing biopharmaceutical and biologic therapeutic products in better understanding current regulatory policy; licensing requirements for products and establishments and cooperative manufacturing arrangements; multiproduct facilities design and operation; clinical trial design and monitoring; points to consider during processing, cell culture, fermentation, harvest, recovery, purification and

ascites production; and current good manufacturing practice requirements in the production of clinical material, including recordkeeping, processing changes, and environmental monitoring.

Dated: April 12, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–9411 Filed 4–14–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Environmental Health Sciences; Meeting of National Advisory Environmental Health Sciences Council

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Environmental Health Sciences Council, May 22–23, 1995, in Building 31C, Conference Room 10, National Institutes of Health, Bethesda, Maryland 20892.

This meeting will be open to the public on May 22 from 9 a.m. to approximately 3:30 p.m. for the report of the Director, NIEHS, and for discussion of the NIEHS budget, program policies and issues, recent legislation, and other items of interest. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting will be closed to the public on May 22 from approximately 3:30 p.m. to recess and from 9 a.m. to adjournment on May 23, for the review, discussion and evaluation of individual grant applications.

These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Kim Whitcher, Council Secretary, NIEHS, P.O. Box 12233, Research Triangle Park, N.C. 27709 (919–541–7723), will provide summaries of the meeting and rosters of council members. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Whitcher in advance of the meeting.

Dr. Anne Sassaman, Director & Executive Secretary, Division of Extramural Research and Training, NIEHS, P.O. Box 12233, Research Triangle Park, North Carolina 27709, (919) 541–7723, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health)

Dated: April 11, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–9310 Filed 4–14–95; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Special Emphasis Panel (SEP) meetings:

Name of SEP: Multidisciplinary Course on the Genetics of Heart, Lung, and Blood Disease (Conference Call).

Date: April 24, 1995.

Time: 12:00 p.m.

Place: Rockledge Building (RKL2), Rm. 7220, Rockville, Maryland.

Contact Person: C. James Scheirer, Ph.D., 6701 Rockledge Drive, Room 7220, Bethesda, Maryland 20892–7924, (301) 435–0266.

Purpose/Agenda: To review and evaluate contract proposals.

Name of SEP: Molecular Genetics of Hypertension—SCOR.

Date: April 30–May 1, 1995.

Time: 7:00 p.m.

Place: Holiday Inn Crowne Plaza, Rockville, Maryland.

Contact Person: Anthony M. Coelho, Jr., Ph.D., 6701 Rockledge Drive, Room 7182, Bethesda, Maryland 20892–7924, (301) 435–0277.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: Programs of Excellence in Molecular Biology.

Date: May 17, 1995.

Time: 8:30 a.m.

Place: Holiday Inn, Bethesda, Maryland.

Contact Person: Lynn M. Amende, Ph.D., 6701 Rockledge Building, Room 7192, Bethesda, Maryland 20892–7924, (301) 435–0287.

Purpose/Agenda: To review and evaluate grant applications.

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.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: April 11, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–9308 Filed 4–14–95; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Meeting of Board of Scientific Counselors

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Heart, Lung, and Blood Institute on June 1–2, 1995, National Institutes of Health, 9000 Rockville Pike, Building 10, Room 7C101, Bethesda, Maryland 20892.

This meeting will be open to the public from 8:30 to 9:00 a.m. on June 1 and from 8:30 to 9:00 a.m. on June 2 for discussion of the general trends in research relating to cardiovascular, pulmonary and certain hematologic diseases. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sec. 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting will be closed to the public from 9:00 a.m. to adjournment on June 1 and from 9:00 a.m. to adjournment on June 2, 1995 for the review, discussion, and evaluation of individual programs and projects conducted by the National Institutes of Health, including consideration of personnel qualifications and performance, the competence of individual investigators, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Terry Long, Chief, Communications and Public Information Branch, National Heart, Lung, and Blood Institute, Building 31, Room 4A21, National Institutes of Health, Bethesda, Maryland 20892, phone (301) 496–4236, will provide a summary of the meeting and a roster of the Board members.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Substantive program information may be obtained from Dr. Edward D. Korn,