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