

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Cathy Conn, Center for Biologics Evaluation and Research (HFM-610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-1070.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of human biological products that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Organon Teknika Corp., 100 Akzo Ave., Durham, NC 27712, has filed an application requesting approval for the export of the human biological product Vironostika® HTLV-I/II Microelisa System to The Netherlands. The Vironostika® HTLV-I/II Microelisa System is an in vitro diagnostic test kit for the detection of antibodies to Human T-Lymphotropic Virus Type I (HTLV-I) and/or Human T-Lymphotropic Virus Type II (HTLV-II) in human serum or plasma. The application was received and filed in the Center for Biologics Evaluation and Research on March 2, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by April 27, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: March 22, 1995.

James C. Simmons,
Acting Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 95-9413 Filed 4-14-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 93N-0122]

Hema Systems, Ltd.; Revocation of U.S. License No. 1052

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. 1052) and product licenses (the licenses) issued to Hema Systems, Ltd., for the manufacture of Whole Blood, Plasma, Fresh Frozen Plasma, Red Blood Cells, Red Blood Cells Frozen, Red Blood Cells Deglycerolized, Red Blood Cells Leukocytes Removed, Red Blood Cells Frozen Rejuvenated, and Red Blood Cells Rejuvenated Deglycerolized. Hema Systems, Ltd., 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. 1052) 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. 1052) and product licenses issued to Hema Systems, Ltd., formerly located at 310 East 44th St., New York, NY 10017, for the manufacture of Whole Blood, Plasma, Fresh Frozen Plasma, Red Blood Cells, Red Blood Cells Frozen, Red Blood Cells Deglycerolized, Red Blood Cells Leukocytes Removed, Red Blood Cells Frozen Rejuvenated,

and Red Blood Cells Rejuvenated Deglycerolized.

An attempted onsite inspection by FDA on August 26, 1992, revealed that the facility was no longer in operation at the location listed on the license. The U.S. Post Office reported no forwarding address for the firm. Based on the inability of authorized FDA employees to conduct a meaningful inspection of the facility, FDA initiated proceedings for the revocation of the licenses under 21 CFR 601.5(b)(1) and (b)(2). FDA issued a certified letter dated November 3, 1992, to the firm stating FDA's intent to revoke the licenses and its intent to offer an opportunity for a hearing on the proposed revocation. The letter was returned to FDA as undeliverable.

Pursuant to 21 CFR 12.21(b), FDA published in the **Federal Register** of May 14, 1993 (58 FR 28589), a notice of opportunity for a hearing on a proposal to revoke the licenses of Hema Systems Ltd. In the notice, FDA explained that the proposed license revocation was based on the inability of authorized FDA employees to conduct a meaningful inspection of the facility because it 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 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. One comment was submitted from the State of New York Department of Health which indicated that the facility was closed according to their records.

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. 1052) and the product licenses issued to Hema Systems, Ltd., are revoked, effective April 17, 1995.

This notice is issued and published under 21 CFR 601.8.

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