Centers for Disease Control and Prevention

Technical Advisory Committee for Diabetes Translation and Community Control Programs: 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 committee meeting.

Name: Technical Advisory Committee for Diabetes Translation and Community Control Programs.

Times and Dates: 1 p.m.–5 p.m., Thursday, May 4, 1995. 8 a.m.–11:30 a.m., Friday, May 5, 1995.

Place: Adam's Mark Hotel, Vail Room, 1550 Court Place, Denver, Colorado 80202–5199, telephone 303/893–3333.

Status: Open to the public, limited only by the space available.

Purpose: This committee is charged with advising the Director, CDC, regarding priorities and feasible goals for translation activities and community control programs designed to reduce risk factors, morbidity, and mortality from diabetes and its complications. The committee advises regarding policies, strategies, goals and objectives, and priorities; identifies research advances and technologies ready for translation into widespread community practice; recommends public health strategies to be implemented through community interventions; advises on operational research and outcome evaluation methodologies; identifies research issues for further clinical investigation; and advises regarding the coordination of programs with Federal, voluntary, and private resources involved in the provision of services to people with diabetes.

Matters To Be Discussed: Committee members will discuss progress towards a National Diabetes Education Program, evolving strategies and scientific activities related to screening for Type II diabetes, possible participation by CDC in the National Institutes of Health-sponsored Diabetes Prevention Trial-Type II, policy and economic activities, and the status of mechanisms of CDC's Division of Diabetes Translation support to States.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Cheryl Shaw, Program Specialist, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, NE, Mailstop K–10, Atlanta, Georgia 30341–3724, telephone 404/488–5004.

Dated: April 11, 1995.

Carolyn J. Russell,

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

[FR Doc. 95–9336 Filed 4–14–95; 8:45 am]

BILLING CODE 4163–18–M

Advisory Committee for Energy-Related Epidemiologic Research: 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 committee meeting.

Name: Advisory Committee for Energy-Related Epidemiologic Research.

Times and Dates: 9 a.m.–5 p.m., May 4, 1995; 9 a.m.–12 noon, May 5, 1995.

Place: Sheraton Suites Hotel, 801 North St. Asaph Street, Alexandria, Virginia 22314.

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

Purpose: This committee is charged with providing advice and recommendations to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, CDC; and the Administrator, Agency for Toxic Substances and Disease Registry, on the establishment of a research agenda and the conduct of a research program pertaining to energy-related analytic epidemiologic studies. The committee will take into consideration information and proposals provided by the Department of Energy (DOE), the Advisory Committee for Environment Safety and Health which was established by DOE under the guidelines of a Memorandum of Understanding between HHS and DOE, and other agencies and organizations, regarding the direction HHS should take in establishing the research plan and in the development of a research plan.

Matters To Be Discussed: The committee will discuss working group recommendations, environmental data and research methods, the research agenda, and public involvement activities. Presentations will be made by DOE on the Conference on Epidemiologic Data Resources and occupational surveillance plans and progress.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Nadine Dickerson, Program Analyst, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC, 4770 Buford Highway NE., Mailstop F–35, Atlanta, Georgia 30341–3724; telephone 404/488–7040.

Dated: April 11, 1995.

Carolyn J. Russell,

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

[FR Doc. 95–9337 Filed 4–14–95; 8:45 am]

BILLING CODE 4163–18–M

Board of Scientific Counselors, National Center for Infectious Diseases: 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 committee meeting.

Name: Board of Scientific Counselors, National Center for Infectious Diseases (NCID).

Times and Dates: 8:30 a.m.–5 p.m., May 4, 1995; 8:15 a.m.–1:15 p.m., May 5, 1995.

Place: CDC, Auditorium B, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Board of Scientific Counselors, NCID, provides advice and guidance to the Director, CDC, and Director, NCID, in the following areas: program goals and objectives; strategies; program organization and resources for infectious disease prevention and control; and program priorities.

Matters To Be Discussed: The agenda will focus on:

1. Update: Implementation of CDC Emerging Infections Plan.
2. CDC Laboratories Master Plan.
3. Linkages between HIV/Sexually Transmitted Diseases/Tuberculosis Laboratories and Programs in other Centers.
4. Fiscal Year (FY) 1995 Budget Rescissions and FY 1996 Budget Outlook.
5. The CDC Foundation.
6. Update—Antibiotic Resistance.

Other agenda items include announcements/introductions; NCID update; late breakers; and follow-up on actions recommended by the board (December 1994).

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Contact Person for More Information: Diane S. Holley, Office of the Director, NCID, CDC, Mailstop C–20, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–0078.

Dated: April 11, 1995.

Carolyn J. Russell,

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

[FR Doc. 95–9335 Filed 4–14–95; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 95N–0098]

Drug Export; Vironostika® HTLV–I/II Microelisa System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Organon Teknika Corp. has filed an application requesting approval for the export of the human biological product Vironostika® HTLV–I/II Microelisa System to The Netherlands.

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 onthe 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.