

Purpose: The Subcommittee on Mental Health Statistics will continue discussion of enrollment and encounter minimum data sets, and receive updates on National Health Interview Survey activities with respect to mental health.

Contact Person for More Information: Substantive program information as well as summaries of the meetings and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436-7050.

Dated: August 8, 1995.

Carolyn J. Russell,

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

[FR Doc. 95-20105 Filed 8-14-95; 8:45 am]

BILLING CODE 4163-18-M

National Center for Environmental Health; Meetings

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) will convene the following meeting cosponsored by the European Commission, the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK), the National Institute of Environmental Health Sciences (NIEHS), and the Oregon Health Sciences University Foundation.

Name: Urinary Biomarkers to Detect Significant Effects of Environmental and Occupational Exposure to Nephrotoxins.

Times and Dates: 8:45 a.m.-5 p.m., September 15, 1995. 9 a.m.-5 p.m., September 16, 1995. 9 a.m.-12:30 p.m., September 17, 1995.

Place: Terrace Garden Inn-Buckhead, 3405 Lenox Road, NE, Atlanta, Georgia 30326.

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

Purpose: The purpose of the meeting is to recommend a battery of tests for use in epidemiologic studies of environmental/occupational nephrotoxicity; determine the utility and applicability of the individual tests of renal injury; provide guidance for interpretation of information obtained from the tests; and provide direction for future useful markers to detect nephrotoxicity.

Matters to be discussed: Agenda items include: a workshop to discuss the latest information on categories of tests for detecting effects of nephrotoxins, interpreting health implications of these tests, nephrotoxins of significant frequency and economic impact, test batteries, monitoring individuals with elevated test patterns, and future research needs. Experts from the United States and Europe will participate in discussions of these issues and provide individual advice and guidance from their respective scientific and clinical experiences.

Contact person for more information: Patricia W. Mueller, Ph.D., Chief, Health

Effects Laboratory (F50), Molecular Biology Branch, Division of Environmental Health Laboratory Sciences, NCEH, CDC, 4770 Buford Hwy., NE, Atlanta, Georgia 30341-3724, telephone 404/488-7983.

Dated: August 9, 1995.

Carolyn J. Russell,

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

[FR Doc. 95-20106 Filed 8-14-95; 8:45 am]

BILLING CODE 4163-18-M

Food and Drug Administration

[Docket No. 95N-0247]

Drug Export; DILAUDID HP-PLUS (Hydromorphone Hydrochloride) 20 Milligram (mg)/Milliliter (mL) Vials and DILAUDID XP (Hydromorphone Hydrochloride) 50mg/mL Vials for Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Knoll Pharmaceutical Co. has filed an application requesting approval for the export of the human drug DILAUDID HP-PLUS (hydromorphone hydrochloride) 20mg/mL Vials and DILAUDID XP (hydromorphone hydrochloride) 50mg/mL Vials for Injection to Canada.

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 drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20857, 301-594-3150.

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 drugs 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 Knoll Pharmaceutical Co., 30 North Jefferson Rd., Whippany, NJ 07981, has filed an application requesting approval for the export of the human drug DILAUDID HP-PLUS (hydromorphone hydrochloride) 20mg/mL Vials DILAUDID XP (hydromorphone hydrochloride) 50mg/mL Vials for Injection to Canada. The firm has an NDA for DILAUDID 10mg/mL (250mg/vial). This product is used for the relief of severe pain in patients who require subcutaneously, intravenously, or intramuscularly administered opioids in doses or concentrations higher than those usually needed. The application was received and filed in the Center for Drug Evaluation and Research on June 26, 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 August 25, 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 Drug Evaluation and Research (21 CFR 5.44).

Dated: July 25, 1995.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95-20187 Filed 8-14-95; 8:45 am]

BILLING CODE 4160-01-F

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meetings of

the following Heart, Lung, and Blood Special Emphasis Panels.

These meetings will be open to the public to provide concept review of proposed contract or grant solicitations.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

Name of Panel: Longitudinal Cohort Studies

Dates of Meeting: September 5–6, 1995
Time of Meeting: 9:00 a.m.

Place of Meeting: National Institutes of Health, Rockledge II Building, Conference Rooms A1 & A2, 6701 Rockledge Drive, Bethesda, Maryland

Agenda: The panel will review the current status of research in the designated areas, identify gaps and make recommendations regarding opportunities and priorities for future contract or grant solicitations.

Contact Person: Teri Manolio, M.D., M.H.S., Rockledge II Building, Rm. 8160, 6701 Rockledge Drive, Bethesda, Maryland 20892, (301) 435-0707

Name of Panel: Homocysteinemia and Cardiovascular Diseases

Dates of Meeting: September 27, 1995
Time of Meeting: 9:30 a.m.

Place of Meeting: National Institutes of Health, Rockledge II Building, Conference Room 8119, 6701 Rockledge Drive, Bethesda, Maryland 20892

Agenda: The panel will review the current status of research in the designated areas, identify gaps and make recommendations regarding opportunities and priorities for future contract or grant solicitations.

Contact Person: Lawrence Friedman, M.D., Rockledge II Building, Room 8100, 6701 Rockledge Drive, Bethesda, Maryland 20892, (301) 435-0422

(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: August 9, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-20040 Filed 8-14-95; 8:45 am]

BILLING CODE 4140-01-M

National Heart, Lung, and Blood Institute; Notice of Meeting of the Sleep Disorders Research Advisory Board

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Sleep Disorders Research Advisory Board, National Center on Sleep Disorders Research, National Heart, Lung, and Blood Institute, September 26–27, 1995. This meeting will be held at the National Institutes of Health, Building 31, Conference Room 10, 9000

Rockville Pike, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 9:00 a.m. to adjournment, to discuss recommendations on the implementation and evaluation of the National Center on Sleep Disorders Research programs. Attendance by the public will be limited to space available.

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.

Dr. James P. Kiley, Executive Secretary and Director, National Center on Sleep Disorders Research, NHLBI, Two Rockledge Center Suite 7024, 6701 Rockledge Drive MSC 7920, Bethesda, Maryland 20892-7920, (301) 435-0199, will furnish meeting and member information.

(Catalog of Federal Domestic Assistance Program No. 93.838, Lung diseases Research, National Institutes of Health)

Dated: August 8, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-20041 Filed 8-14-95; 8:45 am]

BILLING CODE 4140-01-M

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of meetings of the National Institute on Alcohol Abuse and Alcoholism.

The National Advisory Council on Alcohol Abuse and Alcoholism meeting on September 21 will be open to the public, as noted below, to discuss Institute programs and other issues relating to committee activities as indicated in the notice. Attendance by the public will be limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Ida Nestorio at 301-443-4376.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C. and section 10(d) of Public Law 92-463, for the review, discussion and evaluation of individual research 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.

A summary of the meeting and the roster of committee members may be obtained from: Ms. Ida Nestorio, Office of Scientific Affairs, National Institute on Alcohol Abuse and Alcoholism, Willco Building, Suite 409, 6000 Executive Blvd., Rockville, MD 20892-7003, Telephone: 301-443-4375. Other information pertaining to the meeting can be obtained from the contact person indicated.

Name of Committee: National Advisory Council on Alcohol Abuse and Alcoholism

Executive Secretary: James F. Vaughan, 6000 Executive Blvd., Suite 409, Bethesda, MD 20892-7003, 301-443-4375

Dates of Meeting: September 21, 1995

Place of Meeting: Conference Room D, Building 45 (Natcher), NIH Campus, 9000 Rockville Pike, Bethesda, MD 20892

Open: September 21, 10:30 a.m. to adjournment

Agenda: Discussion of Institute extramural research programs, health services research, and other program and peer review issues relevant to Council activities

Closed: September 21, 8 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications

(Catalog of Federal Domestic Assistance Program No. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.281, Scientist Development Award, Research Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.891, Alcohol Research Center Grants; National Institutes of Health)

Dated: August 8, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-20042 Filed 8-14-95; 8:45 am]

BILLING CODE 4140-01-M

National Institute on Drug Abuse; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the National Advisory Council on Drug Abuse, National Institute on Drug Abuse on September 19–20, 1995.

On September 19, from 9 a.m. to 5 p.m., the meeting will be held at the National Institutes of Health, Building 1, Wilson Hall, 9000 Rockville Pike, Bethesda, Maryland 20892. This portion of the meeting will be open to the public for announcements and reports of