

Sterward. Prior to each acquisition, the rolled horseshoe nail market was highly concentrated and concentration increased substantially following each acquisition. The complaint alleges that entry into the production and sale of rolled horseshoe nails would be difficult and time consuming—taking well in excess of two years, entailing significant sunk costs, and requiring technical expertise.

The proposed Order would remedy the alleged violations by replacing the lost competition that has resulted from the acquisitions. The proposed Order would require Mustad to divest either (1) Capewell as an ongoing business, or (2) four fully functioning horseshoe nail machines, one spare nail machine, and grant a perpetual non-exclusive license to technology and know-how. In order to ensure that the acquirer of machinery would be able to quickly begin production at the same level of quality as exists currently, Mustad would be required to provide training and technical assistance to the acquirer for up to one year.

The proposed Order provides that Mustad shall divest Capewell or the machinery no later than May 15, 1996. If Mustad does not complete the required divestiture during the allotted time period, then a trustee may be appointed to divest the machinery within twelve months. The time period for the trustee to complete the divestiture may be extended twice.

The proposed Order requires Mustad to submit a report of compliance with the proposed Order's divestiture requirements within sixty (60) days following the date the proposed Order becomes final, and every sixty (60) days thereafter until Mustad has completed the divestiture.

Finally, the proposed Order prohibits Mustad from acquiring any interest in any other company engaged in, or attempting to engage in, the production or sale of horseshoe nails without giving prior notice to the Commission and observing certain waiting periods for a period of ten years.

The purpose of this analysis is to facilitate public comment on the proposed Order. This analysis is not intended to constitute an official interpretation of the Agreement or the proposed Order or in any way to modify the terms of the Agreement or the proposed Order.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 95-20142 Filed 8-14-95; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC) and Subcommittee on Proficiency Testing, Quality Assurance, and Quality Control; Meetings

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 Federal advisory committee meetings.

Name: Subcommittee on Proficiency Testing, Quality Assurance, and Quality Control, Clinical Laboratory Improvement Advisory Committee (CLIAC).

Time and Date: 8:30 a.m.–12 noon, August 30, 1995.

Place: Swissôtel Atlanta, 3391 Peachtree Road, NE, Atlanta, Georgia 30326.

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

Purpose: This subcommittee advises CLIAC on issues related to proficiency testing, quality assurance, and quality control.

Matters to be discussed: The Subcommittee will discuss quality control requirements for test method verification and appropriate materials for quality control testing.

Agenda items are subject to change as priorities dictate.

Name: Clinical Laboratory Improvement Advisory Committee.

Times and Dates: 1 p.m.–4:30 p.m., August 30, 1995., 8 a.m.–4 p.m., August 31, 1995.

Place: Swissôtel Atlanta, 3391 Peachtree Road, NE, Atlanta Georgia 30326.

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

Purpose: This committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

Matters to be discussed: The agenda will include an update on the implementation of the Clinical Laboratory Improvement Amendments (CLIA), a CDC presentation on CLIA quality control requirements, public presentations on quality control requirements, a discussion of the quality control requirements for the final regulations, and a summary of the meeting of the Subcommittee on Proficiency Testing, Quality Assurance, and Quality Control.

Agenda items are subject to change as priorities dictate.

Written comments on the quality control requirements are welcome. Comments should not exceed five single-spaced, typed pages in length and

should be received by the contact person no later than August 24, 1995.

Anyone wishing to make an oral presentation that would include data pertinent to CLIA quality control requirements should submit their request, in writing, to the contact person by close of business, August 24, 1995. The request should include the name, address, and telephone number of the participant; the approximate time needed; and a brief summary of the topic and data to be presented. Depending on the number of requests, up to 10 minutes will be allowed for each oral presentation.

Contact Person for addition information: John C. Ridderhof, Dr. P.H., Division of Laboratory Systems, Public Health Practice Program Office, CDC, 4770 Buford Highway, NE, Mailstop G-25, Atlanta, Georgia 30341-3724, telephone 404/488-7660, FAX 404-488-7663.

Dated: August 9, 1995.

Carolyn J. Russell,

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

[FR Doc. 95-20104 Filed 8-14-95; 8:45 am]

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National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Mental Health Statistics and NCVHS Subcommittee on Disability and Long-Term Care Statistics; Meetings

Pursuant to Pub. L. 92-463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following subcommittee meetings.

Name: NCVHS Subcommittee on Mental Health Statistics and NCVHS Subcommittee on Disability and Long-Term Care Statistics.

Time and Date: 9 a.m.–5 p.m., September 12, 1995.

Place: Room 503A-529A, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, D.C. 20201.

Status: Open.

Purpose: The Subcommittee on Mental Health Statistics and the Subcommittee on Disability and Long-Term Care Statistics will meet jointly to consider and discuss presentations on a variety of payment and service models. There will be presentations on the Program of All-inclusive Care for the Elderly (PACE), the second phase of the Social Health Maintenance Organizations, consumer choice plans, and demonstration projects.

Name: NCVHS Subcommittee on Mental Health Statistics.

Time and Date: 9 a.m.–12 noon, September 13, 1995.

Place: Room 503A-529A, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, D.C. 20201.

Status: Open.

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