

pay particular attention to parking lots and garages as well as street level parking adjacent to the buildings. In a number of cases, restrictions have been placed on parking next to buildings.

We are committed to continuing these interim heightened security measures through September 30, and are taking steps to maintain these initiatives in FY 1996 until GSA begins implementation of updated security provisions identified in the DOJ study.

I would like to specifically recognize the efforts of the FPS in implementing and maintaining the heightened interim security measures during the past four months. I would also like to commend the entire agency for pulling together to accomplish the enormous task involved in dealing with the devastation of the bombing in Oklahoma City as well as the ensuing operational requirements. Most assuredly this task has been a difficult one, but the tremendous accomplishments of those involved is a fitting tribute to the dedication and professionalism of GSA employees nationwide.

GSA is well on its way to completing the task assigned by the President, and identifying the security needs of its facilities nationwide. To date, we have established Building Security Committees (BSC's) at the higher risk Level IV buildings. The BSC's are meeting and will identify the required security upgrades as outlined in the DOJ report. We continue to maintain the ambitious schedule established by the President. FPS will be monitoring the Level IV BSC activities, and developing guidelines for reporting and evaluating their security recommendations.

The DOJ report specifically stated that the FPS "has the experience and the historical charter to provide security services" in GSA federal buildings by using a wide range of technical and human resources (including both Federal Protective Police Officers (FPPO's) and contract security guards). Finally, an Executive Order establishing an Interagency Security Committee (ISC) headed by the Assistant Commissioner of the FPS has been signed, and the President is issuing a Memorandum for Executive Departments and Agencies recognizing GSA's leadership role in federal building and facility security.

The next few months will be both demanding and challenging as GSA and FPS endeavor to meet the Presidents ambitious schedule for implementing the DOJ study recommendations. During this time, I would ask everyone to remain committed to GSA's mission and responsibility to provide a safe and secure working environment for our clients, customers and visitors.

Dated: August 15, 1995.

Roger W. Johnson,

Administrator.

[FR Doc. 95-21223 Filed 8-25-95; 8:45 am]

BILLING CODE 6820-23-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Medical Classification Systems and NCVHS Subcommittee on Ambulatory and Hospital Care Statistics: Meeting

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

Name: NCVHS Subcommittee on Medical Classification Systems and NCVHS Subcommittee on Ambulatory and Hospital Care Statistics.

Time and Date: 9 a.m.-1 p.m., September 15, 1995.

Place: Room 503A, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

Status: Open.

Purpose: The Subcommittee on Medical Classification Systems and the Subcommittee on Ambulatory and Hospital Care Statistics will meet jointly in a working session to discuss the final report of the compendium on person-level and event-level health care core data sets and to plan the NCVHS public meetings to obtain input from diverse parties who report and use standardized core data sets for enrollment and encounters; to receive an update on the NCHS Morbidity Classification Branch activities; and to review the subcommittees' work plans for 1995-1996.

CONTACT PERSON FOR MORE INFORMATION:

Substantive program information as well as summaries of the meeting 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 22, 1995.

Carolyn J. Russell,

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

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Food and Drug Administration

[Docket No. 95N-0272]

Drug Export; Telfast (Fexofenadine Hydrochloride) Tablets 60 Milligrams (mg)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Marion Merrell Dow Inc., has filed an application requesting conditional approval for the export of the human drug Telfast (fexofenadine hydrochloride) tablets 60 (mg) to France for packaging for transshipment to the United Kingdom.

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 Place, Rockville, MD 20855, 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 Marion Merrell Dow Inc., Marion Park Dr., P.O. Box 9627, Kansas City, MO, 64134-0627, has filed an application requesting conditional approval for the export of the human drug Telfast (fexofenadine hydrochloride) tablets 60 mg to France for packaging for transshipment to the United Kingdom. Telfast (fexofenadine hydrochloride)

tablets is used for the relief of symptoms such as sneezing, watery eyes, blocked or runny nose, that occur with hayfever (seasonal allergic rhinitis). The application was received and filed in the Center for Drug Evaluation and Research on August 10, 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 September 7, 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: August 14, 1995.

Betty L. Jones,

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

[FR Doc. 95-21224 Filed 8-25-95; 8:45 am]

BILLING CODE 4160-01-F

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 53 FR 8978, March 18, 1988) is amended to reflect the following reorganization in the Food and Drug Administration (FDA).

The functional statements for the Office of Compliance, Center for Drug Evaluation and Research (CDER), are being revised and updated to more accurately reflect the activities carried out by this Office.

Under section HF-B, Organization:

1. Delete the subparagraph, Office of Compliance (HFND), under the Center

for Drug Evaluation and Research (HFN) and insert a new subparagraph reading as follows:

Office of Compliance (HFND). Monitors the quality of marketed drugs, including nontraditional drugs, through product testing, surveillance, and compliance programs.

Develops policy and standards for labeling, current good manufacturing practice issues, clinical and good laboratory practice investigations, postmarketing surveillance, and drug industry practices to demonstrate the safety and effectiveness of human drug products and ensures the uniform interpretation of such standards.

Develops and directs drug product quality enforcement programs; postmarketing drug quality surveillance programs; and compliance programs for over-the-counter (OTC), nontraditional, and other drug monographs. Directs the Center's bioresearch monitoring program for human drug products.

Advises the Center Director and other Agency officials on FDA's regulatory and enforcement responsibilities for human drugs.

Initiates Center-field surveillance assignments to monitor pivotal research data submitted as part of premarketing applications. Coordinates preapproval inspections and results as part of the final product approval process.

Coordinates Center-field relations; provides support and guidance to the field on legal actions, case development, and contested cases; and reviews and decides disposition of field submissions involving deviations from standards.

Evaluates, classifies, and recommends human drug recalls and provides Center coordination with field recall activities. Monitors the resolution of all drug shortage situations involving compliance issues.

Coordinates international inspections, results, and communications with inspectorates of other nations. Participates in international standards-setting activities.

5. Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: August 14, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95-21263 Filed 8-25-95; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

[HSQ-230-N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Permit-Holding Laboratories in the State of New York

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: Section 353(p) of the Public Health Service Act provides for the exemption of laboratories from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) when the State in which they are located has requirements equal to or more stringent than those of CLIA. This notice grants exemption from CLIA requirements applicable only to laboratories located within the State of New York, including New York City, that possess a valid permit, as mandated under Part 58, and Article Five of Title V of the Public Health Law of the State of New York. This title is applicable to all laboratories except those operated by an individual, licensed physician, osteopath, dentist, podiatrist, or a physician's group practice which performs laboratory tests personally or through his or her employees, solely as an adjunct to the treatment of his or her own patients.

EFFECTIVE DATE: The provisions of this notice are effective on August 28, 1995 to June 30, 2001.

FOR FURTHER INFORMATION CALL: Val Coppola, (410) 786-3406.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 353 of the Public Health Service Act (PHS Act), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), requires any laboratory that performs tests on human specimens to meet requirements established by the Department of Health and Human Services (HHS). Under the provisions of the sentence following section 1861(s)(14) and paragraph (s)(16) of the Social Security Act, any laboratory that also wants to be paid for services furnished to Medicare beneficiaries must meet the requirements of section 353 of the PHS Act. Subject to specified exceptions, laboratories must have a current and valid CLIA certificate to test human specimens and to be eligible for payment from the Medicare or Medicaid program. Regulations implementing