

SUMMARY: This is a notice of the Presidential declaration of an emergency for the U.S. Virgin Islands (FEMA-3129-EM), dated September 21, 1998, and related determinations.

EFFECTIVE DATE: September 21, 1998.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 21, 1998, the President declared an emergency under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in the U.S. Virgin Islands, resulting from Hurricane Georges on September 21, 1998, and continuing is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. L. 93-288, as amended ("the Stafford Act"). I, therefore, declare that such an emergency exists in the U.S. Virgin Islands.

You are authorized to coordinate all disaster relief efforts which have the purpose of alleviating the hardship and suffering caused by the emergency on the local population, and to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives, protect property and public health and safety, and lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to identify, mobilize, and provide at your discretion, equipment and resources necessary to alleviate the impacts of the disaster. I have further authorized direct Federal assistance for the first 72 hours at 100 percent Federal funding, if deemed necessary. The time period for this direct Federal assistance funding may be extended by FEMA, if warranted.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Barbara T. Russell of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the U.S. Virgin Islands to have been affected adversely by this declared emergency:

The U.S. Virgin Islands for assistance as follows: FEMA is authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives, protect

property and public health and safety, and lessen or avert the threat of a catastrophe in the U.S. Virgin Islands. Specifically, FEMA is authorized to identify, mobilize, and provide at its discretion, equipment and resources necessary to alleviate the impacts of the disaster. Direct Federal assistance is authorized for the first 72 hours at 100 percent Federal funding.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program.)

James L. Witt,

Director.

[FR Doc. 98-26588 Filed 10-2-98; 8:45 am]

BILLING CODE 6718-02-P

FEDERAL EMERGENCY MANAGEMENT AGENCY

Open Meeting, Board of Visitors for the Emergency Management Institute

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice of open meeting.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, FEMA announces the following committee meeting.

NAME: Board of Visitors for the Emergency Management Institute.

DATES OF MEETING: October 26-27, 1998.

PLACE: Federal Emergency Management Agency, National Emergency Training Center, Emergency Management Institute, Conference Room, Building N, Room 408, Emmitsburg, Maryland 21727.

TIME: Monday, October 26, 1998, 8:30 a.m.-5:00 p.m.; Tuesday, October 27, 1998, 8:30 a.m.-5:00 p.m.

PROPOSED AGENDA: Status reports on training in response and recovery, planning, mitigation, and simulation and exercises; informal working sessions regarding EMI activities; expansion of the Independent Study program and EMI's Higher Education Program.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public with approximately 10 seats available on a first-come, first-serve basis. Members of the general public who plan to attend the meeting should contact the Office of the Superintendent, Emergency

Management Institute, 16825 South Seton Avenue, Emmitsburg, MD 21727, (301) 447-1286.

Minutes of the meeting will be prepared and will be available for public viewing in the Office of the Superintendent, Emergency Management Institute, Federal Emergency Management Agency, Building N, National Emergency Training Center, Emmitsburg, MD 21727. Copies of the minutes will be available upon request 30 days after the meeting.

Dated: September 15, 1998.

Kay C. Goss,

Associate Director, Preparedness, Training, and Exercises Directorate.

[FR Doc. 98-26581 Filed 10-2-98; 8:45 am]

BILLING CODE 6718-01-P

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984.

Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW, Room 962. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 217-011634

Title: Australia-New Zealand Direct Line/APL Space Charter Agreement

Parties:

Australia-New Zealand Direct Line ("ANZDL")

APL Co. Ltd. ("APL")

Synopsis: The proposed agreement authorizes ANZDL to charter up to 100 TEUs of space each week from APL in the trade between United States ports, and U.S. points served via those ports, and ports and points in Australia and New Zealand.

Agreement No.: 207-011635

Title: The TMM/CP Ships Agreement

Parties:

Transportacion Maritima Mexicana, S.A. de C.V.

Transportacion Maritima

Grancolombiana, S.A.

Tecomar Limited

Mexican Line Limited

CP Ships Holdings, Inc.

Lykes Lines Limited, LLC

Ivaran Lines Limited

Contship Containerlines Limited

TMC Lines Limited

Synopsis: The proposed Agreement would establish a joint venture among the parties which would operate vessel operating common carrier services in the trades between United States ports, and inland U.S. points, and ports and points in Europe, the Mediterranean, Mexico, Canada, India, Pakistan, Central and South America, the Caribbean, Africa and Southwest Asia.

Dated: September 29, 1998.

By order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 98-26526 Filed 10-2-98; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 63 FR 51579, September 28, 1998.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:00 a.m., Thursday, October 1, 1998.

CHANGES IN THE MEETING: The open meeting has been canceled, and the scheduled item was handled via notation voting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202-452-3204.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 for a recorded announcement of this meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement. (The Web site also includes procedural and other information about the open meeting.)

Dated: October 1, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98-26700 Filed 10-1-98; 10:27 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0512]

Hoechst Marion Roussel, Inc., and Baker Norton Pharmaceuticals, Inc.; Terfenadine; Withdrawal of Approval of Two New Drug Applications and One Abbreviated New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new drug applications (NDA's) and one abbreviated new drug application (ANDA) for drug products containing terfenadine. NDA 18-949 (Seldane) and NDA 19-664 (Seldane-D) are held by Hoechst Marion Roussel, Inc. (HMR), 10236 Marion Park Dr., Kansas City, MO 64134. ANDA 74-475 is held by Baker Norton Pharmaceuticals, Inc. (Baker Norton), 4400 Biscayne Blvd., Miami, FL 33137. The basis for the action is a finding that terfenadine is not shown to be safe for use in the treatment of seasonal allergic rhinitis. HMR and Baker Norton waived their opportunity for a hearing. No other party has requested a hearing.

EFFECTIVE DATE: NOVEMBER 4, 1998.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5648.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 14, 1997 (62 FR 1889), the Director of FDA's Center for Drug Evaluation and Research (the Director) offered an opportunity for a hearing on a proposal to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of NDA 18-949 and NDA 19-664, and all amendments and supplements thereto, and under section 505(j) of the act, withdrawing approval of ANDA 74-475, and all amendments and supplements thereto. The Director based the proposed action on: (1) A finding that new evidence of clinical experience, not contained in NDA 18-949 and NDA 19-664 or not available to the Director until after the applications were approved, evaluated together with the evidence

available to the Director when the applications were approved, demonstrates that terfenadine is not shown to be safe for use under the conditions of use that formed the basis upon which the applications were approved; and (2) a finding that ANDA 74-475 refers to NDA 18-949 as the listed drug. HMR requested a hearing on the proposed action by letter dated February 11, 1997, and Baker Norton requested a hearing by letter dated February 12, 1997. Subsequently, HMR and Baker Norton, by letters dated June 30, 1998, and July 9, 1998, respectively, withdrew their hearing requests and waived their opportunity for a hearing. No other party filed a request for a hearing within the 30 days following publication of the notice in the **Federal Register**.

Accordingly, for the reasons discussed in the notice, the Director, under section 505(e) of the act and under authority delegated to her (21 CFR 5.82), finds that new evidence of clinical experience not contained in the applications for Seldane and Seldane-D and not available at the time of approval, evaluated together with the evidence available at the time the applications were approved, shows that terfenadine is not shown to be safe for use under the conditions of use that formed the basis upon which the applications were approved (21 U.S.C. 355(e)(2)). Therefore, approval of NDA 18-949 and NDA 19-664, is hereby withdrawn, effective November 4, 1998. Furthermore, the Director finds that ANDA 74-475 refers to the drug that is the subject of NDA 18-949 (Seldane, 60-milligram terfenadine oral tablets). Therefore, under section 505(j) of the act, the approval of ANDA 74-475 is also withdrawn, effective November 4, 1998.

Under 21 CFR 314.161 and 314.162(a)(1), the products containing terfenadine named previously will be removed from the list of drug products with effective approvals published in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations." FDA will not approve or accept ANDA's that refer to these drug products.

Dated: September 14, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98-26522 Filed 10-2-98; 8:45 am]

BILLING CODE 4160-01-F