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