

and the final decision of the Commission shall be issued by May 8, 1998.

By the Commission.
Joseph C. Polking,
Secretary.

[FR Doc. 97-829 Filed 1-13-97; 8:45 am]
BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act, including whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices" (12 U.S.C. 1843). Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated

or the offices of the Board of Governors not later than January 29, 1997.

A. Federal Reserve Bank of New York (Christopher J. McCurdy, Senior Vice President) 33 Liberty Street, New York, New York 10045:

1. *Canadian Imperial Bank of Commerce*, Toronto, Canada; to engage *de novo*, through its wholly owned subsidiary, CIBC Investment Corporation, New York, New York ("Company"), in trading for its own account, for purposes other than hedging, in futures, options, and options on futures contracts based on certain securities indices and money market instruments. Canadian Imperial proposes that Company would conduct these activities throughout the world. See *Swiss Bank Corporation*, 81 Fed. Res. Bull. 185 (1995).

Board of Governors of the Federal Reserve System, January 8, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97-828 Filed 1-13-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0512]

Hoechst Marion Roussel, Inc., and Baker Norton Pharmaceuticals, Inc.; Terfenadine; Proposal To Withdraw Approval of Two New Drug Applications and One Abbreviated New Drug Application; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to withdraw 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 (HMR), Inc., P.O. Box 9627, Kansas City, MO 64134-0627. ANDA 74-475 is held by Baker Norton Pharmaceuticals, Inc., 4400 Biscayne Blvd., Miami, FL 33137. On July 25, 1996, FDA approved HMR's NDA 20-625 for fexofenadine hydrochloride (Allegra). Fexofenadine is the active metabolite of terfenadine that is responsible for the desired beneficial properties of terfenadine. When patients take terfenadine, parent terfenadine is ordinarily present in their blood at very

low concentrations, because the terfenadine molecule is metabolized to form fexofenadine. Fexofenadine is responsible for providing patients with essentially all the clinical benefits of taking terfenadine. If terfenadine's metabolism is inhibited, either by another drug or by intrinsic liver disease, the level of parent terfenadine can rise to levels that can cause serious side effects in people as a result of the effect of parent terfenadine on cardiac potassium channels. Inhibition of these channels causes delayed cardiac repolarization (prolonged electrocardiographic QT interval) and increases the risk of a characteristic kind of ventricular tachycardia called torsades de pointes and possibly the risk of other rhythm abnormalities. Fexofenadine hydrochloride, however, has not been shown to affect cardiac potassium channels and has been shown not to cause prolongation of the electrocardiographic QT interval, even at larger-than-recommended doses. Based on all data to date, fexofenadine hydrochloride appears to lack parent terfenadine's risk of serious cardiovascular adverse events. The basis for the proposed withdrawal of the applications is a finding that the availability of fexofenadine hydrochloride provides patients with an alternative that can provide essentially all the benefits of terfenadine, because it is identical in molecular structure to the metabolized (active) form of terfenadine, without the serious and potentially fatal risks associated with terfenadine when terfenadine's metabolism is inhibited either by another drug or by intrinsic liver disease. Because of the availability of fexofenadine hydrochloride, terfenadine is not shown to be safe for use under the conditions of use that formed the basis upon which the applications were approved.

DATES: A hearing request is due on February 13, 1997; data and information in support of the hearing request are due on March 17, 1997.

ADDRESSES: A request for hearing, supporting data, and other comments are to be identified with docket no. 96N-0512 and submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For information on medical/scientific issues: John K. Jenkins, Center for Drug Evaluation and Research (HFD-570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-