

bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 27, 2004.

A. Federal Reserve Bank of Minneapolis (Jacqueline G. Nicholas, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Heritage Bancshares Group, Inc.*, Wilmar, Minnesota; to acquire 100 percent of the voting shares of Raymond Bancshares, Inc., Raymond, Minnesota, and thereby indirectly acquire voting shares of Farmers State Bank of Raymond, Raymond, Minnesota.

Board of Governors of the Federal Reserve System, July 29, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Meeting of the Advisory Committee on Blood Safety and Availability

AGENCY: Office of the Secretary.

ACTION: Notice of meeting.

SUMMARY: The Advisory Committee on Blood Safety and Availability will meet on Thursday, August 26, 2004 and Friday, August 27, 2004 from 8 a.m. to 5 p.m. The meeting will take place at the Hyatt Regency Hotel on Capitol Hill, 400 New Jersey Ave., NW., Washington,

DC 20001. Please note this is a change in location from the previous two meetings. The meeting will be entirely open to the public.

The purpose of this meeting will be to review the progress of prior recommendations and solicit additional comments from the Committee regarding recommendations made over the past year. Specifically the Committee will be asked to review the safety and availability of platelet products since the introduction of the voluntary 100% quality control for bacterial contamination. The Committee may also review the progress made by the American Association of Blood Banks Task Force on Bacterial Contamination to identify potential studies to standardize, validate, and determine the predictive value of bacterial testing with the intent to extend the dating of platelet products from five to seven days and the possible pre-storage pooling of whole blood derived platelets; issues related to hepatitis B testing; and issues related to blood and blood products, including plasma-derived therapeutics and their recombinant analogs. Individuals interested in this meeting are urged to refer to the Committee's Web page at www.dhhs.gov/bloodsafety for further information prior to the meeting.

Public comment will be solicited at the meeting. Public comment will be limited to five minutes per speaker. Those who wish to have printed material distributed to Advisory Committee members should submit thirty (30) copies to the Acting Executive Secretary prior to close of business August 20, 2004. Those who wish to utilize electronic data projection in their presentation to the Committee must submit their material to the Executive Secretary prior to close of business August 20, 2004. In addition, anyone planning to comment is encouraged to contact the Executive Secretary at her/his earliest convenience.

FOR FURTHER INFORMATION CONTACT: Jerry A. Holmberg, PhD, Executive Secretary, Advisory Committee on Blood Safety and Availability, Department of Health and Human Services, Office of Public Health and Science, 1101 Wootton Parkway, Room 275, Rockville, MD 20852, (301) 443-2331, FAX (301) 443-4361, e-mail: jholmberg@osophs.dhhs.gov.

Dated: July 29, 2004.

Jerry A. Holmberg,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0331]

Determination That Esmolol Hydrochloride Injection and Ketorolac Tromethamine Injection Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the two drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) for the drug products, and it will allow FDA to continue to approve ANDAs for the products.

FOR FURTHER INFORMATION CONTACT:

Mary Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the