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.

[FR Doc. 04–17695 Filed 8–3–04; 8:45 am]

BILLING CODE 6210–01–S

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.

[FR Doc. 04–17697 Filed 8–3–04; 8:45 am]

BILLING CODE 4150–28–P

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

agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that referred to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in table 1 of this document have been withdrawn from sale.

TABLE 1.

Application No.	Drug	Applicant
19–386	BREVIBLOC (esmolol HCl) Injection, 10 milligram (mg)/milliliter (mL) (formulation without sodium chloride)	Baxter Healthcare Corp., Route 120 and Wilson Rd., RLT–10, Round Lake, IL 60073–0490
19–698	TORADOL IV/IM (ketorolac tromethamine injection), 15 mg/mL and 30 mg/mL (formulations with and without citric acid)	Roche Pharmaceuticals, 340 Kingsland St., Nutley, NJ 07110–1199

FDA has reviewed our records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list these drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. Approved ANDAs that refer to the NDAs listed in this document are unaffected by the withdrawal of the products subject to those NDAs. Additional ANDAs for the products may also be approved by the agency.

Dated: July 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–17692 Filed 8–3–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services (DHHS).

Date and Time: The meeting will be held on September 15, 2004, from 8 a.m. to 1 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Jan N. Johannessen, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 17–51), Rockville, MD 20857, 301–827–6687, e-mail: *jjohannessen@fda.gov*, or FDA Advisory Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) The recommendation of the Pediatric Ethics Subcommittee from its meeting on September 10, 2004, regarding a referral by an Institution Review Board under 21 CFR 50.54 and 45 CFR 46.407 of a proposed clinical investigation that involves both an FDA-regulated product and research involving children as subjects that is conducted or supported by the DHHS, and (2) a report by the agency on Adverse Event Reporting, as mandated in section 17 of the Best Pharmaceuticals for Children Act, for PULMICORT/RHINOCORT (budesonide), CLARINEX (desloratadine), CUTIVATE/FLONASE/FLOVENT (fluticasone), OCULFOX (ofloxacin), FLUDARA (fludarabine), and FOSAMAX (alendronate).

The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee (PAC) docket Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2004 and scroll down to PAC meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 1, 2004. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 1, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jan N. Johannessen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 29, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–17823 Filed 7–30–04; 3:41 pm]

BILLING CODE 4160–01–S