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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that referred to the listed drug have been approved.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FDA has become aware that the drug products listed in table 1 of this document have been withdrawn from sale.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has reviewed our records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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]

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