

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0331]

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Determination That Esmolol Hydrochloride Injection and Ketorolac Tromethamine Injection Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the two drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

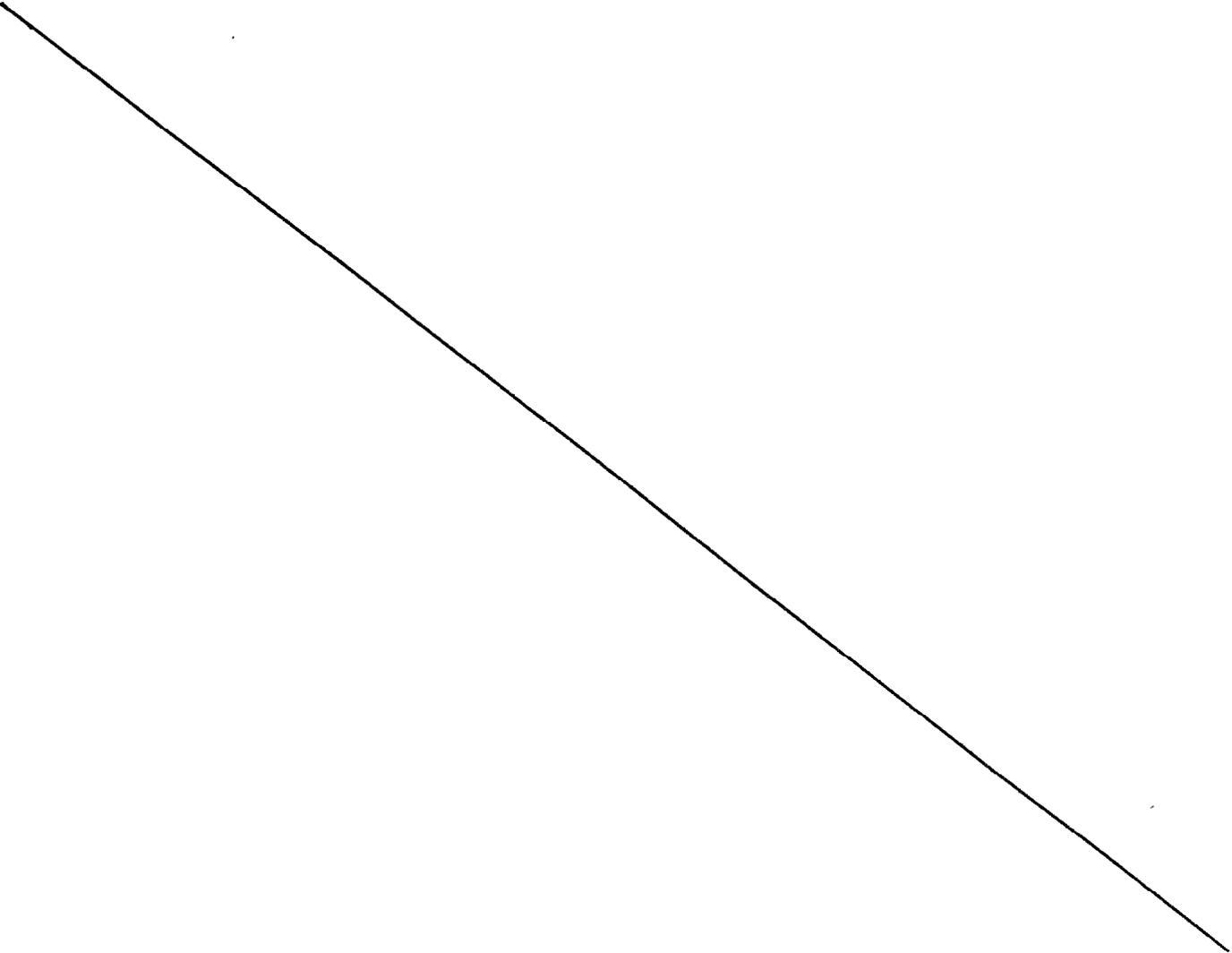
Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that referred 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: 7/27/04

July 27, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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