

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0506]

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cc A. Corbin

Determination That ATROVENT (Ipratropium Bromide) Inhalation Solution and 10 Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the 11 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993-0002, 301-796-3601.

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

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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 (the 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 Under FDA regulations, a drug is withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the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 (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; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR § 10.25(a) and § 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, 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 the table in this document are no longer being marketed. (As requested by the applicant, FDA

withdrew approval of NDA 20-228 for ATROVENT (ipratropium bromide) Inhalation Solution in the **Federal Register** of November 7, 2007 (72 FR 62858).)

Application No.	Drug	Applicant
NDA 20-228	ATROVENT (ipratropium bromide) Inhalation Solution, 0.02%	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877-0368
NDA 20-306	Fludeoxyglucose F-18 (4-40 millicuries (mCi)/milliliter (mL) and 4-90 mCi/mL) Injection	Downstate Clinical PET Center, Methodist Medical Center, 112 Crescent Ave., Peoria, IL 61606
NDA 20-333	AGRYLIN (anagrelide hydrochloride (HCl)) Capsules, equivalent to (EQ) 1 milligram (mg) base	Shire US Inc., 725 Chesterbrook Blvd., Wayne, PA 19087-5637
NDA 20-377	CORDARONE (amiodarone HCl) Injection, 50 mg/mL	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101-8299
NDA 20-974	PROZAC (fluoxetine HCl) Tablets, EQ 10 mg base	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 50-417	NEOSPORIN (bacitracin zinc; neomycin sulfate; polymyxin B sulfate) Ophthalmic Ointment, 400 units/gram (g); EQ 3.5 mg base/g; 10,000 units/g	Monarch Pharmaceuticals, Inc., c/o King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620
NDA 50-461	ANCEF (cefazolin sodium) Injection, 250 mg/vial, 500 mg/vial, and 5 g/vial	GlaxoSmithKline, 2301 Renaissance Blvd., King of Prussia, PA 19406
NDA 50-521	CECLOR (cefactor) Capsules, EQ 250 mg and 500 mg base	Eli Lilly and Co.
NDA 50-522	CECLOR (cefactor) Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL	Do.
NDA 50-527	DURICEF (cefadroxil) Oral Suspension, EQ 125 mg base/5 mL	Warner Chilcott, Inc., Rockaway 80 Corporate Center, 100 Enterprise Dr., suite 280, Rockaway, NJ 07866
ANDA 61-229	POLYSPORIN (bacitracin zinc; polymyxin B sulfate) Ophthalmic Ointment, 500 units/g; 10,000 units/g	Monarch Pharmaceuticals, Inc.

FDA has reviewed its 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 the drug products listed in this document 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 discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the agency if they comply with relevant legal and regulatory requirements.

If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: 9/24/08
September 24, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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