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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0336]

Determination That Bzotropine Mesylate Tablets and Nine Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the 10 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. These are drug products with approved new drug applications (NDAs) to which one or more approved abbreviated new drug applications (ANDAs) refer. This determination means that the approval status of the ANDAs is unaffected by the withdrawal from sale of the reference product.

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 (the 1984 amendments) (Public Law 98-417), 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 under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an 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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

If a listed drug is withdrawn from sale and there are approved ANDAs that refer to that drug, under § 314.161(a)(2) (21 CFR 314.161(a)(2)), the agency must determine whether the listed drug was withdrawn from sale for reasons of safety or effectiveness. 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.

The holders of the applications listed in the table in this document have informed FDA that the drug products have been withdrawn from sale. The drug products in the table are subjects of approved NDAs to which one or more approved ANDAs refer.

NDA No	Drug	Applicant
9-193	Cogentin (benztropine mesylate) Tablets, 0.5, 1, and 2 milligrams (mg).	Merck & Co., Inc., BLA-20, P.O. Box 4, West Point, GA 19486-0004
11-835	HydroDiurni (hydro-chlorothiazide) Tablets, 25, 50, and 100 mg	Do
12-383	Colbenemid (colchicine, probenecid) Tablets, 0.5 mg, 500 mg	Do
15-921	Haldol (haloperidol) Tablets, 0.5, 1, 2, 5, 10, and 20 mg	Ortho-McNeil Pharmaceutical, Inc. 1000 Route 202, P.O. Box 600, Raritan, NJ 08869-0600
17-657	Cephulac (lactulose) Solution, 10 grams/15 mL.	Aventis Pharmaceuticals, 300 Somerset Corporate Blvd., Bridgewater, NJ 08807-2854
17-814	Indocin (indomethacin) Suppositories, 50 mg	Merck & Co., Inc.
17-851	Lioresal (baclofen) Tablets, 10 and 20 mg	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936.
18-654	Versed (midazolam hydrochloride (HCl)) Injection, 1 mg/mL and 5 mg/mL.	Roche Pharmaceuticals, Division of Hoffmann-LaRoche, Inc., 340 Kingsland St., Nutley, NJ 07110
20-095	Zantac (ranitidine HCl) Gelcapsules, 150 and 300 mg	GlaxoSmithKline, P.O. Box 13398, Five Moore Dr., Research Triangle Park, NC 27709.
20-942	Versed (midazolam HCl) Syrup, 2 mg/mL.	Roche Pharmaceuticals.

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. Approved ANDAs that refer to the NDAs listed in this document are unaffected by the withdrawal of the products subject to those NDAs, and 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.

Dated: 7/28/03
July 28, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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