4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1139]

Determination That DRIXORAL (Dexbrompheniramine Maleate; Pseudoephedrine Sulfate) Tablet and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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SUMMARY: The Food and Drug Administration (FDA) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6223, Silver Spring, MD 20993-0002, 301-796-5418, Amy.Hopkins@fda.hhs.gov.

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 applicants 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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

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of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 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 the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 013483	DRIXORAL (dexbrompheniramine maleate and pseudoephedrine sulfate) Tablet, Extended Release; Oral, 6 milligrams (mg)/120 mg	MSD Consumer Care Inc., 556 Morris Ave., Summit, NJ 07901

Application No.	Drug	Applicant
NDA 014685	AVENTYL (nortriptyline hydrochloride (HCl)) Solution; Oral, Equivalent to (EQ) 10 mg Base/5mL	Ranbaxy Pharmaceuticals Inc., 600 College Rd. East, Princeton, NJ 08540
NDA 016418	INDERAL (propranolol HCl) Tablet; Oral, 80 mg	Wyeth Pharmaceuticals Inc., C/O Pfizer Inc., 235 East 42nd St., New York, NY 10017
NDA 016909	LIDEX (fluocinonide) Ointment; Topical 0.05%	County Line Pharmaceuticals, LLC, 13890 Bishop's Dr., Suite 410, Brookfield, WI 53005
NDA 017373	LIDEX (fluocinonide) Gel; Topical 0.05%	Do.
NDA 020073	ROMAZICON (flumazenil) Injectable; Injection, 1 mg/10 milliliters (mL) (0.1 mg/mL); 0.5 mg/5 mL (0.1 mg/mL)	Hoffmann-La Roche Inc., C/O Genentech Inc., 1 DNA Way, South San Francisco, CA 94080-4990
NDA 020229	LEUSTATIN (cladribine) Injectable; Injection, 1 mg/mL	Janssen Pharmaceuticals Inc., C/O Johnson and Johnson Pharmaceutical Research and Development LLC, 920 Rt. 202 South, PO Box 300, Raritan, NJ 08869
NDA 020347	HYTRIN (terazosin HCl) Capsule; Oral, EQ 1 mg Base; EQ 2 mg Base; EQ 5 mg Base; EQ 10 mg Base	Abbott Laboratories Pharmaceutical Products Division, Dept. 491 AP6B 1, Abbott Park, IL 60064
NDA 020560	FOSAMAX (alendronate sodium) Tablet; Oral, EQ 5 mg Base; EQ 10 mg Base; EQ 35 mg Base; EQ 40 mg Base	Merck and Co. Inc., 126 East Lincoln Ave., RY 33 212, PO Box 2000, Rahway, NJ 07065-0900
NDA 020813	KLONOPIN (clonazepam) Tablet, Orally Disintegrating Tablet (ODT); Oral, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, 2 mg	Hoffmann-La Roche Inc., 340 Kingsland St., Nutley, NJ 07110
NDA 021046	CELEXA (citalopram hydrobromide) Solution; Oral, EQ 10 mg Base/5 mL	Forest Laboratories Inc., Harborside Financial Center, Plaza V, Suite 1900, Jersey City, NJ 07311
NDA 022246	METOZOLV ODT (metoclopramide HCl) Tablet, ODT; Oral, EQ 10 mg Base	Salix Pharmaceuticals Inc., 8510 Colonnade Center Dr., Raleigh, NC 27615
NDA 050533	VIBRA-TABS (doxycycline hyclate) Tablet; Oral, EQ 100 mg Base	Pfizer Laboratories Inc., 235 East 42nd St., New York, NY 10017

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: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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