4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1577]

Determination That TOPICORT (Desoximetasone) Cream and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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SUMMARY: The Food and Drug Administration (FDA) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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. (As requested by the applicant, FDA withdrew approval of NDA 020611 for DOVONEX (calcipotriene) Solution and NDA 020239 for KYTRIL (granisetron hydrochloride) in the Federal Register of July 19, 2013 (78 FR 43210)).

Application No.	Drug	Applicant
NDA 017856	TOPICORT (desoximetasone) Cream; Topical 0.25%	Taro Pharmaceuticals North America Inc., 5 Skyline Dr.,

Application No.	Drug	Applicant
		Hawthorne, NY 10532
NDA 020239	KYTRIL (granisetron HCl) Injectable; Injection, Equivalent to (EQ) 0.1 milligram (mg) Base/milliliter (mL); EQ 1 mg Base/mL; EQ 3 mg Base/mL; EQ 4 mg Base/4 mL	Hoffmann La Roche Inc., 340 Kingsland St., Nutley, NJ 07110
NDA 020611	DOVONEX (calcipotriene) Solution; Topical, 0.005%	Leo Pharma Inc., 1 Sylvan Way, Parsippany, NJ 07054
NDA 021275	LUMIGAN (bimatoprost) Solution/Drops; Ophthalmic, 0.03%	Allergan Inc., 2525 Dupont Dr., Irvine, CA 92623
NDA 021864	LYBREL (ethinyl estradiol; levonorgestrel) Tablet; Oral, 0.02 mg/0.09 mg	Wyeth Pharmaceuticals Inc., P.O. Box 8299, Philadelphia, PA 19101
ANDA 075222	Ketorolac Tromethamine Injectable; Injection, 15 mg/mL; 30 mg/mL	Bedford Laboratories Inc., 300 Northfield Rd., Bedford, OH 44146
ANDA 075228	Ketorolac Tromethamine Injectable; Injection, 30 mg/mL	Do.

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 and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. 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: October 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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