4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0924]

Determination That LIDEX (fluocinonide) Cream and LIDEX-E (fluocinonide) Cream and Nine Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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SUMMARY: The Food and Drug Administration (FDA) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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: Mark Geanacopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6206, Silver Spring, MD 20993-0002, 301-796-6925.

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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily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 016908	LIDEX (fluocinonide) Cream; Topical, 0.05%,	Medicis Pharmaceutical Corp., 7720 North Dobson Rd., Scottsdale, AZ 85256
Do.	LIDEX-E (fluocinonide) Cream; Topical, 0.05%	Do.
NDA 018181	MYCELEX (clotrimazole) Solution; Topical, 1%	Bayer Health Care, 100 Bayer Rd., Pittsburgh, PA 15205
NDA 018713	MYCELEX (clotrimazole) Lozenge; Oral, 10 milligrans (mg)	Do.

Application No.	Drug	Applicant
NDA 019510	PEPCID (famotidine) Injection, 10 mg/milliliter (mL)	Merck Research Laboratories, Inc., 770 Sumneytown Pike, West Point, PA 19486
Do.	PEPCID PRESERVATIVE FREE (famotidine) Injection, 10 mg/mL	Do.
NDA 020249	PEPCID PRESERVATIVE FREE IN PLASTIC CONTAINER (famotidine) Injection, 0.4 mg/mL	Do.
NDA 021065	FEMHRT (ethinyl estradiol; norethindrone acetate) Tablet; Oral, 0.005 mg/1 mg	Warner Chilcott LLC, 1 Grand Canal Sq., Docklands, Dublin 2, Ireland
NDA 050763	MITOZYTREX (mitomycin) Injection, 5 mg/vial	SuperGen, Inc., 4140 Dublin Blvd., Suite 200, Dublin, CA 94568
ANDA 086031	ISOSORBIDE DINITRATE (isosorbide dinitrate) Tablet; Sublingual, 5 mg	Watson Laboratories, 577 Chipeta Way, Salt Lake City, UT 84108
ANDA 086033	ISOSORBIDE DINITRATE (isosorbide dinitrate) Tablet; Sublingual, 2.5 mg	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: August 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-20086 Filed 08/16/2013 at 8:45 am; Publication Date: 08/19/2013]