4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4329]

Determination that KENALOG (Triamcinolone Acetonide) Ointment, 0.025% and 0.1%, and Other Drug Products were Not Withdrawn from Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is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

Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 011600	KENALOG	Triamcinolone Acetonide	0.025%; 0.1%	Ointment; Topical	Mylan Pharmaceuticals, Inc.
NDA 012827	ROBINUL ROBINUL FORTE	Glycopyrrolate Glycopyrrolate	1 milligram (mg) 2 mg	Tablet; Oral Tablet; Oral	Casper Pharma LLC

Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 018029	RITALIN-SR	Methylphenidate Hydrochloride	20 mg	Extended-Release Tablet; Oral	Novartis Pharmaceuticals, Corp.
NDA 018164	ANAPROX	Naproxen Sodium	Equivalent to (EQ) 250 mg Base	Tablet; Oral	ATNAHS Pharma U.S., Ltd.
NDA 018405	AYGESTIN	Norethindrone Acetate	5 mg	Tablet; Oral	Teva Branded Pharmaceutical Products R&D, Inc.
NDA 018452	SEPTRA	Sulfamethoxazole; Trimethoprim	16 mg/milliliter (mL); 80 mg/mL	Injectable; Injection	Monarch Pharmaceuticals, Inc.
NDA 018703	ZANTAC 150 ZANTAC 300	Ranitidine Hydrochloride Ranitidine Hydrochloride	EQ 150 mg Base EQ 300 mg Base	Tablet; Oral Tablet; Oral	GlaxoSmithKline
NDA 019111	TUSSIONEX PENNKINETIC	Chlorpheniramine Polistirex; Hydrocodone Polistirex	EQ 8 mg Chlorpheniramine Maleate/5 mL; EQ 10 mg Hydrocodone Bitartrate/5 mL	Extended-Release Suspension; Oral	UCB, Inc.
NDA 019507	KERLONE	Betaxolol Hydrochloride	10 mg; 20 mg	Tablets; Oral	Sanofi-Aventis U.S. LLC
NDA 019537	CIPRO	Ciprofloxacin Hydrochloride	EQ 100 mg Base; EQ 750 mg Base	Tablet; Oral	Bayer Healthcare Pharmaceuticals, Inc.
NDA 019937	ADENOCARD	Adenosine	3 mg/mL	Injectable; Injection	Astellas Pharma U.S., Inc.
NDA 020415	REMERON	Mirtazapine	45 mg	Tablet; Oral	Organon USA, Inc.
NDA 020528	MAVIK	Trandolapril	1 mg; 2 mg; 4 mg	Tablet; Oral	AbbVie, Inc.
NDA 020864	MAXALT	Rizatriptan Benzoate	EQ 5 mg Base	Tablet; Oral	Merck Sharp & Dohme Corp.
NDA 020865	MAXALT-MLT	Rizatriptan Benzoate	EQ 5 mg Base	Orally Disintegrating Tablet; Oral	Do.
NDA 020945	NORVIR	Ritonavir	100 mg	Capsule; Oral	AbbVie, Inc.
NDA 021131	ZYVOX	Linezolid	400 mg/200 mL (2 mg/mL)	Injectable; Injection	Pharmacia & Upjohn Co.
NDA 021381	XYLOCAINE DENTAL WITH EPINEPHRINE	Epinephrine; Lidocaine Hydrochloride	0.01 mg/mL/2%; 0.02 mg/mL/2%	Injectable; Injection	DENTSPLY Pharmaceutical, Inc.
NDA 021511	COPEGUS	Ribavirin	200 mg; 400 mg	Tablet; Oral	Hoffmann La-Roche, Inc.

Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 022325	NEXTERONE	Amiodarone Hydrochloride	50 mg/mL	Injectable; Injection	Baxter Healthcare, Corp.
NDA 050605	CEFTIN	Cefuroxime Axetil	EQ 125 mg Base; EQ 250 mg Base; EQ 500 mg Base	Tablet; Oral	GlaxoSmithKline
NDA 050730	ZITHROMAX	Azithromycin	EQ 600 mg Base	Tablet; Oral	Pfizer, Inc.
NDA 050746	BACTROBAN	Mupirocin Calcium	EQ 2% Base	Cream; Topical	GlaxoSmithKline
NDA 205103	YOSPRALA	Aspirin; Omeprazole	81 mg/40 mg; 325 mg/40 mg	Delayed-Release Tablet; Oral	Genus Lifesciences, Inc.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products 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 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: September 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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