4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0218]

Determination That TRIAMCINOLONE ACETONIDE (Triamcinolone Acetonide) Topical Cream, 0.025% and 0.1%, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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.

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SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved; and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30.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 011601	TRIAMCINOLONE ACETONIDE	Triamcinolone Acetonide	0.025%; 0.1%	Cream; Topical	Mylan
NDA 012575	ACTIFED W/ CODEINE	Codeine Phosphate; Pseudoephedrine Hydrochloride; Triprolidine Hydrochloride	10 Milligrams (mg)/5 Milliliters (mL); 30 mg5 mL; 1.25 mg/5 mL	Syrup; Oral	GlaxoSmithKline
NDA 016267	DESFERAL	Deferoxamine Mesylate	2 Grams (g)/Vial	Injectable; Injection	Novartis
NDA 017922	DDAVP (NEEDS NO REFRIGERATION)	Desmopressin Acetate	0.01 mg/Spray	Spray, Metered; Nasal	Ferring Pharms., Inc.
NDA 018279	K-TAB	Potassium Chloride	8 Milliequivalents	Tablet, Extended Release; Oral	Abbvie
NDA 018830	TAMBOCOR	Flecainide Acetate	200 mg	Tablet; Oral	Alvogen
NDA 018983	COLYTE	Polyethylene Glycol 3350; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Sulfate Anhydrous	227.1 g/Packet, 2.82 g/Packet, 6.36 g/Packet, 5.53 g/Packet, 21.5 g /Packet; 120 g/Packet, 1.49 g/Packet, 3.36 g/Packet, 2.92g/Packet, 11.36g/Packet; 360 g/Packet, 4.47 g/Packet, 10.08 g/Packet, 8.76 g/Packet, 34.08 g/Packet; 240 g/Bottle, 2.98 g/Bottle, 6.72g/Bottle, 5.84 g/Bottle, 22.72 g/Bottle; 227.1 g/Bottle, 2.82 g/Bottle, 6.36g/Bottle, 5.53 g/Bottle, 21.5g/Bottle; 227.1 g/Bottle, 2.82 g/Bottle, 6.36 g/Bottle, 5.53 g/Bottle, 21.5 g/Bottle; 240 g/Bottle, 2.98 g/Bottle, 6.72 g/Bottle, 5.84 g/Bottle, 22.72 g/Bottle	For Solution; Oral	Mylan Specialty, L.P.
NDA 019641	TERAZOL 3	Terconazole	80 mg	Suppository; Vaginal	Janssen Pharms.

NDA 019821	SORIATANE	Acitretin	10 mg; 17.5 mg; 22.5 mg; 25 mg	Capsule; Oral	Stiefel Labs, Inc.
NDA 019898	PRAVACHOL	Pravastatin Sodium	20 mg; 40 mg; 80 mg	Tablet; Oral	Bristol Myers Squibb Co.
NDA 019963	RENOVA	Tretinoin	0.05%	Cream; Topical	Valeant
NDA 020103	ZOFRAN	Ondansetron Hydrochloride	Equivalent to (EQ) 4 mg Base; EQ 8 mg Base; EQ 24 mg Base	Tablet; Oral	Novartis
NDA 020114	ASTELIN	Azelastine Hydrochloride	0.137 mg/Spray	Spray, Metered; Nasal	Mylan Specialty
NDA 020130	ESTROSTEP FE	Ethinyl Estradiol; Norethindrone Acetate	0.02 mg, 0.03 mg, 0.035 mg; 1 mg, 1 mg, 1 mg	Tablet; Oral-28	Apil
NDA 020279	DERMATOP E EMOLLIENT	Prednicarbate	0.1%	Cream; Topical	Valeant Bermuda
NDA 020408	TRUSOPT	Dorzolamide Hydrochloride	EQ 2% Base	Solution/Drops; Ophthalmic	Merck
NDA 020658	REQUIP	Ropinirole Hydrochloride	EQ 0.25 mg Base; EQ 0.5 mg Base; EQ 1; EQ 2 mg Base; EQ 3 mg Base; EQ 4 mg Base; EQ 5 mg Base	Tablet; Oral	GlaxoSmithKline
NDA 020667	MIRAPEX	Pramipexole Dihydrochloride	0.125 mg; 0.25 mg; 0.5 mg; 0.75 mg; 1 mg; 1.5 mg	Tablet; Oral	Boehringer Ingelheim
NDA 020793	CAFCIT	Caffeine Citrate	EQ 30 mg Base/3 mL	Solution; Oral	Hikma
NDA 021076	ALEVE-D SINUS & COLD	Naproxen Sodium; Pseudoephedrine Hydrochloride	220 mg, 120 mg	Tablet, Extended Release; Oral	Bayer
NDA 021158	FACTIVE	Gemifloxacin Mesylate	EQ 320 mg Base	Tablet; Oral	LG Chem. Ltd.
NDA 021513	ENABLEX	Darifenacin Hydrobromide	EQ 7.5 mg Base; EQ 15 mg Base	Tablet, Extended Release; Oral	Apil
NDA 021611	OPANA	Oxymorphone Hydrochloride	5 mg; 10 mg	Tablet; Oral	Endo Pharms.
NDA 021842	ACTOPLUS MET	Metformin Hydrochloride; Pioglitazone Hydrochloride	500 mg; EQ 15 mg Base	Tablet; Oral	Takeda Pharms. USA
NDA 022203	ASTEPRO	Azelastine Hydrochloride	0.137 mg/Spray	Spray, Metered; Nasal	Mylan Specialty
NDA 022434	ARGATROBAN IN SODIUM CHLORIDE	Argatroban	50 mg/50 mL	Injectable; Intravenous	Eagle Pharms.
NDA 050537	CLEOCIN T	Clindamycin Phosphate	EQ 1% Base	Solution; Topical	Pfizer
NDA 050580	AZACTAM	Aztreonam	500 mg/Vial	Injectable; Injection	Bristol Myers Squibb

NDA 204031	XARTEMIS XR	Acetaminophen; Oxycodone Hydrochloride	325 mg; 7.5 mg	Tablet, Extended Release; Oral	Mallinckrodt, Inc.
NDA 209481	VANCOMYCIN HYDROCHLORIDE	Vancomycin Hydrochloride	EQ 250 mg Base/Vial	Powder; Intravenous	Mylan Labs Ltd.
NDA 209905	EVEKEO ODT	Amphetamine Sulfate	2.5 mg	Tablet, Orally Disintegrating; Oral	Azurity

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 drug products listed are unaffected by the discontinued marketing of the products subject to these applications. 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: February 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-02442 Filed: 2/3/2023 8:45 am; Publication Date: 2/6/2023]