



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4758]

Determination That CORTONE (Cortisone Acetate) Tablets and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 007750	CORTONE	Cortisone Acetate	25 milligrams (mg)	Tablet; Oral	Merck & Co., Inc.
NDA 008662	NYDRAZID	Isoniazid	100 mg/milliliter (mL)	Injectable; Injection	Sandoz Canada Inc.

NDA 010571	COMPAZINE	Prochlorperazine Maleate	Equivalent to (EQ) 5 mg Base; EQ 10 mg Base; EQ 25 mg Base	Tablet; Oral	SmithKline Beecham Corporation d/b/a GlaxoSmithKline
NDA 010670	ORINASE	Tolbutamide	250 mg; 500 mg	Tablet; Oral	Pharmacia and Upjohn Co.
NDA 011127	COMPAZINE	Prochlorperazine	2.5 mg; 5 mg; 25 mg	Suppository; Rectal	SmithKline Beecham Corporation d/b/a GlaxoSmithKline
NDA 011808	MELLARIL	Thioridazine Hydrochloride (HCl)	30 mg/mL; 100 mg/mL	Concentrate; Oral	Novartis Pharmaceuticals Corp.
NDA 012145	PROLIXIN	Fluphenazine HCl	2.5 mg/5 mL	Elixir; Oral	Apothecon Inc., Division of Bristol Myers Squibb
NDA 014713	ETRAFON 2-10; ETRAFON 2-25; ETRAFON-A; ETRAFON-FORTE	Perphenazine; Amitriptyline HCl	2 mg/10 mg; 2 mg/25 mg; 4 mg/10 mg; 4 mg/25 mg	Tablet; Oral	Schering Corp.
NDA 014715	TRIAVIL 2-10; TRIAVIL 2-25; TRIAVIL 4-10; TRIAVIL 4-25; TRIAVIL 4-50	Perphenazine; Amitriptyline HCl	2 mg/10 mg; 2 mg/25 mg; 4 mg/10 mg; 4 mg/25 mg; 4 mg/50 mg/	Tablet; Oral	New River Pharmaceuticals Inc.
NDA 015539	SERAX	Oxazepam	10 mg; 15 mg; 30 mg 15 mg	Capsule; Oral Tablet; Oral	Alpharma U.S. Pharmaceuticals Division
NDA 015922	HALDOL	Haloperidol Lactate	EQ 2 mg Base/mL	Concentrate; Oral	Ortho-McNeil Pharmaceutical
NDA 016584	NAVANE	Thiothixene	1 mg; 2 mg; 5 mg; 10 mg; 20 mg	Capsule; Oral	Pfizer Inc.
NDA 016721	DALMANE	Flurazepam HCl	15 mg; 30 mg	Capsule; Oral	Valeant Pharmaceuticals International
NDA 017923	MELLARIL-S	Thioridazine	EQ 25 mg HCl/5 mL; EQ 100 mg HCl/5mL	Suspension; Oral	Novartis Pharmaceuticals Corp.
NDA 018374	BACTRIM	Sulfamethoxazole; Trimethoprim	80 mg/mL; 16 mg/mL	Injectable; Injection	Sun Pharmaceutical Industries, Inc.
NDA 018485	ISOPTIN	Verapamil HCl	2.5 mg/mL	Injectable; Injection	Mt. Adams Technologies LLC
NDA 018596	INTAL	Cromolyn Sodium	10 mg/mL	Solution; Inhalation	King Pharmaceuticals LLC
NDA 018644	WELLBUTRIN	Bupropion HCl	50 mg; 75 mg; 100 mg	Tablet; Oral	GlaxoSmithKline LLC
NDA 019287	DIZAC	Diazepam	5 mg/mL	Injectable; Injection	Pharmacia and Upjohn Co.

NDA 019982	ZEBETA	Bisoprolol Fumarate	5 mg; 10 mg	Tablet; Oral	Teva Branded Pharmaceutical Products R&D, Inc.
NDA 020007	ZOFTRAN; ZOFTRAN PRESERVATIVE FREE	Ondansetron HCl	EQ 2 mg Base/mL	Injectable; Injection	Novartis Pharmaceuticals Corp.
NDA 020205	PSORCON	Diflorasone Diacetate	0.05%	Cream; Topical	Taro Pharmaceuticals North America Inc.
NDA 020947	PENNSAID	Diclofenac Sodium	1.5%	Solution; Topical	Nuvo Pharmaceuticals Inc.
NDA 021575	FOSAMAX	Alendronate Sodium	EQ 70 mg Base/75 mL	Solution; Oral	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
NDA 050542	AMOXIL	Amoxicillin	125 mg; 250 mg	Chewable Tablet; Oral	Dr. Reddy's Laboratories, Inc.
NDA 050564	AUGMENTIN '250'; AUGMENTIN '500'	Amoxicillin; Clavulanate Potassium	250 mg/EQ 125 mg Base; 500 mg/EQ 125 mg Base	Tablet; Oral	Do.
NDA 050581	MEFOXIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER; MEFOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER	Cefoxitin Sodium	EQ 20 mg Base/mL; EQ 40 mg Base/mL; EQ 20 mg Base/mL; EQ 40 mg Base/mL	Injectable; Injection	Merck & Co., Inc.
NDA 050591	BACTROBAN	Mupirocin	2%	Ointment; Topical	SmithKline Beecham (Cork) Ltd., Ireland
NDA 050594	ERYCETTE	Erythromycin	2%	Swab; Topical	Johnson & Johnson Consumer Inc.
NDA 050754	AMOXIL	Amoxicillin	500 mg; 875 mg	Tablet; Oral	Dr. Reddy's Laboratories, Inc.
NDA 050760	AMOXIL	Amoxicillin	200 mg/5 mL; 400 mg/5 mL	For Suspension; Oral	Do.

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 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy,

Planning, Legislation, and Analysis.

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