



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2018-N-4142]**

**Determination that REGITINE (Phentolamine Mesylate) Injection, 5 Milligrams/Vial, and Other Drug Products were Not Withdrawn from Sale for Reasons of Safety or Effectiveness**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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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](mailto: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of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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 008278	REGITINE	Phentolamine Mesylate	5 milligrams (mg)/vial	Injectable; Injection	Novartis Pharmaceuticals Corp.
NDA 011287	KAYEXALATE	Sodium Polystyrene	453.6 grams (g)/bottle	Powder; Oral, Rectal	Concordia Pharmaceuticals,

		Sulfonate			Inc.
NDA 011751	PROLIXIN	Fluphenazine Hydrochloride (HCl)  Fluphenazine HCl	2.5 mg/milliliter (mL)  1 mg; 2.5 mg; 5 mg; 10 mg	Injectable; Injection;  Tablet; Oral	Bristol-Myers Squibb Co.
NDA 012249	LIBRIUM	Chlordiazepoxide HCl	5 mg; 10 mg; 25 mg	Capsule; Oral	Valeant Pharmaceuticals North America, LLC
NDA 016008	PERMITIL	Fluphenazine HCl	5 mg/mL	Concentrate; Oral	Schering Corp., Subsidiary of Schering Plough, Corp.
NDA 016110	PROLIXIN ENANTHATE	Fluphenazine Enanthate	25 mg/mL	Injectable; Injection	Bristol-Myers Squibb Co.
NDA 017007	HEPARIN SODIUM	Heparin Sodium	1,000 units/mL; 2,500 units/mL; 5,000 units/mL; 7,500 units/mL; 10,000 units/mL; 15,000 units/mL; 20,000 units/mL; 5,000 units/0.5 mL;	Injectable; Injection	West-Ward Pharmaceuticals International, Ltd.
NDA 017105	TRANXENE  TRANXENE  TRANXENE SD	Clorazepate Dipotassium  Clorazepate Dipotassium  Clorazepate Dipotassium	3.75 mg; 7.5 mg; 15 mg  3.75 mg; 7.5 mg; 15 mg  11.25 mg; 22.5 mg	Tablet; Oral;  Capsule; Oral;  Tablet; Oral	Recordati Rare Diseases, Inc.
NDA 017488	MODICON 21	Ethinyl Estradiol; Norethindrone	0.035 mg; 0.5 mg	Tablet; Oral	Ortho-McNeil Pharmaceutical, Inc.
NDA 017489	ORTHO-NOVUM 1/35-21	Ethinyl Estradiol; Norethindrone	0.035 mg; 1 mg	Tablet; Oral	Ortho-McNeil Pharmaceutical, Inc.
NDA 017575	DTIC-DOME	Dacarbazine	100 mg/vial; 200 mg/vial	Injectable; Injection	Bayer Healthcare Pharmaceuticals, Inc.
NDA 017576	OVCON-50	Ethinyl Estradiol; Norethindrone	0.05 mg; 1 mg	Tablet; Oral	Warner Chilcott Co., LLC
NDA 017619	LOTRIMIN	Clotrimazole	1%	Cream; Topical	Schering Plough Healthcare Products, Inc.
NDA 017831	DIDRONEL	Etidronate Disodium	200 mg; 400 mg	Tablet; Oral	Allergan Pharmaceuticals International, Ltd.

NDA 018017	BLOCADREN	Timolol Maleate	5 mg; 10 mg; 20 mg	Tablet; Oral	Merck & Co., Inc.
NDA 018052	GYNE-LOTRIMIN	Clotrimazole	1%	Cream; Vaginal	Bayer HealthCare, LLC
NDA 018148	NASALIDE	Flunisolide	0.025 mg/spray	Metered Spray; Nasal	IVAX Research, Inc.
ANDA 018551	POTASSIUM IODIDE	Potassium Iodide	1 g/mL	Solution; Oral	Roxane Laboratories, Inc.
NDA 019004	ORTHO-NOVUM 7/14-28	Ethinyl Estradiol; Norethindrone	0.035 mg/0.5 mg; 0.035 mg/1 mg	Tablet; Oral	Ortho-McNeil Pharmaceutical, Inc.
	ORTHO-NOVUM 7/14-21	Ethinyl Estradiol; Norethindrone	0.035 mg/0.5 mg; 0.035 mg/1 mg		
NDA 019309	VASOTEC	Enalaprilat	1.25 mg/mL	Injectable; Injection	Biovail Laboratories International SRL
NDA 019621	VENTOLIN	Albuterol Sulfate	Equivalent to (EQ) 2 mg base/5 mL	Syrup; Oral	GlaxoSmithKline
NDA 019847	CIPRO	Ciprofloxacin	400 mg/40 mL; 200 mg/20 mL; 1200 mg/120 mL	Injectable; Injection	Bayer Healthcare Pharmaceuticals, Inc.
NDA 019857	CIPRO IN DEXTROSE 5% IN PLASTIC CONTAINER	Ciprofloxacin	200 mg/100 mL; 400 mg/200 mL	Injectable; Injection	Bayer Healthcare Pharmaceuticals, Inc.
NDA 019972	OCUPRESS	Carteolol HCl	1%	Solution/Drops; Ophthalmic	Novartis Pharmaceuticals, Corp.
NDA 020107	NOVAMINE 15% SULFITE FREE IN PLASTIC CONTAINER	Amino Acids	15%	Injectable; Injection	Baxter Healthcare, Corp.
NDA 020207	ALKERAN	Melphalan HCl	EQ 50 mg base/vial	Injectable; Injection	Apotex, Inc.
NDA 020261	LESCOL	Fluvastatin Sodium	EQ 20 mg base; EQ 40 mg base	Capsule; Oral	Novartis Pharmaceuticals, Corp.
NDA 020264	MEGACE	Megestrol Acetate	40 mg/mL	Suspension; Oral	Bristol-Myers Squibb Co.
NDA 020363	FAMVIR	Famciclovir	125 mg; 250 mg; 500 mg	Tablet; Oral	Novartis Pharmaceuticals, Corp.
NDA 020792	CARDIZEM	Diltiazem HCl	100 mg/vial	Injectable; Injection	Biovail Laboratories, Inc.
NDA 021127	OPTIVAR	AzelaStine HCl	0.05%	Solution/Drops; Ophthalmic	Mylan Specialty, L.P.

NDA 021178	GLUCOVANCE	Glyburide; Metformin HCl	2.5 mg/500 mg; 5 mg/500 mg	Tablet; Oral	Bristol-Myers Squibb Co.
NDA 21277	AVELOX IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER	Moxifloxacin HCl	400 mg/250 mL	Solution; IV Infusion	Bayer HealthCare Pharmaceuticals, Inc.
NDA 021406	FORTICAL	Calcitonin Salmon Recombinant	200 international units/spray	Metered Spray; Nasal	Upsher-Smith Laboratories, LLC
NDA 021530	MOBIC	Meloxicam	7.5 mg/5 mL	Suspension; Oral	Boehringer Ingelheim Pharmaceuticals, Inc.
NDA 021689	NEXIUM IV	Esomeprazole Sodium	EQ 20 mg base/vial	Injectable; Intravenous	AstraZeneca Pharmaceuticals LP
NDA 022033	LUVOX CR	Fluvoxamine Maleate	100 mg; 150 mg	Extended- Release Capsule; Oral	Jazz Pharmaceuticals, Inc.
NDA 050299	NILSTAT	Nystatin	100,000 units/mL	Suspension; Oral	Glenmark Generics Inc., USA
NDA 050484	CERUBIDINE	Daunorubicin HCl	EQ 20 mg base/vial	Injectable; Injection	Wyeth Research
NDA 050662	BIAXIN	Clarithromycin	250 mg; 500 mg	Tablet; Oral	AbbVie, Inc.
ANDA 060076	STREPTOMYCIN SULFATE	Streptomycin Sulfate	EQ 1g base/vial; EQ 5 g base/vial	Injectable; Injection	Pfizer, Inc.
ANDA 080472	HYTONE	Hydrocortisone	1%, 2.5%	Cream; Topical	Valeant Pharmaceuticals North America, LLC
ANDA 080473	HYTONE	Hydrocortisone	1%; 2.5%	Lotion; Topical	Valeant Pharmaceuticals North America, LLC
ANDA 080474	HYTONE	Hydrocortisone	1%, 2.5%	Ointment; Topical	Dermik Laboratories, Inc.
NDA 202088	SUPRENZA	Phentermine HCl	15 mg; 30 mg; 37.5 mg	Orally Disintegrating Tablet; Oral	Citius Pharmaceuticals, LLC

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: November 13, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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