and thus is not a regulatory action for the purposes of E.O. 13771.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Dated: October 19, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–25012 Filed 11–16–18; 8:45 am]

BILLING CODE 4120–01–P

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Determination That REGITINE (Phentolamine Mesylate) Injection, 5 Milligrams/Vial, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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*.

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 Sulfonate.	453.6 grams (g)/bottle	Powder; Oral, Rectal	Concordia Pharmaceuticals, Inc.
NDA 011751.	PROLIXIN	Fluphenazine Hydrochloride (HCl).	2.5 mg/milliliter (mL)	Injectable; Injection;	Bristol-Myers Squibb Co.
			1 mg; 2.5 mg; 5 mg; 10 mg.	Tablet; Oral	
		Fluphenazine HCl			
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	Clorazepate Dipotassium.	3.75 mg; 7.5 mg; 15 mg	Tablet; Oral;	Recordati Rare Diseases, Inc.
	TRANXENE		3.75 mg; 7.5 mg; 15 mg	Capsule; Oral;	
	TRANXENE SD	Clorazepate Dipotassium.	11.25 mg; 22.5 mg	Tablet; Oral	
		Clorazepate Dipotassium.			
NDA 017488.	MODICON 21	Ethinyl Estradiol; Norethindrone.	0.035 mg; 0.5 mg	Tablet; Oral	Ortho-McNeil Pharmaceutical, Inc.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
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.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
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.

[FR Doc. 2018–25187 Filed 11–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3771]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct is on the FDA's ''Postmarketing Requirements and Commitments: Reports'' web page (*https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Post-marketing PhaseIVCommitments/ucm064436.htm*).

FOR FURTHER INFORMATION CONTACT: Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 506B(c) of the FD&C Act (21 U.S.C. 356b(c)) requires FDA to publish an annual report on the status of postmarketing study commitments that applicants have committed to, or are required to conduct, and for which annual status reports have been submitted.

Under §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70), applicants of approved drugs and licensed biologics are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA (PMRs) or that they have committed to conduct (PMCs), either at the time of approval or after approval of their new drug application, abbreviated new drug application, or biologics license application. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act (21 U.S.C. 355(o)(3)(E)) requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial ''otherwise undertaken . . . to investigate a safety issue . . .''

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval[1] until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information.

II. Fiscal Year 2017 Report

With this notice, FDA is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Information in this report covers any PMR/PMC that was established, in writing, at the time of approval or after approval of an application or a supplement to an application, and summarizes the status of PMRs/PMCs in fiscal year (FY) 2017 (*i.e.,* as of September 30, 2017). Information summarized in the report reflects combined data from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and includes the following: (1) The number of applicants with open PMRs/PMCs; (2) the number of open PMRs/PMCs; (3) the timeliness of applicant submission of the annual status reports

[1] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.