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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1551]

Determination that DEMEROL (Meperidine Hydrochloride) Injectable and Other Drug Products Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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. Through this notice, FDA is hoping to stimulate the economy and increase the regulatory certainty with respect to generic versions of these drug products by confirming that generic versions of the subject drug products may continue to be marketed.

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 in this document are no longer being marketed.

Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 005010	DEMEROL	Meperidine Hydrochloride	50 milligrams (mg)/5 milliliter (mL)	Syrup; Oral	U.S. Pharmaceutical Holdings II, LLC
NDA 006035	METHERGINE	Methylergonovine Maleate	0.2 mg	Tablet; Oral	Edison Therapeutics LLC
NDA 007337	PERCODAN and PERCODAN-DEMI	Aspirin, Oxycodone Hydrochloride, Oxycodone Terephthalate	325 mg, 4.5 mg, 0.38 mg; and 325 mg, 2.25 mg, 0.19 mg	Tablet; Oral	Endo Pharmaceuticals Inc.
NDA 008720	LEVO-DROMORAN	Levorphanol Tartrate	2 mg	Tablet; Oral	Valeant Pharmaceuticals North America LLC.
NDA 008848	PAMINE and PAMINE FORTE	Methscopolamine Bromide	2.5 mg and 5 mg	Tablet; Oral	Fougera Pharmaceuticals Inc.
NDA 009470	XYLOCAINE VISCOUS	Lidocaine Hydrochloride	2%	Solution; Oral	Fresenius Kabi USA, LLC
NDA 010485	ATARAX	Hydroxyzine Hydrochloride	10 mg/5 mL	Syrup; Oral	Pfizer Inc.
NDA 010742	COMPAZINE	Prochlorperazine Edisylate	Equivalent to (EQ) 5 mg Base/mL	Injectable; Injection	GlaxoSmithKline
NDA 012111	MYDRIACYL	Tropicamide	0.5%; 1%	Solution/Drops; Ophthalmic	Alcon Laboratories Inc.
NDA 012248	PLEGINE	Phendimetrazine Tartrate	35 mg	Tablet; Oral	Wyeth Ayerst Laboratories
NDA 012365	SOMA COMPOUND	Aspirin; Carisoprodol	325 mg; 200 mg	Tablet; Oral	Meda Pharmaceuticals Inc.
NDA 012366	SOMA COMPOUND W/CODEINE	Aspirin; Carisoprodol; Codeine Phosphate	325 mg; 200 mg; 16 mg	Tablet; Oral	Ditto
NDA 016012	VIVACTIL	Protriptyline Hydrochloride	5 mg; 10 mg	Tablet; Oral	Teva Women's Health, Inc.
NDA 017352	FASTIN	Phentermine Hydrochloride	30 mg	Capsule; Oral	GlaxoSmithKline
NDA 017690	IMODIUM	Loperamide Hydrochloride	2 mg	Capsule; Oral	Johnson & Johnson Consumer Inc.
NDA 017694	IMODIUM	Loperamide Hydrochloride	2 mg	Capsule; Oral	Ditto
NDA 017741	FLORONE	Diflorasone Diacetate	0.05%	Cream; Topical	Pharmacia and Upjohn Co.
NDA 017802	LO/OVRAL-28	Ethinyl Estradiol; Norgestrel	0.03 mg; 0.3 mg	Tablet; Oral-28	Wyeth Pharmaceuticals Inc.
NDA 017857	STADOL	Butorphanol Tartrate	2 mg/mL	Injectable; Injection	Delcor Asset Corporation
NDA 017857	STADOL PRESERVATIVE FREE	Butorphanol Tartrate	1 mg/mL; 2 mg/mL	Injectable; Injection	Ditto

NDA 018342	WELLCOVORIN	Leucovorin Calcium	EQ 5 mg Base; EQ 25 mg Base	Tablet; Oral	GlaxoSmithKline
NDA 018353	FLAGYL I.V.	Metronidazole Hydrochloride	EQ 500 mg Base/Vial	Injectable; Injection	G.D. Searle LLC, a subsidiary of Pfizer Inc.
NDA 018733	TALWIN NX	Naloxone Hydrochloride; Pentazocine Hydrochloride	EQ 0.5 mg Base; EQ 50 mg Base	Tablet; Oral	Sanofi-Aventis U.S. LLC
NDA 019488	CARDENE	Nicardipine Hydrochloride	20 mg; 30 mg	Capsule; Oral	Chiesi USA, Inc.
NDA 019578	MEFLOQUINE HYDROCHLORIDE	Mefloquine Hydrochloride	250 mg	Tablet; Oral	U.S. Army Walter Reed Army Institute Research
NDA 019591	LARIAM	Mefloquine Hydrochloride	250 mg	Tablet; Oral	Hoffmann-La Roche Inc.
NDA 019735	FLOXIN	Ofloxacin	200 mg; 300 mg; 400 mg	Tablet; Oral	Janssen Pharmaceuticals, Inc.
NDA 019890	STADOL	Butorphanol Tartrate	1 mg/Spray	Spray, Metered; Nasal	Bristol-Myers Squibb Co.
NDA 020142	CATAFLAM	Diclofenac Potassium	50 mg	Tablet; Oral	Novartis Pharmaceuticals Corp.
NDA 020254	VOLTAREN-XR	Diclofenac Sodium	100 mg	Extended-Release Tablet; Oral	Ditto
NDA 020312	UNIVASC	Moexipril Hydrochloride	7.5 mg; 15 mg	Tablet; Oral	UCB, Inc.
NDA 020346	ZYRTEC	Cetirizine Hydrochloride	5 mg/5 mL	Syrup; Oral	Johnson & Johnson Consumer Inc.
NDA 020584	LODINE XL	Etodolac	400 mg; 500 mg; 600 mg	Extended-Release Tablet; Oral	Wyeth Pharmaceuticals Inc.
NDA 020625	ALLEGRA	Fexofenadine Hydrochloride	60 mg	Capsule; Oral	Sanofi-Aventis U.S. LLC
NDA 020729	UNIRETIC	Hydro chlorothiazide; Moexipril Hydrochloride	12.5 mg/7.5 mg; 12.5 mg/ 15 mg; 25 mg/15 mg	Tablet; Oral	UCB, Inc.
NDA 021066	ZADITOR	Ketotifen Fumarate	EQ 0.025% Base	Solution/Drops; Ophthalmic	Alcon Pharmaceuticals, Ltd.
NDA 021224	RAZADYNE	Galantamine Hydrobromide	4 mg/mL	Solution; Oral	Janssen Pharmaceuticals, Inc.
NDA 021378	COMBUNOX	Ibuprofen; Oxycodone Hydrochloride	400 mg; 5 mg	Tablet; Oral	Forest Laboratories, Inc.
NDA 021473	CIPRO XR	Ciprofloxacin; Ciprofloxacin Hydrochloride	212.6 mg; EQ 287.5 mg Base; 425.2 mg; EQ 574.9 mg Base	Extended-Release Tablet; Oral	Bayer HealthCare Pharmaceuticals, Inc.

NDA 021606	ZEMPLAR	Paricalcitol	4 micrograms (mcg)	Capsule; Oral	AbbVie Inc.
NDA 021729	ABILIFY	Aripiprazole	10 mg and 15 mg	Tablet, Orally Disintegrating; Oral	Otsuka Pharmaceutical Co., Ltd.
NDA 050072	PENBRITIN-S	Ampicillin Sodium	EQ 125 mg Base/Vial; EQ 250 mg Base/Vial; EQ 500 mg Base/Vial; EQ 1 gram (g) Base/Vial; EQ 2 g Base/Vial; EQ 4 g Base/Vial	Injectable; Injection	Wyeth Ayerst Laboratories
NDA 050309	POLYCILLIN-N	Ampicillin Sodium	EQ 125 mg Base/Vial; EQ 250 mg Base/Vial; EQ 500 mg Base/Vial; EQ 1 g Base/Vial; EQ 2 g Base/Vial	Injectable; Injection	Bristol Laboratories Inc.
NDA 050674	VANTIN	Cefpodoxime Proxetil	EQ 100 mg Base; EQ 200 mg Base	Tablet; Oral	Pharmacia and Upjohn Co.
ANDA 064170	CEFAZOLIN SODIUM	Cefazolin Sodium	EQ 10 g Base/Vial; EQ 20 g Base/Vial	Injectable; Injection	Fresenius Kabi USA, LLC
ANDA 075406	OGESTREL 0.5/50-21	Ethinyl Estradiol; Norgestrel	0.05 mg; 0.5 mg	Tablet; Oral-21	Watson Laboratories, Inc.
ANDA 085106	PERCOCET	Acetaminophen; Oxycodone Hydrochloride	325 mg; 5 mg	Tablet; Oral	Vintage Pharmaceuticals LLC
ANDA 089351	ROXICET	Acetaminophen; Oxycodone Hydrochloride	325 mg/5 mL; 5 mg/5 mL	Solution; Oral	West-Ward Pharmaceuticals International Ltd.
ANDA 089456	PERPHENAZINE	Perphenazine	8 mg	Tablet; Oral	ANI Pharmaceuticals, Inc.
ANDA 089457	PERPHENAZINE	Perphenazine	16 mg	Tablet; Oral	Teva Pharmaceuticals USA
ANDA 089707	PERPHENAZINE	Perphenazine	2 mg	Tablet; Oral	Ditto
ANDA 089708	PERPHENAZINE	Perphenazine	4 mg	Tablet; Oral	Do.

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

document 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 in this document 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.

This is not a significant regulatory action subject to Executive Order 12866, and does not impose any additional burden on regulated entities.

Dated: April 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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