4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0508]

Parke-Davis, Subsidiary of Pfizer, Inc. et al.; Withdraw of Approval of 38 New Drug Applications and 43 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 38 new drug applications (NDAs) and 43 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an

application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Table 1

Application No.	Drug	Applicant
NDA 010151	Dilantin (phenytoin sodium) Injection USP, 50 milligrams (mg)/milliliter (mL)	Parke-Davis, Subsidiary of Pfizer, Inc., 235 East 42nd St., New York, NY 10017
NDA 011903	Zolyse (chymotrypsin) for Ophthalmic Solution, 750 units/vial	Alcon Laboratories, Inc., 6201 S. Freeway, TC-45, Fort Worth, TX 76134-2099
NDA 012125	Carbocaine (mepivacaine hydrochloride (HCl)) Injection USP, 3% Carbocaine with Neo-Cobefrin (mepivacaine HCl; levonordefrin) Injection USP, 2%; 0.05 mg/mL	Hospira Inc., 8401 W. 102nd St., Pleasant Prairie, WI 53158
NDA 012516	Sansert (methysergide maleate) Tablets, 2 mg	Novartis Pharmaceuticals Corp., One Health Pl., East Hanover, NJ 07936-1080
NDA 016774	Serentil (mesoridazine besylate) Tablets, Equivalent to (EQ) 10 mg base, 25 mg base, 50 mg base, and 100 mg base	Do.
NDA 016775	Serentil (mesoridazine besylate) Injection, EQ 25 mg base/mL	Do.
NDA 016793	Cytosar-U (cytarabine) for Injection USP, 100 mg/vial, 500 mg/vial, 1 gram (g)/vial, and 2 g/vial	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
NDA 016997	Serentil (mesoridazine besylate) Oral Concentrate, EQ 25 mg base/mL	Novartis Pharmaceuticals Corp.
NDA 017364	Aquatensen (methyclothiazide) Tablets USP, 5 mg	Meda Pharmaceuticals, Inc., 265 Davidson Ave., Suite 400, Somerset, NJ 08873
NDA 017575	DTIC-Dome (dacarbazine) for Injection, 100 mg/vial and 200 mg/vial	Bayer Healthcare Pharmaceuticals, Inc., 100 Bayer Blvd., Whippany, NJ 07981
NDA 017717	Gyne-Lotrimin (clotrimazole) Vaginal Tablets, 100 mg	Bayer HealthCare, LLC, 100 Bayer Blvd., P.O. Box 915, Whippany, NJ 07981-0915
NDA 017869	Funduscein-25 (fluorescein sodium) Injection, 25%	Novartis Pharmaceuticals Corp.
NDA 017993	Hydergine (ergoloid mesylates) Tablets, 0.5 mg and 1 mg	Do.
NDA 018052	Gyne-Lotrimin (clotrimazole) Vaginal Cream, 1%	Bayer HealthCare, LLC
NDA 018128	Ovcon-50 (norethindrone and ethinyl estradiol) Tablets USP (21-Day Regimen), 1 mg and 0.05 mg	Warner Chilcott Co., LLC, c/o Warner Chilcott (US), LLC, 100 Enterprise Dr., Rockaway, NJ 07866
NDA 018397	Chlor-Trimeton (chlorpheniramine maleate and pseudoephedrine sulfate) Extended-Release Tablets, 8 mg and	Bayer HealthCare, LLC

Application No.	Drug	Applicant
	120 mg	
NDA 018418	Hydergine (ergoloid mesylates) Oral Solution, 1 mg/mL	Novartis Pharmaceuticals Corp.
NDA 018439	Multi-Vitamins Concentrate for Infusion, Injection	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
NDA 018471	Ocuclear (oxymetazoline HCl) Ophthalmic Solution, 0.025%	Bayer HealthCare, LLC
NDA 018517	Metronidazole Tablets USP, 250 mg and 500 mg	IVAX Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
NDA 018969	Liposyn III 10% (soybean oil) Injection, 10%	Hospira, Inc.
NDA 020045	Shade UVAGuard (avobenzone, octinoxate, oxybenzone) Lotion, 3%/7.5%/3%	Bayer HealthCare, LLC
NDA 020289	Gyne-Lotrimin Combination Pack (clotrimazole) Vaginal Cream and Vaginal Tablets, 1% and 100 mg	Do.
NDA 020421	Femstat-3 (butoconazole nitrate) Vaginal Cream, 2%	Do.
NDA 020499	Actron (ketoprofen) Tablets, 12.5 mg	Do.
NDA 020525	Gyne-Lotrimin 3 (clotrimazole) Vaginal Tablets, 200 mg	Do.
NDA 020526	Gyne-Lotrimin 3 Combination Pack (clotrimazole) Vaginal Cream and Vaginal Tablets, 1% and 200 mg	Do.
NDA 020574	Gyne-Lotrimin 3 (clotrimazole) Vaginal Cream, 2%	Do.
NDA 020619	Betoptic Pilo (betaxolol HCl; pilocarpine HCl) Ophthalmic Suspension, EQ 0.25% base; 1.75%	Alcon Laboratories, Inc.
NDA 020665	Diovan (valsartan) Capsules, 80 mg and 160 mg	Novartis Pharmaceuticals Corp.
NDA 020807	Refludan (lepirudin recombinant) for Injection, 50 mg/vial	Bayer HealthCare Pharmaceuticals, Inc.
NDA 020888	Lotrimin AF (clotrimazole) Cream, 1%	Bayer HealthCare, LLC
NDA 020889	Lotrimin AF (clotrimazole) Lotion, 1%	Do.
NDA 020890	Lotrimin AF (clotrimazole) Topical Solution, 1%	Do.
NDA 021257	Travatan (travoprost) Ophthalmic Solution, 0.004%	Alcon Pharmaceuticals, Ltd., 6201 S. Freeway, TC-45, Fort Worth, TX 76134

Application No.	Drug	Applicant
NDA 021711	Ablavar (gadofosveset trisodium) Injection, 2440 mg/10 mL and 3660 mg/15 mL	Lantheus Medical Imaging, Inc., 331 Treble Cove Rd., Building 300-2, North Billerica, MA 01862
NDA 050081	Poly-Pred (neomycin sulfate; polymyxin B sulfate; prednisolone acetate) Ophthalmic Suspension, EQ 0.35% base; 10,000 units/mL; 0.5%	Allergan, Inc., 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92623-9534
ANDA 061758	Penicillin V Potassium for Oral Solution USP, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL	Purepac Pharm., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 061980	Ampicillin Trihydrate for Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL	Do.
ANDA 063116	Tobramycin Sulfate Injection USP, EQ 40 mg base/mL (Pharmacy Bulk Package)	Hospira, Inc.
ANDA 065057	Cefaclor Extended-Release Tablets, EQ 500 mg base	World Gen, LLC, 120 Route 17 North, Suite 127, Paramus, NJ 07652
ANDA 071295	Atropine Injection, EQ 2 mg sulfate/0.7 mL	AbbVie, Inc., Dept. PA77/Bldg. AP30, 1 N. Waukegan Rd., North Chicago, IL 60064
ANDA 071536	Metoclopramide Tablets USP, EQ 5 mg base and EQ 10 mg base	Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540
ANDA 071541	N.E.E. 1/35 21-day (norethindrone and ethinyl estradiol) Tablets USP, 1 mg/0.035 mg	LPI Holdings, Inc., 5000 Plaza on the Lake, No. 270, Austin, TX 78746
ANDA 071542	N.E.E. 1/35 28-day (norethindrone and ethinyl estradiol) Tablets USP, 1 mg/0.035 mg	Do.
ANDA 071545	Norcept-E 1/35 21-day (norethindrone and ethinyl estradiol) Tablets USP, 1 mg/0.035 mg	Janssen Pharmaceuticals, Inc., 1000 U.S. Highway 202, P.O. Box 300, Raritan, NJ 08869-0602
ANDA 071546	Norcept-E 1/35 28-day (norethindrone and ethinyl estradiol) Tablets USP, 1 mg/0.035 mg	Do.
ANDA 071690	Metoprolol Tartrate Tablets USP, 50 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 071691	Metoprolol Tartrate Tablets USP, 100 mg	Do.
ANDA 074633	Atracurium Besylate Injection, 10 mg/mL (Single-dose Vials)	Hospira, Inc.
ANDA 074639	Atracurium Besylate Injection, 10 mg/mL (Abboject Syringe)	Do.
ANDA 074929	Etodolac Capsules USP, 300 mg	ECI Pharmaceuticals, LLC, 5311 NW 35th Terrace, Fort Lauderdale, FL 33309
ANDA 075870	Famotidine Injection, 10 mg/mL	Hospira, Inc.

Application No.	Drug	Applicant
ANDA 076058	Midazolam HCl Syrup, EQ 2 mg base/mL	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540
ANDA 083140	Hydrocortisone Tablets, 20 mg	Nexgen Pharma, Inc., 46 Corporate Park, Suite 200, Irvine, CA 92606
ANDA 083633	Isoniazid Tablets, 300 mg	Sun Pharmaceutical Industries, Inc.
ANDA 083634	Diphenhydramine HCl Capsules, 25mg	Nexgen Pharma, Inc.
ANDA 084050	Isoniazid Tablets, 100 mg	Do.
ANDA 084220	Meprobamate Tablets, 200 mg	Do.
ANDA 084238	Pentobarbital Sodium Tablets, 100 mg	Do.
ANDA 084487	Phentermine HCl Capsules USP, 30 mg	Upsher-Smith Laboratories, LLC, 301 South Cherokee St., Denver, CO 80223
ANDA 084589	Meprobamate Tablets, 400 mg	Nexgen Pharma, Inc.
ANDA 084915	Folic Acid Tablets, 1 mg	Do.
ANDA 085499	Potassium Chloride for Injection Concentrate USP, 2 milliequivalents/mL	Baxter Healthcare Corp., 1620 Waukegan Rd., McGaw Park, IL 60085
ANDA 085985	Dimenhydrinate Tablets, 50 mg	Nexgen Pharma, Inc.
ANDA 086020	Phendimetrazine Tartrate Tablets, 35 mg	Do.
ANDA 086187	Brompheniramine Maleate Tablets, 4 mg	Do.
ANDA 086392	Meclizine HCl Tablets, 25 mg (Chewable)	Do.
ANDA 086835	Polaramine (dexchlorpheniramine maleate) Tablets, 2 mg	Merck Sharp & Dohme Corp., Subsidiary of Merck & Co., Inc.
ANDA 086837	Polaramine (dexchlorpheniramine maleate) Syrup, 2 mg/5 mL	Do.
ANDA 087766	Thioridazine HCl Oral Concentrate, 30 mg/mL	Alpharma US Pharms., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 087858	Isoetharine Mesylate Metered Dose Inhaler, 0.34 mg/inhalation	Do.
ANDA 088430	Phentermine HCl Capsules USP, 30 mg	Upsher-Smith Laboratories, LLC.
ANDA 089381	Hydroxyzine HCl Tablets USP, 10 mg	Sun Pharmaceutical Industries, Inc.
ANDA 089382	Hydroxyzine HCl Tablets USP, 25 mg	Do.
ANDA 089383	Hydroxyzine HCl Tablets USP, 50 mg	Do.
ANDA 089481	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg	American Therapeutics, Inc., 89 Carlough Rd., Bohemia, NY 11716
ANDA 089482	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg	Do.
ANDA 089489	Diphenhydramine HCl Capsules, 50 mg	Sun Pharmaceutical Industries, Inc.
ANDA 091258	Furosemide Tablets USP, 20 mg, 40 mg,	Do.

Application No.	Drug	Applicant
	and 80 mg	
NDA 208056	Dexilant Solutab (dexlansoprazole) Delayed-Release Orally Disintegrating Tablets, 30 mg	Takeda Pharmaceuticals U.S.A., Inc., One Takeda Pkwy., Deerfield, IL 60015

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: February 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-03607 Filed: 2/21/2018 8:45 am; Publication Date: 2/22/2018]