4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0662]

Aurobindo Pharma Ltd. et al.; Withdrawal of Approval of Eighty-Six Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 86 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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: EFFECTIVE DATE: [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. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 in this document 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
ANDA 065395	Cefazolin for Injection USP, 500 milligrams (mg) and 1 gram (g)	Aurobindo Pharma Ltd., c/o AuroMedics Pharma LLC, 6 Wheeling Rd. Dayton, NJ 08810
ANDA 065481	Ceftazidime for Injection USP, 500 mg, 1 g, and 2 g	Do.
ANDA 065482	Ceftazidime for Injection USP, 6 g	Do.
ANDA 065504	Ceftriaxone for Injection USP, 10 g	Do.
ANDA 065505	Ceftriaxime for Injection, 250 mg, 500 mg, 1 g, and 2 g	Do.
ANDA 065516	Cefotaxime for Injection USP, 10 g	Do.
ANDA 065517	Cefotaxime for Injection USP	Do.
ANDA 077467	Nateglinide Tablets, 60 mg and 120 mg	Teva Pharmaceuticals USA, 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454
ANDA 077472	Cetirizine Hydrochloride (HCl) Syrup, 5 mg/5 milliliters (mL)	Ranbaxy Laboratories Limited, c/o Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540
ANDA 077540	Zolpidem Tartrate Tablets, 5 mg and 10 mg	Synthon Pharmaceuticals, Inc., 9000 Development Dr., P.O. Box 110487, Research Triangle Park, NC 27709
ANDA 077717	Ondansetron Orally	Nesher Pharmaceuticals (USA) LLC,

Application No.	Drug	Applicant
	Disintegrating Tablets USP, 4 mg and 8 mg	13910 St. Charles Rock Rd., Bridgeton, MO 63044
ANDA 077730	Pravastatin Sodium Tablets, 10 mg, 20 mg, 30 mg, 40 mg, and 80 mg	Pliva HRVATSKA, c/o Barr Laboratories, Inc., 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 077826	Fenoldopam Mesylate Injection USP, 10 mg (base)/mL	Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618
ANDA 077888	Ciprofloxacin Injection USP, 2 mg/mL	Baxter Healthcare Corp., 1620 Waukegan Rd., McGaw Park, IL 60085
ANDA 077905	Topiramate Tablets, 25 mg, 50 mg, 100 mg, and 200 mg	Pliva HRVATSKA, c/o Barr Laboratories, Inc.
ANDA 078016	Zolpidem Tartrate Tablets, 5 mg and 10 mg	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26505-4310
ANDA 078053	Sertraline HCl Oral Concentrate, 20 mg/mL	Ranbaxy Laboratories Limited, c/o Ranbaxy Inc.
ANDA 078114	Ciprofloxacin Injection USP in 5% Dextrose, 2 mg/mL	Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146
ANDA 078132	Ibuprofen Tablets USP, 400 mg, 600 mg, and 800 mg	Quality Regulatory Consultants, U.S. Agent for Northstar Healthcare Holdings, 501 Ivy Lake Dr., Forest, VA 24551
ANDA 078187	Risperidone Tablets USP, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg	Synthon Pharmaceuticals, Inc.

Application No.	Drug	Applicant
ANDA 078322	Anastrozole Tablets, 1 mg	Do.
ANDA 078448	Ranitidine HCl Solution, 15 mg/mL	Ranbaxy Inc., U.S. Agaent for Ranbaxy Laboratories Limited
ANDA 078606	Mitoxantrone Injection USP	Washington Food and Drug Consultants, U.S. Agent for Fresenius Kabi Oncology Plc., 3631 Martins Dairy Circle, Olney, MD 20832
ANDA 080043	Nitrofurantoin Tablets, 50 mg and 100 mg	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80038-0446
ANDA 080203	Potassium Chloride Injection USP, 2 milliequivalents/mL	Baxter Healthcare Corp., 25212 W. IL Route 120, Round Lake, IL 70073
ANDA 080642	Hydrocortisone Tablets, 20 mg	Sandoz Inc.
ANDA 081142	Aminophylline Injection USP, 25 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 081169	Glycopyrrolate Injection USP, 0.2 mg/mL	Do.
ANDA 081266	Methyprednisolone Sodium Succinate for Injection USP, 125 mg	Do.
ANDA 081267	Methylprednisolone Sodium Succinate for Injection USP, 500 mg	Do.
ANDA 081268	Methyprednisolone Sodium Succinate for Injection USP, 1 g	Do.

Application No.	Drug	Applicant
ANDA 081278	Leucovorin Calcium for Injection, 50 mg/vial	Do.
ANDA 083254	Halothane USP	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045
ANDA 083263	Alcohol in Dextrose Injection USP, 5%/5%	Do.
ANDA 083306	Niacin Tablets, 50 mg	Sandoz Inc.
ANDA 083486	Isoproterenol HCl Injection USP, 0.2 mg/mL	Baxter Healthcare Corp.
ANDA 084051	Dextroamphetamine Sulfate Tablets USP, 5 mg and 10 mg	Shire Development Inc., 725 Chesterbrook Blvd., Wayne, PA 19087
ANDA 084233	Promethazine HCl Tablets, 12.5 mg	Sandoz Inc.
ANDA 084472	Folic Acid Capsules, 1 mg	Do.
ANDA 084827	Hydrochlorothiazide and Reserpine Tablets, 25 mg/0.125 mg	Do.
ANDA 085034	Phendimetrazine Tartrate Tablets, 35 mg	Do.
ANDA 085133	Imipramine HCl Tablets, 50 mg	Do.
ANDA 085200	Imipramine HCl Tablets, 10 mg	Do.
ANDA 085213	Hydrochlorothiazide and Reserpine Tablets, 50 mg/0.125 mg.	Do.
	Estrogens, Esterified Tablets,	Do.

Application No.	Drug	Applicant
ANDA 085302	1.25 mg	
ANDA 085362	Novocaine (procaine HCl Injection USP)	Hospira, Inc.
ANDA 085370	Dextroamphetamine Sulfate Tablets, 5 mg	Sandoz Inc.
ANDA 085371	Dextroamphetamine Sulfate Tablets, 10 mg	Do.
ANDA 085402	Phendimetrazine Tartrate Tablets, 35 mg	Do.
ANDA 085601	Triamcinolone Tablets, 4 mg	Do.
ANDA 085633	Phendimetrazine Tartrate Capsules, 35 mg	Do.
ANDA 085671	Phentermine HCl Tablets, 8 mg	Do.
ANDA 085689	Phentermine HCl Tablets USP, 8 mg	Do.
ANDA 085694	Phendimetrazine Tartrate Capsules, 35 mg	Do.
ANDA 085702	Phendimetrazine Tartrate Capsules, 35 mg	Do.
ANDA 085830	Phendimetrazine Tartrate Tablets, 35 mg	Do.
ANDA 085852	A-Methapred (methylprednisolone sodium succinate for injection USP), 1,000 mg/vial	Hospira, Inc.

Application No.	Drug	Applicant
ANDA 085853	A-Methapred (methylprednisolone sodium succinate for injection USP), 40 mg/vial	Do.
ANDA 085854	A-Methapred (methylprednisolone sodium succinate for injection USP), 500 mg/vial	Do.
ANDA 085929	A-Hydrocort (hydrocortisone sodium succinate for injection USP), 100 mg/vial	Hospira, Inc.
ANDA 085930	A-Hydrocort (hydrocortisone sodium succinate for injection USP), 250 mg/vial	Do.
ANDA 085931	A-Hydrocort (hydrocortisone sodium succinate for injection USP), 500 mg/vial	Do.
ANDA 085932	A-Hydrocort (hydrocortisone sodium for injection USP), 1,000 mg/val	Do.
ANDA 086370	Phendimetrazine Tartrate Tablets, 35 mg	Sandoz Inc.
ANDA 086589	Barbidonna Tablets (phenobarbital, hyoscyamine sulfate, scopolamine hydrobromide, and atropine sulfate)	Meda Pharmaceuticals, Meda Pharmaceuticals, Inc., 265 Davidson Ave., Suite 300, Somerset, NJ 08873-4120
ANDA 086590	Barbidonna Elixir (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide)	Do.

Application No.	Drug	Applicant
ANDA 086664	Butibel Elixir (sodium butabarbital and belladonna extract), 15 mg/5 mL and 15 mg/5 mL	Do.
ANDA 087208	Phentermine HCl Capsules, 30 mg	Sandoz Inc.
ANDA 087223	Phentermine HCl Capsules, 30 mg	Do.
ANDA 087759	Prochlorperazine Edisylate Injection USP	Baxter Healthcare Corp.
ANDA 087572	Barbidonna No. 2 Tablets (phenobarbital, hyoscyamine sulfate, atropine sulfate, and scopolamine hydrobromide) 32 mg, 0.1286 mg, 0.025 mg, and 0.0074 mg	Meda Pharmaceuticals
ANDA 088099	Heparin Lock Flush Solution USP, 2,500 units/Ml	Hospira, Inc.
ANDA 088175	Chlorpropamide Tablets, 100 mg	Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977
ANDA 088176	Chlorpropamide Tablets, 250 mg	Do.
ANDA 088184	Hydroxyzine HCl Injection USP, 25 mg/mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 088185	Hydroxyzine HCl Injection USP, 50 mg/mL	Do.
ANDA 088330	1.5% Lidocain HCl Injection	Hospira, Inc.

Application No.	Drug	Applicant
	USP	
ANDA 089158	Methotrexate Injection USP, 25 mg/mL	Pharmachemie B.V., c/o Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618
ANDA 089420	Azdone Tablets (hydrocodone bitartrate 5 mg and aspirin 500 mg)	Schwarz Pharma, Inc., c/o UCB, Inc., 1950 Lake Park Dr., Smyrna, GA 30080
ANDA 090183	Cetirizine HCl Syrup, 5 mg/5mL	Ranbaxy Laboratories Limited, c/o Ranbaxy Inc.
ANDA 090196	Letrozole Tablets USP, 2.5 mg	Synthon Pharmaceuticals, Inc.
ANDA 090464	Mycophenolate Mofetil Tablets, 500 mg	Dr. Reddy's Laboratories Limited, c/o Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Blvd., 7th Floor, Bridgewater, NJ 08807
ANDA 090567	Polyethylene Glycol 3350 Powder for Oral Solution	Paddock Laboratories, LLC, a Perrigo Co., 3940 Quebec Ave. North, Minneapolis, MN 55427
ANDA 090712	Polyethylene Glycol 3350 and Electrolytes for Oral Solution	Do.
ANDA 090769	Clenz-Lyte (polyethylene glyol 3350 and electrolytes for oral solution)	Do.
ANDA 091315	Mycophenolalte Mofetil Capsules USP, 250 mg	Dr. Reddy's Laboratories Limited, c/o Dr. Reddy's Laboratories, Inc.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in

this document, and all amendments and supplements thereto, is hereby withdrawn, effective [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 FD&CAct (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the DATES section) 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: June 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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