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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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:* July 21, 2014.

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 Disintegrating Tablets USP, 4 mg and 8 mg.	Nesher Pharmaceuticals (USA) LLC, 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.
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.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 081267	Methylprednisolone Sodium Succinate for Injection USP, 500 mg.	Do.
ANDA 081268	Methyprednisolone Sodium Succinate for Injection USP, 1 g.	Do.
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.
ANDA 085302	Estrogens, Esterified Tablets, 1.25 mg	Do.
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.
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.
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 USP	Hospira, Inc.
ANDA 089158	Methotrexate Injection USP, 25 mg/mL	Pharmachemie B.V., c/o Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618.

TABLE 1—Continued

Application No.	Drug	Applicant
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 July 21, 2014. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (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.

[FR Doc. 2014–14288 Filed 6–18–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0640]

Draft Guidance for Industry on Uncomplicated Gonorrhea: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Uncomplicated Gonorrhea: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of uncomplicated gonorrhea.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 17, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Uncomplicated Gonorrhea: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of uncomplicated gonorrhea.

This draft guidance describes approaches for trial designs for the evaluation of new drugs for the treatment of uncomplicated gonorrhea. The draft guidance focuses on the noninferiority trial design and describes an efficacy endpoint for which there is a well-defined treatment effect. The draft guidance also provides the justification for the noninferiority margin. In addition, this guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of uncomplicated gonorrhea.

Issuance of this draft guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144) that requires FDA to ''. . . review and, as appropriate, revise not fewer than 3 guidance documents per year . . . for the conduct of clinical trials with respect to antibacterial and antifungal drugs. . . .'' In 1998, FDA published a draft guidance entitled ''Uncomplicated Gonorrhea: Developing Drugs for Treatment'' (1998 draft guidance). In a **Federal Register** notice dated August 7, 2013 (78 FR 48175), FDA announced an initiative in the Center for Drug Evaluation and Research involving the review of draft guidance documents issued before 2010 to determine their status and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. In the August 7, 2013, **Federal Register** notice, FDA announced that the 1998 draft guidance, as well as other draft guidances, was being withdrawn (78 FR 48175). FDA is now issuing a new draft guidance that revises the recommendations in the 1998 draft