4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6591]

Barr Laboratories, Inc. et al.; Withdrawal of Approval of 68 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 68 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945.

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 040135	Estropipate Tablets USP, 0.75 milligrams (mg), 1.5 mg, and 3 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 040755	Carisoprodol Tablets USP, 350 mg	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512
ANDA 062588	Gentamicin Sulfate in 0.9% Sodium Chloride Injection, Equivalent to (EQ) 1.2 mg base/milliliter (mL), EQ 1.4 mg base/mL, EQ 1.6 mg base/mL, EQ 1.8 mg base/mL, EQ 2 mg base/mL, EQ 60 mg base/100 mL, EQ 70 mg base/100 mL, EQ 80 mg base/100 mL, EQ 90 mg base/100 mL, and EQ 100 mg base/100 mL	Hospira, Inc., a Pfizer Company, 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 062591	Kefurox (cefuroxime) for Injection USP, EQ 750 mg base/vial, EQ 1.5 grams (g) base/vial, and EQ 7.5 g base/vial	ACS Dobfar S.p.A., c/o Interchem Corp., 120 Route 17 North, Paramus, NJ 07652
ANDA 062756	Primaxin IV (imipenem and cilastatin) for Injection USP, 250 mg/vial; EQ 250 mg base/vial and 500 mg/vial; EQ 500 mg base/vial	Merck Sharp & Dohme Corp., Subsidiary of Merck & Co., Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889
ANDA 063207	Cefazolin for Injection USP, EQ 1	Facta Farmaceutici S.p.A., c/o

Application No.	Drug	Applicant
	g base/vial	Interchem Corp., 120 Route 17 North, Suite 115, Paramus, NJ 07652
ANDA 063209	Cefazolin for Injection USP, EQ 10 g base/vial and EQ 20 g base/vial (Pharmacy Bulk Package)	Do.
ANDA 063214	Cefazolin for Injection USP, EQ 500 mg base/vial	Do.
ANDA 063263	Amikacin Sulfate Injection USP, EQ 50 mg base/mL	Hospira, Inc.
ANDA 065268	Ceftriaxone for Injection USP, EQ 1 g base/vial and EQ 2 g base/vial	Facta Farmaceutici S.p.A.
ANDA 065269	Ceftriaxone for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package)	Do.
ANDA 065348	Cefotaxime for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package)	Cephazone Pharma, LLC, 250 E. Bonita Ave., Pomona, CA 91767
ANDA 065464	Cefoxitin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package)	ACS Dobfar S.p.A.
ANDA 065467	Cefoxitin for Injection USP, EQ 1 g base/vial and EQ 2 g base/vial	Do.
ANDA 070048	Cotrim D.S. (sulfamethoxazole and trimethoprim) Tablets USP, 800 mg/160 mg	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 070195	Valproic Acid Capsules USP, 250 mg	Catalent Pharma Solutions, LLC, 2725 Scherer Dr. North, St. Petersburg, FL 33716
ANDA 070513	Tolazamide Tablets USP, 100 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 070514	Tolazamide Tablets USP, 250 mg	Do.

Application No.	Drug	Applicant
ANDA 071358	Tolazamide Tablets USP, 250 mg	Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512
ANDA 071359	Tolazamide Tablets USP, 500 mg	Do.
ANDA 071667	Ibuprofen Tablets USP, 600 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 071668	Ibuprofen Tablets USP, 800 mg	Do.
ANDA 071735	Ibuprofen Tablets USP, 200 mg	Contract Pharmacal Corp., c/o SciRegs International Inc., 6333 Summercrest Dr., Columbia, MD 21045
ANDA 071773	Ibuprofen Tablets USP, 200 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 073254	Loperamide Hydrochloride (HCl) Tablets USP, 2 mg	Contract Pharmacal Corp.
ANDA 074075	Clemastine Fumarate Syrup, EQ 0.5 mg base/5 mL	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 074536	Haloperidol Oral Solution USP, EQ 1 mg base/mL	Do.
ANDA 074782	Ibuprofen Capsules, 200 mg	Contract Pharmacal Corp.
ANDA 074789	Naproxen Sodium Tablets USP, EQ 200 mg base	Do.
ANDA 074931	Ibuprofen Tablets USP, 200 mg	Do.
ANDA 074961	Cimetidine Tablets USP, 200 mg	Do.
ANDA 074963	Cimetidine Tablets USP, 200 mg	Do.
ANDA 075094	Ranitidine Tablets USP, EQ 75 mg base	Do.
ANDA 075588	Ibuprofen and Pseudoephedrine HCl Tablets USP, 200 mg/30 mg	Do.
ANDA 077058	Pantoprazole Sodium Delayed-Release Tablets USP, EQ 20 mg base and EQ 40 mg base	Sun Pharmaceutical Industries, Ltd.

Application No.	Drug	Applicant
ANDA 077172	Ondansetron Injection USP, EQ 2 mg base/mL	Do.
ANDA 077329	Octreotide Acetate Injection, EQ 0.05 mg base/mL, EQ 0.1 mg base/mL, and EQ 0.5 mg base/mL	Do.
ANDA 077330	Octreotide Acetate Injection, EQ 0.2 mg base/mL	Do.
ANDA 077331	Octreotide Acetate Injection, EQ 1 mg base/mL	Do.
ANDA 078108	Sertraline HCl Tablets, EQ 25 mg base, EQ 50 mg base, and EQ 100 mg base	Do.
ANDA 078478	Torsemide Tablets, 5 mg, 10 mg, 20 mg, and 100 mg	Do.
ANDA 083000	Folic Acid Tablets, 1 mg	Ivax Pharmaceutical USA, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 085549	Reserpine, Hydralazine HCl, and Hydrochlorothiazide Tablets, 0.1 mg/25 mg/15 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 086109	Tolbutamide Tablets USP, 500 mg	Do.
ANDA 086577	Trimethobenzamide HCl Injection, 100 mg/mL	Do.
ANDA 087191	Triamcinolone Acetonide Lotion USP, 0.025%	Alpharma U.S. Pharms, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 087398	Spironolactone and Hydrochlorothiazide Tablets USP, 25 mg/25 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088229	Thioridazine HCl Oral Solution USP, 100 mg/mL	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.

Application No.	Drug	Applicant
ANDA 088563	Thioridazine HCl Tablets USP, 50 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088567	Thioridazine HCl Tablets USP, 25 mg	Do.
ANDA 088733	Meclizine HCl Tablets, 25 mg (Chewable)	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088869	Thioridazine HCl Tablets USP, 150 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 090800	Quinapril Tablets USP, EQ 5 mg base, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base	Sun Pharmaceutical Industries, Ltd.
ANDA 091177	Anastrozole Tablets, 1 mg	Do.
ANDA 091466	Letrozole Tablets USP, 2.5 mg	Do.
ANDA 200486	Norethindrone and Ethinyl Estradiol Tablets USP, 0.5 mg/0.035 mg, 0.75 mg/0.035 mg, and 1 mg/0.035 mg	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504
ANDA 200488	Norethindrone and Ethinyl Estradiol Tablets USP, 0.5 mg/0.035 mg	Do.
ANDA 200489	Norethindrone and Ethinyl Estradiol Tablets USP, 1 mg/0.035 mg	Do.
ANDA 201250	Vancomycin HCl for Injection USP, EQ 5 g base/vial and EQ 10 g base/vial (Pharmacy Bulk Package)	Teva Pharmaceuticals USA, Inc.
ANDA 201251	Vancomycin HCl for Injection USP, EQ 500 mg base/vial and EQ 1 g base/vial	Do.
ANDA 201828	Norgestrel and Ethinyl Estradiol Tablets USP, 0.3 mg/0.03 mg	Mylan Laboratories, Ltd.
ANDA 202203	Topotecan HCl for Injection, EQ 4 mg base/vial	Sun Pharmaceutical Industries, Ltd.
ANDA 202746	Zoledronic Acid Injection, EQ 4 mg base/5 mL	Sun Pharma Global FZE, c/o Sun Pharmaceutical Industries, Inc., 2

Application No.	Drug	Applicant
		Independence Way, Princeton, NJ 08540
ANDA 202875	Norgestrel and Ethinyl Estradiol Tablets USP, 0.5 mg/0.05 mg	Mylan Laboratories, Ltd.
ANDA 203476	Zolmitriptan Tablets, 2.5 mg and 5 mg	Sun Pharma Global FZE
ANDA 203685	Irbesartan Tablets USP, 75 mg, 150 mg, and 300 mg	Ajanta Pharma Ltd., c/o Ajanta Pharma USA, Inc., One Grande Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807
ANDA 203838	Hydrocodone Bitartrate, Chlorpheniramine Maleate, and Pseudoephedrine HCl Oral Solution, 5 mg/4 mg/60 mg per 5 mL	Tris Pharma, Inc., 2033 Route 130, Monmouth Junction, NJ 08852
ANDA 203839	Hydrocodone Bitartrate and Pseudoephedrine HCl Oral Solution, 5 mg/60 mg per 5 mL	Do.

Therefore, approval of the applications listed in table 1 of this document, 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 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: November 27, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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