



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5526]

Department of Health and Human Services, Supply Service Center et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 27 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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: *Applied Date:* [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 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 abbreviated application under § 314.150(c) is without prejudice to refiling.

Table 1

Application No.	Drug	Applicant
ANDA 061071	Tetracycline Hydrochloride (HCl) Tablets, 250 milligrams (mg)	Department of Health and Human Services, Supply Service Center, PSC Bldg. 14 Boiler House Rd., Perry Point, MD 21902
ANDA 062279	Grifulvin V (griseofulvin microsize) Tablets USP, 125 mg, 250 mg, and 500 mg	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 062398	Cephalexin Capsules, 250 mg and 500 mg	Department of Health and Human Services, Supply Service Center, PSC Bldg. 14 Boiler House Rd., Perry Point, MD 21902
ANDA 062756	Primaxin (cilastatin sodium and imipenem) for Injection, Equivalent to (EQ) 250 mg base/vial; 250 mg/vial and EQ 500 mg base/vial; 500 mg/vial	Merck Sharp & Dohme Corp., Subsidiary of Merck & Co., Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889
ANDA 062814	Gentamicin Sulfate in 0.9% Sodium Chloride Injection, EQ 0.8 mg base/milliliter (mL), EQ 1.2 mg base/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 2.4 mg base/mL, EQ 40 mg base/100 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, EQ 100 mg base/100 mL, and EQ 120 mg base/100 mL	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109
ANDA 063239	Rocephin (ceftriaxone sodium) for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, and EQ 1 gram (g) base/vial	Hoffmann-La Roche, Inc., c/o Genentech Inc., 1 DNA Way, MS 241B, South San Francisco, CA 94080
ANDA 064127	Erythromycin Topical Solution, 2%	Renaissance Pharma, Inc., 411 South State St., Suite E-100, Newton, PA 18940
ANDA 064146	Amikacin Sulfate in Sodium Chloride 0.9% Injection, EQ 500 mg base/100 mL	Hospira, Inc., Subsidiary of Pfizer Inc., 375 N. Field Dr., Lake Forest, IL 60045

Application No.	Drug	Applicant
ANDA 070598	Metoclopramide HCl Tablets, EQ 10 mg base	Merck Sharp & Dohme Corp., Subsidiary of Merck & Co., Inc.
ANDA 072080	Furosemide Injection USP, 10 mg/mL	Hospira, Inc., Subsidiary of Pfizer Inc.
ANDA 074601	Dipyridamole Injection, 5 mg/mL	Do.
ANDA 074720	Acyclovir Sodium Injection, EQ 25 mg base/mL	Do.
ANDA 076564	Adenosine Injection USP, 3 mg/mL	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 078211	Quinapril HCl and Hydrochlorothiazide Tablets, EQ 10 mg base/12.5 mg, EQ 20 mg base/12.5 mg, and EQ 20 mg base/25 mg	Sun Pharmaceutical Industries Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540
ANDA 078935	Tramadol HCl Tablets USP, 50 mg	Northstar Healthcare Holdings, c/o Quality Regulatory Consultants, 1966 Anglers Cove, Vero Beach, FL 32963
ANDA 080810	Halothane USP, 99.99%	Halocarbon Products Corp., 1100 Dittman Ct., North Augusta, SC 29841
ANDA 085458	Dexamethasone Tablets USP, 0.5 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 085883	Acetaminophen and Codeine Phosphate Oral Suspension USP, 120 mg/5 mL and 12 mg/5 mL	Actavis Mid Atlantic LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 085884	Cortisone Acetate Tablets USP, 25 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 086179	Carisoprodol Tablets USP, 350 mg	Do.
ANDA 086440	Atropine Sulfate and Diphenoxylate HCl Capsules, 0.025 mg/2.5 mg	Catalent Pharma Solutions, Inc., 2725 Scherer Dr. North, St. Petersburg, FL 33716
ANDA 087535	Methylprednisolone Sodium Succinate for Injection USP, EQ 500 mg base/vial and EQ 1 g base/vial	Organon USA, Inc., Subsidiary of Merck and Co., Inc., 126 E. Lincoln Ave., P.O. Box 2000, Rahway, NJ 07065

Application No.	Drug	Applicant
ANDA 087711	Dexamethasone Acetate Injectable Suspension USP, EQ 16 mg base/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088346	Heparin Lock Flush Solution USP and 0.9% Sodium Chloride Injection USP, 10 USP heparin units/mL and 100 USP heparin units/mL	Hospira, Inc.
ANDA 088852	Chlorpropamide Tablets USP, 100 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 091201	Meropenem for Injection USP, 500 mg/vial and 1 g/vial	Sandoz Inc., 100 College Rd. West, Princeton, NJ 08540
ANDA 200156	Armodafinil Tablets, 100 mg and 200 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.

Therefore, approval of the applications listed in table 1, 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 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: September 15, 2017.

Anna K. Abram,

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

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