4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2876]

Fougera Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 20 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 20 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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, Trang.Tran@fda.hhs.gov.

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 described 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.

Application No.	Drug	Applicant
ANDA 060133	Chloramphenicol Ophthalmic Ointment, 1%	Fougera Pharmaceuticals, Inc., 60 Baylis Rd., P.O. Box 2006, Melville, NY 11747
ANDA 060572	Mycolog II (nystatin and triamcinolone acetonide) Ointment USP, 100,000 units/gram (g) and 0.1%	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504
ANDA 061107	Hydrocortisone Acetate and Neomycin Sulfate Ointment, 0.5%/0.5% and 1.5%/0.5%	Fougera Pharmaceuticals, Inc.
ANDA 061988	Polycillin (ampicillin) Capsules, 250 milligrams (mg) and 500 mg	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543
ANDA 072097	Cap-Profen (ibuprofen) Tablets USP, 200 mg (White)	L. Perrigo Co., 515 Eastern Ave., Allegan, MI 49010
ANDA 072098	Ibuprofen Tablets, 200 mg (Brown)	Do.
ANDA 074334	Vecuronium Bromide for Injection, 10 mg/vial and 20 mg/vial	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 074874	Pentoxifylline Extended-Release Tablets, 400 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 074945	Atracurium Besylate Injection, 10 mg/milliliter (mL)	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 077251	Finasteride Tablets USP, 5 mg	Gedeon Richter Plc., c/o Gedeon Richter USA, Inc., 119 Cherry Hill Rd., Suite 325, Parsippany, NJ 07054
ANDA 077983	Gemcitabine for Injection USP, Equivalent to (EQ) 200 mg base/vial and EQ 1 g/vial	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 080425	Texacort (hydrocortisone) Topical Solution, 1%	Mission Pharmacal Co., 10999 IH 10 West, Suite 1000, San Antonio, TX 78230
ANDA 083242	Amen (medroxyprogesterone acetate) Tablets, 10 mg	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 085455	Dexamethasone Tablets USP, 0.25 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 086308	Homapin-10 (homatropine methylbromide) Tablets USP, 10 mg	Mission Pharmacal Co.
ANDA 086309	Homapin-5 (homatropine methylbromide) Tablets USP, 5 mg	Do.
ANDA 086310	Equipin (homatropine methylbromide) Chewable Tablets, 3 mg	Do.
ANDA 086711	Beta-2 (isoetharine hydrochloride (HCl)) Inhalation Solution, 1%	Nephron Pharmaceuticals, Corp., 4500 12th St. Extension, West Columbia, SC 20172
ANDA 087438	Folicet (folic acid) Tablets USP, 1 mg	Mission Pharmacal Co.
ANDA 087939	Trimethobenzamide HCl Injection,	Watson Laboratories, Inc., Subsidiary of

Application No.	Drug	Applicant
	100 mg/mL	Teva Pharmaceuticals USA, Inc.

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: August 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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