4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1528]

Pfizer Inc., et.al.; Withdrawal of Approval of 12 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 12 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants 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 060567	Lidocaine Hydrochloride (HCl); Oxytetracycline Injection, 2%; 50 milligrams (mg)/milliters (mL), and 2%; 125 mg/mL	Pfizer Inc., 235 East 42nd St., New York, NY 10017
ANDA 062612	Gentamicin Sulfate Injection, Equivalent to (EQ) 10 mg base/mL	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 062811	Clindamycin Phosphate Solution, EQ 1% base	G&W Laboratories Inc., 301 Helen St., South Plainfield, NJ 07080
ANDA 063333	Cefoperazone Sodium for Injection, EQ 1 gram (gm) base/vial	Pfizer Inc.
ANDA 078288	Ondansetron HCl Injection, EQ 2 mg base/mL	Baxter Healthcare Corp., 1 Baxter Parkway, Deerfield, IL 60015
ANDA 080426	Hydrocortisone Lotion, 0.5%	Bausch Health Americas Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 090813	Levetiracetam Injection, 500 mg/5 mL (100 mg/mL)	Fresenius Kabi USA, LLC., Three Corporate Dr., Lake Zurich, IL 60047
ANDA 201751	Articaine HCl; Epinephrine Bitartrate Injection, 4%; EQ 0.0085 mg base/1.7 mL; 4%; EQ 0.005 mg base/mL	Hansamed Ltd., 4761 Tara Ct., West Bloomfield, MI 48323
ANDA 202684	Levonorgestrel Tablets, 0.75 mg	Alvogen PB Research and Development LLC, U.S. Agent for Lotus Pharmaceutical Co., Ltd. Nantou Plant, 44 Whippany Rd., Suite 300, Morristown, NJ 07960

ANDA 204796	Capreomycin Sulfate for Injection, EQ 1 gm base/vial	Hisun Pharmaceuticals USA, Inc., U.S. Agent for Hisun Pharmaceutical (Hangzhou) Co., Ltd., 200 Crossing Blvd., 2nd Floor, Bridgewater, NJ 08807
ANDA 205943	Ethinyl Estradiol; Levonorgestrel Tablets, 0.02 mg, 0.15 mg; 0.025 mg, 0.15 mg; 0.03 mg, 0.15 mg; 0.01 mg, N/A	Lupin Pharmaceuticals, Inc., 111 South Calvert St., Baltimore, MD 21202
ANDA 212191	Fluoxetine HCl Tablets, EQ 60 mg base	G&W Laboratories, 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*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. 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: June 19, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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