4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-6077]

Pfizer Inc., U.S. Agent for King Pharmaceuticals LLC, 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 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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, 301-796-3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants 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 application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Table 1.-- ANDAs for Which Approval Is Withdrawn

Application No.	Drug	Applicant
ANDA 040320	TAPAZOLE (methimazole) tablets, 5 milligrams (mg) and 10 mg	Pfizer Inc., U.S. Agent for King Pharmaceuticals LLC, 66 Hudson Blvd. East, New York, NY 10001
ANDA 060582	NEOSPORIN (gramicidin; neomycin sulfate; polymyxin B sulfate) solution/drops, 0.025 mg/milliliter (mL); Equivalent to (EQ) 1.75 mg base/mL; 10,000 units/mL	Pfizer Inc., U.S. Agent for Monarch Pharmaceuticals, LLC, a subsidiary of Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001
ANDA 060707	NEOSPORIN G.U. Irrigant (neomycin sulfate; polymyxin B sulfate) solution, EQ 40 mg base/mL; 200,000 units/mL	Do.
ANDA 062310	HUMATIN (paromomycin sulfate) capsule, EQ 250 mg base	Pfizer Inc., U.S. Agent for Monarch Pharmaceuticals, LLC
ANDA 062414	Gentamicin Sulfate in sodium chloride 0.9% in plastic container, injectable, 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 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., 275 North Field Dr., Building H1-3S, Lake Forest, IL 60045
ANDA 063165	ADRIAMYCIN PFS (doxorubicin HCl) injectable, 2 mg/mL and 200 mg/100 mL	Pfizer Inc.
ANDA 072320	Pancuronium Bromide injectable, 1 mg/mL	Hospira, Inc.
ANDA 075221	ALFENTANIL (alfentanil HCl) injectable, EQ 0.5 mg base/mL	Do.
ANDA 075458	Enalaprilat injectable, 1.25 mg/mL	Do.
ANDA 075885	Milrinone Lactate in Dextrose 5% in plastic container, injectable, EQ 20 mg base/100 mL (EQ 0.2 mg base/mL) and EQ 40 mg base/200 mL (EQ 0.2 mg base/mL)	Do.

Application No.	Drug	Applicant
ANDA 076304	Fluconazole in Dextrose 5% in plastic container, injectable, 200 mg/100 mL (2mg/mL) and 400 mg/200 mL (2 mg/mL)	Do.
ANDA 077394	Sodium Bicarbonate injectable, 0.9 milliequivalent (mEq)/mL and 1 mEq/mL	Do.
ANDA 089070	Procainamide HCl injectable, 500 mg/mL	Do.
ANDA 090621	Zoledronic Acid injectable, EQ 4 mg base/5 mL	Do.
ANDA 202837	Zoledronic Acid injectable, EQ 5 mg base/100 mL	Do.
ANDA 203709	Fludeoxyglucose F 18 injectable, 20-500 millicurie (mCi)/mL	B&H Consulting Services, Inc., U.S. Agent for Wisconsin Medical Radiopharmacy, LLC, 50 Division St., Suite 206, Somerville, NJ 08876
ANDA 203883	Adenosine solution, 60 mg/20 mL (3mg/mL) and 90 mg/30 mL (3 mg/mL)	Hospira, Inc.
ANDA 204118	Indomethacin Sodium injectable, EQ 1 mg base/vial	Do.
ANDA 208016	Lurasidone HCl tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg	Watson Laboratories, Inc. (an indirect, wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054
ANDA 208833	Celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg	Amneal Pharmaceuticals of New York, LLC, 50 Horseblock Rd., Brookhaven, NY 11719

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, are 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 table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 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.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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