4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-4414]

American Regent, Inc., et al.; Withdrawal of Approval of Eight Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is withdrawing approval of eight 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 the 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 040515	Promethazine Hydrochloride	American Regent, Inc., 5 Ramsey Rd.,

Application No.	Drug	Applicant
	Injectable, 25 milligrams (mg)/milliliter (mL)	Shirley, NY 11967
ANDA 080028	Sulfacetamide Sodium Solution/Drops, 10% and 30%	Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612
ANDA 091300	Riluzole Tablet, 50 mg	Apotex Corp., U.S. Agent for Apotex Inc., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326
ANDA 200271	Hydroxyprogesterone Caproate Solution, 1,250 mg/5 mL (250 mg/mL)	Lachman Consultant Services, Inc., U.S. Agent for Aspen Global Inc., 1600 Stewart Ave., Suite 604, Westbury, NY 11590
ANDA 201570	Abacavir Sulfate Tablet, Equivalent to (EQ) 300 mg base	Apotex Corp., U.S. Agent for Apotex Inc.
ANDA 202784	Esomeprazole Magnesium Capsule, Delayed Release Pellets, EQ 20 mg base and EQ 40 mg base	Hetero USA, Inc., U.S. Agent for Hetero Labs Ltd., Unit-III, 1035 Centennial Ave., Piscataway, NJ 08854
ANDA 208413	Choline C-11 Injectable, 4-33.1 millicurie/mL	Washington University School of Medicine, 510 South Kingshighway Blvd., St. Louis, MO 63110
ANDA 208939	Esomeprazole Magnesium Capsule, Delayed Release, EQ 20 mg base	Hetero USA, Inc., U.S. Agent for Hetero Labs Ltd.

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 listed in the table without an approved new drug application or abbreviated new drug application 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 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: October 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-23064 Filed: 10/18/2023 8:45 am; Publication Date: 10/19/2023]