www.healthaffairs.org/doi/full/10.1377/hlthaff.25.2.313.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21433 Filed 9–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4289]

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of October 21, 2024.

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TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN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 062452	Gentamicin Sulfate solution/drop, Equivalent to (EQ) 0.3% base.	Allergan, Inc., 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92612.
ANDA 064124	Cefuroxime Sodium injectable, EQ 7.5 grams (g) base/vial ...	ACS Dobfar S.p.A., U.S. Agent Interchem Corp., 120 Route 17 North, Paramus, NJ 07652.
ANDA 077151	Milrinone Lactate injectable, EQ 40 milligrams (mg) base/200 milliliters (mL) (EQ 0.2 mg base/mL) EQ 20 mg base/100 mL (EQ 0.2 mg base/mL).	Woodward Pharma Services, LLC, 47220 Cartier Dr., Suite A, Wixom, MI 48393.
ANDA 079032	Ondansetron Hydrochloride preservative free injectable, EQ 2 mg base/mL.	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
ANDA 079075	Fentanyl Citrate tablet, EQ 0.1 mg base, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base.	Watson Laboratories, Inc., (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A, Parsippany, NJ 07054.
ANDA 206155	Olanzapine tablet, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg.	Indoco Remedies Ltd., U.S. Agent RegCon Solutions, LLC, 9920 Pacific Heights Blvd., Suite 250, San Diego, CA 92121.
ANDA 206204	Piperacillin Sodium and Tazobactam Sodium injectable, EQ 12 gm base/vial, EQ 1.5 gm base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 207919	Acyclovir Sodium injectable, EQ 50 mg base/mL	Dr. Reddy's Laboratories, Inc., 107 College Rd. East, Princeton, NJ 08540.
ANDA 209708	Mivacurium Chloride solution, EQ 10 mg base/5 mL (EQ 2 mg base/mL) and EQ 20 mg base/10 mL (EQ 2 mg base/mL).	Woodward Pharma Services, LLC.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of October 21, 2024. 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 October 21, 2024 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 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21432 Filed 9–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4189]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments: Strain Selection for Influenza Vaccines

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related