missing from this notice. Introduction or delivery for introduction into interstate commerce of ZULRESSO (brexanolone) solution, 100 mg/20 mL, without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Any ZULRESSO (brexanolone) solution, 100 mg/20 mL, that is in inventory on April 14, 2025 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: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04101 Filed 3–13–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0124]

Bausch & Lomb Incorporated, 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 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of April 14, 2025.

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TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN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 040063	ACETIC ACID 2% IN AQUEOUS ALUMINUM ACETATE (acetic acid, glacial; aluminum acetate) solution/drop, 2%; 0.79%.	Bausch & Lomb Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 060359	ERYTHROCIN STEARATE (erythromycin stearate) tablet, Equivalent to (EQ) 125 milligrams (mg) base, EQ 250 mg base, and EQ 500 mg base.	Azurity Pharmaceuticals, Inc., 8 Cabot Rd., Suite 2000, Woburn, MA 01801.
ANDA 074307	Levobunolol Hydrochloride (HCl) solution/drop, 0.25%	Bausch & Lomb Inc.
ANDA 074443	CROLOM (cromolyn sodium) solution/drop, 4%	Do.
ANDA 075546	Carteolol HCl solution/drop, 1%	Do.
ANDA 075819	Amantadine HCl syrup, 50 mg/5 milliliters (mL)	CMP Pharma, Inc., 8026 East Marlboro Rd., P.O. Box 147, Farmville, NC 27828.
ANDA 091307	Metoprolol Tartrate injectable, 1 mg/mL	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
ANDA 207243	Azelastine HCl metered spray, 0.2055 mg/spray	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of April 14, 2025. 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 April 14, 2025 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: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04106 Filed 3–13–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0104]

Bausch & Lomb Incorporated, et al.; Withdrawal of Approval of Four 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 four 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 April 14, 2025.

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