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]

BILLING CODE 4164–01–P

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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of April 14, 2025.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TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN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]

BILLING CODE 4164–01–P

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

under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 040065	Prednisolone Sodium Phosphate solution/drops, Equivalent to (EQ) 0.11% phosphate.	Bausch & Lomb Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 202031	Gemcitabine Hydrochloride (HCl) injectable, EQ 200 milligrams (mg) base/vial and EQ 1 gram (g) base/vial.	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
ANDA 202562	Dactinomycin injectable, 0.5 mg/vial	Do.
ANDA 213390	Vigabatrin for solution, 500 mg/packet	KubsTech Inc., U.S. Agent for Propel Pharma Corp, 22 Tanner Dr., Princeton, NJ 08540.

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. 2025–04107 Filed 3–13–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4938]

Bernardo Garmendia; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying a request for a hearing submitted by Bernardo Garmendia, also known as Bernardo Germendia, (Garmendia) and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Garmendia from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Garmendia was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. FDA provided notice to Garmendia of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Garmendia submitted a request for hearing but failed to file with the Agency information and analyses sufficient to create a basis for a hearing.

DATES: The order is applicable March 14, 2025.

ADDRESSES: Any application for termination of debarment by Garmendia under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–4938. An application will be placed in the docket and, unless submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20