



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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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](mailto: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Table 1.--ANDAs for Which Approval Is Withdrawn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)	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967

Application No.	Drug	Applicant
	base/vial	
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Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1.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.

Dated: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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