



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; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* on March 14, 2025 (90 FR 49), appearing on page 12163 in FR Doc. 2025-04106. The document announced the withdrawal of approval of eight abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of April 14, 2025. The document indicated that FDA was withdrawing approval of the ANDA 075819 for amantadine hydrochloride syrup, 50 milligrams /5 milliliters, held by CMP Pharma, Inc., 8026 East Marlboro Rd., P.O. Box 147, Farmville, NC 27828. Before FDA withdrew the approval of this ANDA, CMP Pharma, Inc., 8026 East Marlboro Rd., P.O. Box 147, Farmville, NC 27828, informed FDA that they did not want the approval of the ANDA withdrawn. Because CMP Pharma, Inc., timely requested that approval of the ANDA not be withdrawn, the approval is still in effect. This notice corrects this error.

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: In the *Federal Register* of Friday, March 14, 2025 (90 FR 49), appearing on page 12163 in FR Doc. 2025-04106, the following correction is made:

On page 12163, in the table, the entry for ANDA 075819 is removed.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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