4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA-2025-N-3346]

Elite Laboratories, Inc., et al.; Withdrawal of Approval of 72 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 September 24, 2025 (90 FR 183), appearing on page 45942 in FR Doc. 2025-18453. The document announced the withdrawal of approval of 72 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of October 23, 2025. The document indicated that FDA was withdrawing approval of the ANDA 070631 for valproic acid, capsule, 250 milligrams, held by Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369. Before FDA withdrew the approval of this ANDA, Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369, informed FDA that they did not want the approval of the ANDA withdrawn. Because Upsher-Smith Laboratories, LLC, timely requested that approval of the ANDA not be withdrawn, the approval is still in effect.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 Wednesday September 24, 2025 (90 FR 183), appearing on page 45942 in FR Doc. 2025-18453, the following correction is made:

On page 45943, in the table, the entry for ANDA 070631 is removed.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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