



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2197]

VistaPharm, Inc., et.al.; Withdrawal of Approval of 10 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 December 11, 2020. The document announced the withdrawal of approval (as of January 11, 2021) of 10 abbreviated new drug applications (ANDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of the following two ANDAs after receiving a withdrawal request from VistaPharm, Inc., 7265 Ulmerton Rd., Largo, FL 33771: ANDA 040323, Prednisolone Syrup, 15 milligrams (mg)/5 milliliters (mL); and ANDA 075782, Valproic Acid Syrup, 250 mg/5 mL. Before FDA withdrew the approval of these ANDAs, VistaPharm, Inc., informed FDA that it did not want the approval of the ANDAs withdrawn. Because VistaPharm, Inc., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 040323 and 075782 are still in effect.

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, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Friday, December 11, 2020 (85 FR 80119), appearing in FR Doc. 2020-27303, the following correction is made:

On page 80119, in the table, the entries for ANDAs 040323 and 075782 are removed.

Dated: March 1, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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