4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1866]

Wockhardt Ltd., et al.; Withdrawal of Approval of Nine 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 entitled "Wockhardt Ltd., et al.; Withdrawal of Approval of Nine Abbreviated New Drug Applications" that appeared in the *Federal Register* on October 9, 2020. The document announced the withdrawal of approval (as of November 9, 2020) of nine abbreviated new drug applications (ANDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of the following ANDA after receiving a withdrawal request from VistaPharm, Inc., 7265 Ulmerton Rd., Largo, FL 33771: ANDA 077788, Albuterol Sulfate Syrup, Equivalent to 2 milligrams base/5 milliliters. Before FDA withdrew the approval of this ANDA, VistaPharm, Inc., informed FDA that it did not want the approval of the ANDA withdrawn. Because VistaPharm, Inc., timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 077788 is still in effect.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 October 9, 2020 (85 FR 64150), in FR Doc. 2020-22403, the following correction is made:

On page 64150, in the table, the entry for ANDA 077788 is removed.

Dated: December 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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