4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0492]

Watson Laboratories, Inc., et.al.; Withdrawal of Approval of 36 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* of June 25, 2021. The document announced the withdrawal of approval of 36 abbreviated new drug applications (ANDAs) from multiple applicants as of July 26, 2021. The document indicated that FDA was withdrawing approval of the following ANDA, after receiving a withdrawal request from Yung Shin Pharmaceutical Ind. Co. Ltd., authorized U.S. agent, Carlsbad Technology, Inc./Simon Law, 5922 Farnsworth Ct., Suite 101, Carlsbad, CA 92008: ANDA 065152, Cephalexin Capsules, Equivalent to (EQ) 250 milligrams (mg) base and EQ 500 mg base. Before FDA withdrew the approval of this ANDA, Yung Shin Pharmaceutical Ind. Co. Ltd. informed FDA that it did not want the approval of the ANDA withdrawn. Because Yung Shin Pharmaceutical Ind. Co. Ltd. timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 065152 is still in effect.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 Friday, June 25, 2021 (86 FR 33718), FR Doc. 2021-13593, the following correction is made:

On page 33718, in the table, the entry for ANDA 065152 is removed.

Dated: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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