



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5843]

Pharmacia and Upjohn Co., et al.; Withdrawal of Approval of 19 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 January 8, 2020. The document announced the withdrawal of approval of 19 new drug applications (NDAs) from multiple applicants, withdrawn as of February 7, 2020. The document indicated that FDA was withdrawing approval of NDA 202342, Esomeprazole Strontium Delayed-Release Capsules, Equivalent to (EQ) 20 milligrams (mg) base and EQ 40 mg base, after receiving a withdrawal request from R2 Pharma, LLC, 11550 North Meridian St., Suite 290, Carmel, IN 46032–5505 (R2 Pharma). Because of clerical errors in the Agency’s processing of communications regarding this application, FDA has determined that NDA 202342 remains approved. Accordingly, FDA’s approval of NDA 202342 remains in effect. There are no changes with respect to the other 18 NDA withdrawals announced in the January 8, 2020 *Federal Register* notice.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Correction

In the *Federal Register* of Wednesday, January 8, 2020 (85 FR 915), appearing on page 916 in FR Doc. 2020-00075, the following correction is made:

On page 916, in the table, the entry for NDA 202342 is removed.

Dated: November 12, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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