



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-5323]

Hoffmann-La Roche, Inc., et al.; Withdrawal of Approval of Two 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 18, 2023. The document announced the withdrawal of approval of two new drug applications (NDA), withdrawn as of January 17, 2024. The document indicated that FDA was withdrawing approval of NDA 022424, FLOWTUSS (guaifenesin 200 milligrams (mg)/5 milliliters (mL) and hydrocodone bitartrate 2.5 mg/5 mL) Oral Solution held by Chartwell RX Sciences, LLC, 77 Brenner Dr., Congers, NY 10920. Before FDA withdrew the approval of this NDA, Chartwell RX Sciences, LLC informed FDA that it did not want the approval of the NDA withdrawn. Because Chartwell RX Sciences, LLC timely requested that approval of NDA 022424 not be withdrawn, the approval is still in effect. This notice corrects that error.

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: In the *Federal Register* of Monday, December 18, 2023 (88 FR 87433), appearing on page 87433 in FR Doc. 2023-27661, the following correction is made:

On page 87433, in the table, the entry for NDA 022424 is removed.

Dated: March 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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