



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2422]

Teva Branded Pharmaceutical Products R&D, Inc., et al.; Withdrawal of Approval of 39 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 August 4, 2025 (90 FR 36440). The document announced the withdrawal of approval of 39 new drug applications (NDA) from multiple applicants, withdrawn as of September 3, 2025. The document erroneously included NDA number 021290. The correct NDA number is 020212 for Zinecard (dexrazoxane hydrochloric acid (HCl)) Injectable, equivalent to (EQ) 250 milligrams (mg) base/vial and EQ 500 mg base/vial. This document 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. 6250 Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register issue published August 4, 2025 (90 FR 36440), the NDA number for Zinecard (dexrazoxane HCl) Injectable, EQ 250 mg base/vial and EQ 500 mg base/vial is corrected to 020212.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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