



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2025-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Address; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting a final rule entitled “New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Address” that appeared in the *Federal Register* of August 22, 2025. That final rule updated regulations to reflect application-related actions for new animal drug applications and abbreviated new animal drug applications during April, May, and June of 2025. The final rule published with an inadvertent error. This document corrects that error.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Cathie Marshall, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240-402-5693, cathie.marshall@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* document 2025-16079 published on August 22, 2025 (90 FR 40966), the amendatory language in instruction 24 directing revisions in paragraph (e)(1)(vii) was an error. On page 40971, the table under § 558.68 Avilamycin, contained an extra row with information that was not part of this drug application.

This document corrects these errors.

CORRECTION:

In FR Doc. 2025-16079, published August 22, 2025, at 90 FR 40966, make the following correction:

1. On page 40971, in the third column, correct instruction 24 to read as follows:

“24. In §558.68, revise paragraph (e)(1)(ii) to read as follows:”

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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