not appear in the Code of Federal Regulations.

CFTC Appendix to Form PF; Reporting Requirements for All Filers and Large Hedge Fund Advisers; Further Extension of Compliance Date—CFTC Voting Summary

On this matter, Acting Chairman Pham voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2025–18228 Filed 9–18–25; 8:45 am]

BILLING CODE 8011–01–P; 6351–01–P

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 September 19, 2025.

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.

[FR Doc. 2025–18217 Filed 9–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 809

[Docket No. FDA–2025–N–1730]

Regulation Identification Number 0910–AJ05 Medical Devices; Laboratory Developed Tests; Implementation of Vacatur

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: On May 6, 2024, the Food and Drug Administration (FDA, the Agency, or we) issued a final rule amending the definition of ''in vitro diagnostic products'' in FDA's regulations. On March 31, 2025, a federal district court vacated that rule. This final rule reverts to the text of the regulation as it existed prior to the effective date of the May 2024 final rule.

DATES: This rule is effective September 19, 2025.

FOR FURTHER INFORMATION CONTACT: Eitan Bernstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–9812, *LDTFinalRule@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 6, 2024, FDA published a final rule entitled ''Medical Devices; Laboratory Developed Tests'' (89 FR 37286) (codified at 21 CFR 809.3) (the Rule). The Rule added the words ''including when the manufacturer of these products is a laboratory'' to the Agency's regulations at 21 CFR 809.3(a).

On March 31, 2025, the United States District Court for the Eastern District of Texas issued a final judgment in *Am. Clinical Lab'y Ass'n* v. *FDA,* No. 4:24–CV–479–SDJ, 2025 U.S. Dist. LEXIS 59869 (E.D. Tex. Mar. 31, 2025), vacating and setting aside the Rule and remanding the matter to the Secretary of Health and Human Services for further consideration.

II. Description of the Amendment

FDA is removing the words ''including when the manufacturer of these products is a laboratory'' from 21 CFR 809.3(a), reverting to the text of the regulation as it existed prior to the effective date of the Rule. This update is being made to reflect the court's order vacating the Rule.[1]

III. Notice and Public Comment

Under the Administrative Procedure Act (APA) at 5 U.S.C. 551(4), a rule means ''the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency.'' Under the APA at 5 U.S.C. 553(b)(B), notice and comment rulemaking procedures generally do not apply when an agency for good cause finds that such procedures would be ''impracticable, unnecessary, or contrary to the public interest.''

FDA has determined that this final rule meets the APA's notice and comment exemption under 5 U.S.C. 553(b)(B). On March 31, 2025, the United States District Court for the Eastern District of Texas vacated and set aside the Rule. Because the Rule has already been vacated, this action is ministerial in nature and merely removes text from the Code of Federal Regulations to reflect the court's order. Accordingly, FDA for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

The APA allows an effective date less than 30 days after publication of a rule as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). An effective date 30 or more days from the date of publication is unnecessary because a court has already vacated the Rule. This action does not impose any new regulatory requirements on affected parties, and affected parties do not need time to ''adjust to the new regulation''

[1] The Rule also amended the statutory citation for the device definition included in 21 CFR 809.3 to reflect that the statutory definition is now codified at section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Reverting to the text of the regulation as codified prior to the effective date of the Rule includes amending the statutory citation to revert to section 201(h) of the FD&C Act, which citation remains accurate but is less specific.