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.

before the rule takes effect. *Am. Federation of Government Emp., AFL–CIO* v. *Block,* 655 F.2d 1153, 1156 (D.C. Cir. 1981). Therefore, FDA for good cause finds that this action may become effective on the date of its publication.

IV. Economic Analysis of Impacts

We have examined the impacts of this action under Executive Order 12866, Executive Order 13563, and Executive Order 14192.

Executive Orders 12866 and 13563 direct us to assess all benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are economically significant under Executive Order 12866 if they have an annual effect on the economy of $100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The Office of Information and Regulatory Affairs (OIRA) has determined that this action is a significant regulatory action under Executive Order 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant regulatory actions ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' This action is considered an Executive Order 14192 deregulatory action.

On May 6, 2024, FDA published the Rule. The primary estimate of the total annualized cost of the Rule over a 20-year time horizon was $1.29 billion at a 7 percent discount rate and $1.37 billion at a 3 percent discount rate, both reported in constant 2022 dollars. We report these costs in constant 2024 dollars as $1,384.98 million at 7 percent discount rate and $1,475.93 million at 3 percent discount rate after adjusting for inflation using the GDP deflator. For purposes of estimating the cost savings of the vacatur of the Rule, costs for reading and understanding the Rule represent sunk costs while the remaining costs constitute cost savings.[2] The estimated sunk cost of the Rule is $0.34 million at 7 percent discount rate and $0.25 million at 3 percent discount rate.

Table 1 summarizes the estimated forgone benefits and cost savings resulting from the Rule no longer being in effect. A simple reversal of the estimates published with the Rule indicates that now, the annualized forgone benefits over 20 years would be $3,723.39 million and $4,606.01 million and at 7 and 3 percent discount rate, respectively. The total annualized cost savings are $1,444.45 million and $1,539.50 million at 7 and 3 percent discount rate, respectively. The annualized cost savings of $1,444.45 million represent $1,365.53 million to domestic entities and $78.92 million in pass-through cost savings from foreign entities at a 7 percent discount rate. Similarly, the annualized cost savings of $1,539.50 million represent $1,455.14 million to domestic entities and $84.35 million in pass-through cost savings from foreign entities at a 3 percent discount rate.[3] Portions of the broader benefit and cost uncertainty ranges overlap, thus indicating the possibility of negative net benefits of the Rule and positive net benefits of its no longer being in effect. Moreover, the quantitative estimates omit various regulatory consequences that are especially challenging to assess, such as any possible effect on innovation related to laboratory-developed tests (LDTs) associated with the Rule.

TABLE 1—SUMMARY OF BENEFITS AND COSTS ASSOCIATED WITH THE VACATUR OF THE RULE

[Millions of 2024 dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized ($millions/year).	$(3,723.39) (4,606.01)	$(11,773.23) (14,450.60)	$(1,048.05) (1,319.58)	2024 2024	7 3	2025–2044	
Annualized Quantified	....	....	....	....	7 3	.....	
Qualitative							
Costs:							
Annualized Monetized ($millions/year).	(1,444.45) (1,539.50)	(3,882.26) (4,134.71)	(671.17) (715.01)	2024 2024	7 3	2025–2044	Total cost savings include domestic cost savings and foreign pass-through cost savings.
Annualized Quantified	....	....	....	....	7 3	.....	
Qualitative							
Transfers:							
Federal Annualized Monetized ($millions/year).	....	....	....	2024 2024	7 3	.....	
	From:			To:			

[2] The costs associated with reading and understanding the Rule would have been incurred any time after publication of the rule (May 2024) up to the start of the first stage of the phaseout policy described in the preamble to the Rule (May 2025). Because the Rule has been vacated, these costs are now considered ''sunk costs.'' A sunk cost is money that has already been spent that cannot be recovered, no matter what decision is made going forward. Since we don't have data on what portion of affected entities has already incurred these costs, we use the total estimated costs for reading and understanding the Rule to estimate sunk costs. The actual sunk cost is likely lower.

[3] We estimate pass-through cost savings from foreign entities by assuming that 50 percent of foreign costs would be passed on to the U.S. market. Costs to foreign entities of the Rule in 2024 dollars over 20 years were estimated at $157.85 million and $168.71 million at 7 and 3 percent discount rate, respectively. The estimated pass-through costs savings are $78.92 ($157.85 × 0.5) million and $84.35 ($168.71 × 0.5) million at 7 and 3 percent discount rate, respectively.

TABLE 1—SUMMARY OF BENEFITS AND COSTS ASSOCIATED WITH THE VACATUR OF THE RULE—Continued
[Millions of 2024 dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Other Annualized Monetized ($millions/year).	....	....	....	....	7 3	....	
	From:			To:			

Effects:
State, Local or Tribal Government:
Small Business:
Wages:
Growth:

Note: Values in parentheses denote negative values.

In line with Executive Order 14192, in Table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. For this analysis, we assume that the costs of the Rule in years 21 and beyond would be equal to the costs of the Rule in year 20. When estimating the cost savings of the vacatur of the Rule, we include cost savings that will similarly extend in perpetuity. We estimate that this action is associated with $1,423.23 million in annualized net cost savings at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

TABLE 2—EXECUTIVE ORDER 14192 SUMMARY TABLE
[Millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate]

	Primary estimate	Low estimate	High estimate
Present Value of Costs	$0	$0	$0
Present Value of Cost Savings	20,331.91	12,675.63	44,468.47
Present Value of Net Costs	(20,331.91)	(12,675.63)	(44,468.47)
Annualized Costs	0	0	0
Annualized Cost Savings	1,423.23	887.29	3,112.79
Annualized Net Costs	(1,423.23)	(887.29)	(3,112.79)

Note: Values in parentheses denote net negative costs (*i.e.,* net cost savings).

List of Subjects in 21 CFR Part 809

Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 809 is amended as follows:

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

■ 1. The authority citation for part 809 continues to read as follows:

Authority: 21 U.S.C. 321(h)(1), 331, 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 371, 372, 374, 381, and 42 U.S.C. 262.

■ 2. In § 809.3, revise the last sentence of paragraph (a) to read as follows:

§ 809.3 Definitions.

(a) * * * These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act.

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services

[FR Doc. 2025–18239 Filed 9–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 972

[Docket Number FHWA–2025–0017]

RIN 2125–AG23

Rescinding Regulations Regarding Management Systems Pertaining to the Fish and Wildlife Service and the Refuge Roads Program

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FHWA is rescinding the regulations issued on February 27, 2004 on the Fish and Wildlife Service (FWS) Management Systems.

DATES: This final rule is effective October 20, 2025.

FOR FURTHER INFORMATION CONTACT: Corey Bobba, Office of Federal Lands Highways, (202) 366–9489, *corey.bobba@dot.gov;* or James Esselman, Office of the Chief Counsel, (202) 366–6181, *James.Esselman@dot.gov,* Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, as well as the notice of proposed rulemaking (NPRM), and all comments received may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic