List of Subjects for 15 CFR Part 272

Labeling, Consumer protection, Safety.

Alicia Chambers,

NIST Executive Secretariat.

PART 272—[REMOVED AND RESERVED]

■ Accordingly, for the reasons set forth above and under the authority of 15 U.S.C. 277, part 272 of title 15 of the Code of Federal Regulations is removed and reserved.

[FR Doc. 2026–03307 Filed 2–18–26; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

15 CFR Parts 295 and 296

[Docket No. 260210–0042]

RIN 0693–AB72

Eliminating Obsolete Regulations Related to the Advanced Technology Program and the Technology Innovation Program

AGENCY: National Institute of Standards and Technology (NIST), Department of Commerce (Department).

ACTION: Final rule.

SUMMARY: By this rule, NIST removes the regulations outlining the Advanced Technology Program (ATP) and the Technology Innovation Program (TIP), both of which now lack authorization and, operationally, are no longer active. This action is necessary to reflect the repeal of the underlying statutory provision and to ensure that NIST's regulations remain current and up-to-date. This action is intended to minimize the risk of confusion and/or distraction and to promote efficiency.

DATES: The rule is effective February 19, 2026.

FOR FURTHER INFORMATION CONTACT: Daniel Sweeney, Senior Counsel, Office of the General Counsel, at (202) 482–1395.

SUPPLEMENTARY INFORMATION: This action eliminates NIST's regulations at 15 CFR parts 295 and 296, which outline the ATP and the TIP, respectively. The ATP and the TIP were grant programs operated by NIST and related to the development of technology. Part 295, which outlines the ATP, was promulgated by a final rule published on July 24, 1990 (55 FR 30145); and part 296, which outlines the TIP, was promulgated by a final rule published on June 25, 2008 (73 FR 35915). Both parts were promulgated pursuant to 15 U.S.C. 278n, and 15 U.S.C. 278n is their cited statutory authority. But 15 U.S.C. 278n has since been repealed. *See* Public Law 114–329, Title II, § 205(a)(1), Jan. 6, 2018, 130 Stat. 3000. And neither the ATP nor the TIP is operationally active today. The elimination of 15 CFR parts 295 and 296 is therefore necessary to remove outdated regulatory language, minimize the possibility of public confusion regarding the status of these programs, and ensure that NIST's regulations remain accurate and up-to-date.

Regulatory Classifications

A. Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b)(B), the Department finds good cause to waive the prior notice and opportunity for public participation requirements of the Administrative Procedure Act for this final rule. The Department considers this rule to be uncontroversial, and has determined that prior notice and opportunity for public participation is unnecessary, because this rule only removes two regulations that both lack a valid statutory authorization, no longer serve any purpose, and pose some genuine risk of confusing the public; public participation would not justify the continued maintenance of either 15 CFR part 295 or 15 CFR part 296 under the Department's regulatory policy. For the same reason, the Department has determined that delaying the effectiveness of this elimination would be contrary to the public interest. Eliminating parts 295 and 296, which are obsolete and pose some risk of confusion, will immediately benefit the public at little to no cost. The Department therefore finds good cause to waive the public notice and comment period under 553(b)(B) and to waive the 30-day delay in effectiveness under 553(d).

B. Executive Orders 12866, 14192, and 13132

The Office of Management and Budget has determined this rule is not significant pursuant to Executive Order (E.O.) 12866. This rule is an E.O. 14192 deregulatory action. This rule does not contain policies having federalism implications as the term is defined in E.O. 13132.

C. Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public participation are not required to be given for this rule by 5 U.S.C. 553(b)(B), the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

D. Paperwork Reduction Act

This rule will not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

List of Subjects for 15 CFR Parts 295 and 296

Business and industry, Grant programs—science and technology, Inventions and patents, Reporting and recordkeeping requirements, Research, Science and technology.

Alicia Chambers,

NIST Executive Secretariat.

PARTS 295 AND 296—[REMOVED AND RESERVED]

■ Accordingly, for the reasons set forth above and under the authority of 15 U.S.C. 277, parts 295 and 296 of title 15 of the Code of Federal Regulations are removed and reserved.

[FR Doc. 2026–03303 Filed 2–18–26; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 26

[Docket No. FDA–2024–N–4016]

RIN 0910–AI92

Revocation of Regulations Regarding the Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: United States and the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule revoking the regulations entitled ''Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: United States and The European Community.'' FDA is taking this action because the

regulations at 21 CFR part 26 have been superseded in part by the ''United States-European Union Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs)'' that entered into force in 2017 (2017 Amended Pharmaceutical Annex), are outdated, do not reflect current Agency practice, and are unnecessary.

DATES: This rule is effective March 23, 2026.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Megan Andersen, Office of Inspections and Investigations, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 202–684–5901, *megan.andersen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

FDA is revoking the regulations at part 26 (21 CFR part 26), which substantially reflect certain provisions of the ''Agreement on Mutual Recognition Between the United States of America and the European Community'' that was signed in 1998 (1998 MRA). These regulations have been superseded in part by the 2017 Amended Pharmaceutical Annex, are outdated, do not reflect current Agency practice, and are unnecessary.

B. Summary of the Major Provisions of the Final Rule

The final rule revokes part *26,* ''Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: United States and The European Community.'' This part substantially reflects certain provisions of the 1998 MRA between the United States and the European Community (EC) that were created to better utilize the inspectional resources of each signatory by recognizing one another's inspection reports. Part 26 consists of 3 subparts: Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices (which substantially reflects the 1998 MRA's ''pharmaceutical sectoral annex''), Subpart B—Specific Sector Provisions for Medical Devices (which substantially reflects the 1998 MRA's ''medical device sectoral annex''), and Subpart C—''Framework'' Provisions (which substantially reflects the 1998 MRA's ''umbrella'' agreement that contained general provisions applicable to the operation of all of the sectoral annexes).

C. Legal Authority

FDA is taking this action under the general administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see generally 21 U.S.C. 301–399). We discuss our legal authority in greater detail in part IV.

D. Costs and Benefits

Because this final rule would not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact, if any, is expected to be minimal.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation	What it means
EC	European Community.
EU	European Union.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
GMP	Good Manufacturing Practice.
MRA	Mutual Recognition Agreement.

III. Background

A. Need for the Regulation/History of This Rulemaking

Part 26 was issued in response to the 1998 MRA between the United States and the EC, under which both parties would recognize certain drug and device inspection/evaluation reports of the other, in order to more effectively allocate limited inspection resources (Mutual Recognition of Pharmaceutical Good Manufacturing Practice Inspection Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports Between the United States and the European Community, 63 FR 60122 at 60141 (November 6, 1998)). Subparts A and B of part 26 substantially reflect the 1998 MRA's pharmaceutical and medical device sectoral annexes, respectively. Subpart C of part 26 sets forth the framework provisions by which Subparts A and B can be implemented. Subpart A governs ''the exchange between the parties and normal endorsement by the receiving regulatory authority of official [pharmaceutical] good manufacturing practices (GMP) inspection reports[.]'' (21 CFR 26.2). Subpart B specifies ''the conditions under which a party will accept the results of quality system-related evaluations and inspections and premarket evaluations of the other party with regard to medical devices as conducted by listed conformity assessment bodies (CAB's)'' and provides for ''other related cooperative activities.'' (21 CFR 26.31(a)).

The pharmaceutical sectoral annex to the 1998 MRA was superseded by the 2017 Amended Pharmaceutical Annex (*https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements-mra*). The 2017 Amended Pharmaceutical Annex included new terms, rendering Subpart A obsolete. The medical device sectoral annex was not addressed in the 2017 Amended Pharmaceutical Annex, but since the 1998 MRA went into effect, it has never been fully implemented. As other mechanisms (*e.g.,* Medical Device Single Audit Program) now exist for mutual recognition with Europe with respect to medical device inspections, Subpart B is no longer necessary. Subpart C contains general provisions applicable to both Subparts A and B that will be unnecessary once Subparts A and B are revoked.

FDA published a notice of proposed rulemaking that would revoke 21 CFR part 26 in the **Federal Register** on September 20, 2024 (89 FR 77062). The public was invited to submit electronic

or written comments during the comment period, which closed on November 19, 2024.

B. Summary of Comments to the Proposed Rule

FDA received eight submissions on the proposed rule by the close of the 60-day comment period with each containing one or more comments on one or more issues. Some of the comments were submitted by individuals and some were submitted anonymously. Some of the comments supported the proposed rule while others were opposed to the proposed rule.

IV. Legal Authority

We are issuing this final rule under the drugs, medical devices, and general administrative provisions of the FD&C Act (21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 384e, and 393) and under certain provisions of the Public Health Service Act (42 U.S.C. 216, 241, 242l, 262, 264, and 265). Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA has the authority to issue regulations, and under section 809 of the FD&C Act (21 U.S.C. 384e), FDA has the authority to ''enter into arrangements and agreements with a foreign government or an agency of a foreign government to recognize the inspection of foreign establishments registered under section 510(i) in order to facilitate preapproval or risk-based inspections in accordance with the schedule established in paragraph (2) or (3) of section 510(h)[.]''

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received eight comment submissions on the proposed rule by the close of comment period, with each containing one or more comments on one or more issues. Some of the comments were submitted by individuals while others were submitted anonymously.

We describe and respond to the comments in section V.B. and V.C. of this document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

We also received several comments that were not responsive to the content of the proposed rule, and therefore, were not considered in its final development. After reviewing and considering all comments that were responsive to the proposed rule, we are finalizing the proposed rule without change.

B. Description of General Comments and FDA Response

Several comments make general remarks either supporting or opposing the proposed rule. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) Three comments are in support of finalizing the proposed rule and recommend FDA provide clear guidance about the changes and their impact to help maintain compliance and uphold high safety and quality standards.

(Response 1) We agree with the comments and in the proposed rule we stated that the rule would not impose any new changes or additional regulatory burdens. The rule is not anticipated to result in any compliance costs and the economic impact, if any, is expected to be minimal.

C. Specific Comments and FDA Response

(Comment 2) One comment asks how an MRA has the force of law such that it could supersede a regulation for which the American public received advanced notice and opportunity to comment.

(Response 2) MRAs are agreements between two or more countries or regulatory counterparts to recognize certain processes or procedures. In the context of FDA, MRAs have generally focused on recognizing the inspections and accepting the inspectional documents of foreign regulatory authorities. FDA's current MRAs, including the 2017 Amended Pharmaceutical Annex, are binding international agreements entered into by the United States. (22 CFR 181.2) In 2012, the 112th Congress passed, and the President signed into law, Title VII of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144*)* amending the FD&C Act. Under the FD&C Act as amended, FDA itself has the authority to enter into agreements to recognize inspections conducted by foreign regulatory authorities if FDA determines those authorities are capable of conducting inspections that meet the applicable requirements of the FD&C Act.

When the United States entered into an MRA with the EC in 1998, FDA issued part 26, which substantially reflects certain provisions of the 1998 MRA. Under 21 CFR 26.80(b), the 1998 MRA can be ''amended in writing by the parties to that agreement.'' In 2017, the 1998 MRA was amended through an exchange of letters between the United States and the European Union (EU).

The regulations at part 26 also provide that ''[i]f the parties to the MRA subsequently amend or terminate the MRA, FDA will modify this part accordingly, using appropriate administrative procedures[.]'' (21 CFR 26.0). We have determined that this rulemaking is an appropriate procedure for revoking the regulations at part 26.

As we explained in the proposed rule, we do not believe it is required or would be beneficial for FDA to issue regulations that substantially reflect the 2017 Amended Pharmaceutical Annex with the EU. The 2017 Amended Pharmaceutical Annex is in force and has been successfully implemented without regulations that substantially reflect it. The same is true for the MRAs that the United States entered into subsequently with Switzerland and the United Kingdom (*https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements-mra*).

(Comment 3) One comment asserts that revoking the MRA on pharmaceutical inspections would lead to increased costs, reduced access to affordable medications, and potentially less international collaboration.

(Response 3) This rule does not revoke an MRA. This rule revokes the regulations that substantially reflect certain provisions of the 1998 MRA. As noted, in 2017, the United States and the EU completed an exchange of letters to amend the 1998 MRA. Under the 2017 Amended Pharmaceutical Annex, which is in force and has been successfully implemented, United States and EU regulators are able to utilize each other's GMP inspections of pharmaceutical manufacturing facilities. FDA's revocation of part 26 should not be interpreted as FDA retreating from our commitment to working with our foreign counterparts, including through MRAs, to achieve greater efficiencies and increase our inspectional reach.

VI. Effective Date/Compliance Date(s)

This final rule is effective 30 days after publication in the **Federal Register**.

VII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

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 ''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 final rule is not 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 final rule is considered an Executive Order 14192 deregulatory action.

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule does not add any new regulatory burden on the pharmaceutical or medical device industries, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $187 million, using the most current (2024) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

We believe industry will maintain its current practices following the removal of part 26. In line with Executive Order 14192, in Table 1 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. We estimate that this rule will generate no quantifiable costs or cost savings. Therefore, we expect this final rule to be cost neutral.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

[Millions of 2024 dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$0	$0	$0	2024	7	10	
	0	0	0	2024	3	10	
Annualized Quantified							
Qualitative	Avoid confusion created by outdated and unnecessary regulations that do not reflect current Agency practice.						
Costs:							
Annualized Monetized $millions/year	0	0	0	2024	7	10	
	0	0	0	2024	3	10	
Annualized Quantified					7		
					3		
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			
Effects:							
State, Local or Tribal Government: No estimated effect.							
Small Business: No estimated effect.							
Wages: No estimated effect.							
Growth: No estimated effect.							

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. We estimate that this rule will generate $0 in annualized net costs 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 (7%)	Lower bound (7%)	Upper bound (7%)
Present Value of Costs	$0	$0	$0
Present Value of Cost Savings	0	0	0
Present Value of Net Costs	0	0	0
Annualized Costs	0	0	0
Annualized Cost Savings	0	0	0
Annualized Net Costs	0	0	0

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that this final rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

List of Subjects in 21 CFR Part 26

Animal, Animal drugs, Biologics, Drugs, Exports, Imports.

PART 26—[REMOVED]

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 26 is removed.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–03286 Filed 2–18–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2.19

[Docket No. FDA–2020–N–1383]

RIN 0910–AI65

Revocation of Methods of Analysis Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to revoke the methods of analysis regulation, which describes an FDA policy to use certain methods of analysis for FDA enforcement programs when the method of analysis is not prescribed in a regulation. FDA is issuing this action because the existing regulation is no longer necessary.

DATES: This rule is effective on March 23, 2026.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Managements Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Nadine Dominique, Office of Inspections and Investigations, Food and Drug Administration, 12420 Parklawn Drive, Rockville, MD 20852, 301–348–1868, *nadine.dominique@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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