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:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

This final rule revokes the methods of analysis regulation, § 2.19 (21 CFR 2.19), 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. The regulation is no longer necessary.

B. Summary of the Major Provisions of the Final Rule

This final rule revokes § 2.19, which states that, where a method of analysis is not prescribed by regulation, it is FDA policy in its enforcement programs to utilize the methods of analysis of AOAC INTERNATIONAL (hereinafter referred to as ''AOAC'') [1] as published in the latest edition (13th Ed., 1980) of their publication ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' and their supplements thereto, which are incorporated by reference, when available and applicable.

C. Legal Authority

FDA is taking this action under the general administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

D. Costs and Benefits

There may be qualitative benefits to removing § 2.19 because there will no longer be any inefficiencies due to keeping unnecessary regulations on the books. Revocation of § 2.19 will not change Agency current practice; therefore, there are no costs. Annualized over 10 years, the estimated benefits (*i.e.,* cost savings) of the final rule will be $0 at both the 3 and 7 percent discount rates. The annualized costs of the final rule will be $0 at both the 3 and 7 percent discount rates.

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

Abbreviation/acronym	What it means
AOAC	ASSOCIATION OF OFFICIAL ANALYTICAL COLLABORATION.
FDA	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
HHS	U.S. Department of Health and Human Services.
OMB	U.S. Office of Management and Budget.
OII	Office of Inspections and Investigations.

III. Background

A. History of This Rulemaking

FDA's regulation concerning its policy of methods of analysis in enforcement programs dates back more than 50 years (37 FR 16174, Aug. 11, 1972). Early versions of the regulation stated that unless a regulation prescribed a specific method of analysis, it would be FDA's policy to use the methods of analysis in the ''latest edition of [the AOAC's] publication . . . and the supplements thereto . . .'' 21 CFR 3.89 (later reorganized and republished as 21 CFR 2.19 (42 FR 15559 (Mar. 22, 1977))). However, in 1982, 1 CFR 51.1 was amended to limit incorporation by reference of a publication to the edition of the publication that is approved, and to exclude future amendments or revisions of the publication.

FDA has revised the methods of analysis regulation several times, including in 1982 to meet the drafting requirements for incorporation by reference set forth in 1 CFR 51.1(f), and after to make several editorial amendments to update names and addresses. However, since the 1982 revision, the regulation has referred to the methods of analysis in the 13th Edition, 1980 of AOAC's publication and supplements thereto (''Changes in Methods'' as published in the March issues of the ''Journal of the Association of Official Analytical Chemists''). FDA is now revoking the methods of analysis regulation as specified in this final rule.

B. Need for the Regulation

The Agency believes that the methods of analysis regulation is unnecessary as a general matter. Absent a method of analysis specified in statute or regulation, FDA believes it is more appropriate, flexible, and efficient to identify the Agency's preferred methods of analysis in documents such as compliance program guidance documents, Agency methods compendia, and other resources. FDA is revoking this rule because it is not FDA's preferred policy to always use the 13th edition of the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' or the supplements thereto, for enforcement programs when the method is not prescribed by statute or regulation. Unless a method of analysis is specified in law, FDA believes it is more appropriate, flexible, and efficient to identify the Agency's preferred and validated methods of analysis in documents that can be updated more frequently and efficiently as the science and technologies advance while continuing to maintain transparency about FDA analytical methods.

C. Summary of Comments to the Proposed Rule

We published a proposed rule entitled ''Revocation of Methods of Analysis Regulation'' (the proposed rule) in the **Federal Register** on July 15, 2022 (87 FR 42398). The comment period closed on September 28, 2022. We received comments supporting and opposing the proposed rule. Some comments expressed concerns that revoking § 2.19 would result in a lack of quality control or in FDA using non-validated methods. Some comments recommended retaining the regulation with updated language.

D. Clarifications from the Proposed Rule

We are making some clarifications in this final rule. In the proposed rule, under the Analysis of Environmental Impact section, we stated that, in accordance with 21 CFR 25.31(h), this action does not individually or cumulatively have a significant effect on the human environment. However, the correct applicable exemption for this rule is 21 CFR 25.30(h).

In the proposed rule we also stated that, absent specifying a method of analysis in law, FDA believes it is more appropriate, flexible, and efficient to identify the Agency's preferred methods of analysis in documents such as the Office of Inspections and Investigations'

[1] Section 2.19 and the proposed rule refer to AOAC as the ''Association of Analytical Chemists International,'' as it was previously known. The organization is now known as ''AOAC INTERNATIONAL,'' which stands for ''ASSOCIATION OF OFFICIAL ANALYTICAL COLLABORATION (AOAC) INTERNATIONAL.''

(OII's) Laboratory Procedures Manual, FDA compliance programs, and other resources. However, OII's laboratory manual does not contain actual methods of analysis; rather, it describes policy on methods of validation and verification, irrespective of the source of the method. Further, we identify methods of analysis in Agency methods compendia. Therefore, we are clarifying that FDA believes it is more appropriate, flexible, and efficient to identify preferred methods of analysis in documents such as compliance programs, Agency methods compendia, and other resources.

IV. Legal Authority

FDA is issuing this final rule under the following provisions of the (FD&C Act): 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received approximately 40 comments on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from consumers, food associations, accreditation bodies, laboratory associations, laboratories, consumer groups, and other organizations.

We describe and respond to the comments in sections V.B through E 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 comments 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, importance, or the order in which comments were received. After review and consideration of all relevant comments, as stated above, FDA is removing the prescriptive requirements of § 2.19.

B. Description of General Comments and FDA Response

Some comments make remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) The comments generally support the revocation of the methods of analysis regulation and do not foresee the revocation as having a negative impact. Comments go on to say that the proposed revocation may encourage more laboratories to adopt a laboratory quality systems approach and adopt a more flexible technology strategy.

(Response 1) We appreciate the support expressed in the comments received. Revoking the methods of analysis regulation is intended to make it more flexible and efficient for the Agency to use its preferred methods of analysis by identifying those analyses in documents such as compliance program guidance documents and other resources.

(Comment 2) One comment suggests the loss of AOAC as a Federal partner would be very expensive and add a large economic burden to the Federal Government.

(Response 2) This rulemaking does not preclude FDA from using AOAC official methods or working with AOAC as a partner. FDA may continue to use AOAC official methods when they are appropriate for the particular analysis needed. In fact, as some of the comments point out, FDA has existing manuals and guidelines that recommend FDA use AOAC official methods for certain analyses. Revoking this regulation does not affect those recommendations. The comment does not provide any evidence of the rule being expensive or how it would create an economic burden to the Federal Government.

C. Comments on Quality Control and FDA Response

(Comment 3) Many comments express concerns about the lack of quality control that may follow from the rule, and how AOAC's rigorous standards and systematic evaluations are heavily relied upon. Some of the comments assert that the withdrawal of this regulation by FDA would undermine the credibility of many analytical methods used by industry and governments. Other comments maintain that AOAC's official methods are used as a basis for most of their tests, and that revoking the regulation would make test results less transparent and accurate.

(Response 3) As previously mentioned, revoking § 2.19 will not end FDA's use of AOAC's official methods of analysis when these methods are appropriate. Methods used by the Agency undergo rigorous qualification, validation, and fitness-of-use in accordance with international standards, including the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 accreditation framework. FDA remains committed to using the appropriate methods for any given analysis, whether or not the methods are AOAC official methods. FDA has and does use non-AOAC-approved methods for analyses unrelated to enforcement, such as for scientific research and risk assessment, and we did not receive any comments that challenged the validity of these methods.

For example, with the issuance of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) Final Rule on Laboratory Accreditation for Analyses of Foods (LAAF) in 2021,[2] many private laboratories conducting analyses of FDA regulated products are now governed by an Agency-approved accrediting body. Under the LAAF regulation, that accreditation body must ensure that the methods, and scientific results are valid, adequate, and reliable, regardless of the method source.[3]

To the extent comments suggest that revoking the methods of analysis regulation would undermine the credibility of methods or tests used by industry, the regulation only established a policy for FDA to use AOAC official methods. This rulemaking does not create new testing requirements for the regulated industry nor prevent industry from using AOAC official methods. Neither revoking nor maintaining the regulation affects what industry uses for analytical testing, as they are still free to use AOAC official methods as appropriate and permissible.

(Comment 4) One comment claims that revoking § 2.19 would undermine the standing of thousands of methods of analysis used by industry and governments worldwide. As an example, this comment explains how AOAC methods have been used as a basis to arbitrate trade disputes under the General Agreement on Tariffs and Trade (GATT, pre-1995) and the World Trade Organization (WTO) agreements. The commenter asserted that, without a codified recognition of AOAC methods, the United States will likely be at a disadvantage in future trade disputes.

(Response 4) As the proposed rule explained, § 2.19 states, in part, that where a method of analysis is not prescribed by regulation, it is FDA policy in its enforcement programs to utilize the methods of analysis of the AOAC as published in the latest edition (13th Ed., 1980) of their publication ''and the supplements thereto.'' Section 2.19 does not address or establish which methods of analysis are used ''as a basis for trade disputes under [the WTO]'' or

[2] 86 FR 68728 (Dec. 3, 2021).

[3] 21 CFR 1.1120.

any other forum external to FDA. The comment does not provide information as to how the WTO determines which methods of analysis to use as a basis to arbitrate trade disputes. Additionally, the WTO is still free to reference AOAC Official Methods as a basis to arbitrate trade disputes with or without § 2.19, as this regulation pertains only to methods of analyses used by FDA. Thus, revoking § 2.19 does not affect or preclude the reference to AOAC official methods in trade disputes arbitrated by the WTO.

(Comment 5) Several comments express concern about revoking a policy that commits to using a validated method and assert that revoking § 2.19 would result in FDA using non-validated methods of analysis.

(Response 5) The revocation of FDA's policy of only using AOAC methods in its enforcement programs does not condone the use of unvalidated methods of analysis. FDA is a science-based agency and is committed to using only methods that are validated. For instance, in the foods program, FDA's Compendium of Analytical Methods contains analytical methods that have a defined validation status and are currently used by FDA regulatory laboratories. In these cases, the validation status of a method may have been established through the FDA Foods Program Method Development, Validation, and Implementation Program using the Foods Program Method Validation Guidelines or by internal FDA Foods Program committees that have established the equivalency of the method validation level to the FDA guidelines.[4] The regulatory laboratories are all accredited to an ISO standard that requires FDA to validate the methods. Further, FDA has developed a methods portal that is publicly facing on FDA's website.[5]

D. Comments on How the Language of the Regulation Should Be Revised and FDA Response

(Comment 6) Some comments recommend retaining the regulation with updated language reflecting the use of the latest versions of AOAC Official Methods of Analysis.

(Response 6) Retaining the regulation only to update it with the latest version would still be a policy of using only AOAC official methods at the exclusion of other, potentially more suitable methods. Our revocation of this rule is intended to allow FDA the discretion to use methods more fit for the purpose of any given analysis, as science and technologies continually evolve, and FDA needs the flexibility to use other methods that might be more recent, accurate, and efficient.

E. Comments on Necessity of the Regulation and FDA Response

(Comment 7) Some comments suggest that revoking the regulation could weaken the validity of many analytical methods used by industries and governments globally, potentially harming the Agency's operations.

(Response 7) The rule does not govern analytical methods used by industry and foreign governments, so revoking it will not impact the validity of methods used by industry and governments worldwide. FDA may continue, as appropriate, to use AOAC official methods and will encourage and refer stakeholders to use methods that are best for the given analysis. AOAC official methods are widely regarded as the default standard rather than the sole standard. FDA acknowledges AOAC's significant influence and methodologies, yet believes that in certain cases, alternative methods may be more suitable and fit for purpose.

(Comment 8) Several comments express concern about revoking a policy that provides a level of certainty to stakeholders about which methods of analysis FDA will use and claim that revoking the regulation will reduce predictability about the methods FDA will use for any given analysis.

(Response 8) FDA has multiple public-facing resources that provide the methods FDA intends to use for any given analysis, and therefore, does not agree that revoking this regulation will result in uncertainty as to what methods FDA may use. For example, FDA's web page on laboratory methods for foods has resources containing some of the analytical laboratory methods the Agency uses FDA to help ensure food safety.[6] These include validated methods for chemical, microbiological, and microanalytical analyses. FDA also has published Compliance Policy Guides (CPGs), such as CPG Sec. 150.500 Analytical Methodology Used by FDA—Drugs,[7] that set forth specific analytical methods. Compliance programs issued by FDA, such as Compliance Program 7321.008 Dietary Supplements—Foreign and Domestic Inspections, Sampling, and Imports,[8] may also specify tailored analytical methods used by FDA laboratories.

(Comment 9) One comment references the U.S. Office of Management and Budget (OMB) Circular A–119, which states that voluntary consensus standards are appropriate or adaptable for the government's purposes. These standards ''eliminate the cost to the government of developing its own standards'' and ''promote efficiency and economic competition through harmonization of standards.'' The comment maintains that this final rule appears in conflict with the circular.

(Response 9) Revoking the methods of analysis regulation is not inconsistent with OMB Circular A–119. FDA agrees that voluntary standards are appropriate for government purposes and relieve FDA of developing its own standards. However, FDA is not in favor of maintaining a Federal regulation that establishes a policy for FDA to utilize a singular approving body's standard or method for all analyses not prescribed by regulation in its enforcement programs. It is in the public's best interest for FDA to have the flexibility to select the methods or standards deemed more suitable for a specific analysis.

VI. Effective Date

This rule is effective on the date of 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 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

[4] FDA's Method Validation Guidelines are available at *https://www.fda.gov/science-research/field-science-and-laboratories/method-validation-guidelines.*

[5] *https://www.fda.gov/food/laboratory-methods-food/foods-program-compendium-analytical-laboratory-methods.*

[6] *https://www.fda.gov/food/science-research-food/laboratory-methods-food.*

[7] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-150500-analytical-methodology-used-fda-drugs.*

[8] *https://www.fda.gov/food/compliance-enforcement-food/food-compliance-programs#food_ds.*

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 significant new regulations ''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 an Executive Order 14192 deregulatory action because it eliminates an unnecessary regulation.

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or to meet 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 industry, 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 1 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

This final rule will revoke 21 CFR 2.19 Methods of analysis, which states that FDA policy is to use the Association of Official Analytical Chemists (AOAC) methods of analysis as published in the 1980 edition of ''Official Methods of Analysis of the Association of Official Analytical Chemists'' to analyze samples in FDA enforcement programs when the method of analysis is not prescribed in a regulation. FDA is proposing this action because a general reference to the 1980 edition of the ''Official Methods of Analysis of the Association of Official Analytical Chemists'' is unnecessary and because newer, updated methods of analysis may exist. FDA believes it is more appropriate, flexible, and efficient to identify the Agency's preferred methods of analysis in documents such as the Agency methods compendium, FDA compliance programs, and other resources. Thus, § 2.19 is an unnecessary policy. We expect the economic impact on FDA resulting from revoking an unnecessary regulation to be minimal.

Table 1 summarizes the estimated benefits and costs of the final rule. Annualized over 10 years, the estimated benefits (*i.e.,* cost savings) of the final rule will be $0 at both the 3 and 7 percent discount rates. The present value of the estimated benefits (*i.e.,* cost savings) of the final rule will also be $0 at both the 3 and 7 percent discount rates. The annualized costs of the final rule will be $0 at both the 3 and 7 percent discount rates. The present value of costs of the final rule will also be $0 at both the 3 and 7 percent discount rates.

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	There will no longer be any inefficiencies due to keeping unnecessary regulations on the books.						
Costs:							
Annualized Monetized $millions/year	0	0	0	2024	7	10	
	0	0	0	2024	3	10	
Annualized Quantified					7		
					3		
Quantified							
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: None.
Small Business: None.
Wages: None.
Growth: None.

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 million 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 estimate	Low estimate	High estimate
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

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 5) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(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

FDA concludes that this final rule contains no collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) 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 this final 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 this final 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 final rule in accordance with the principles set forth in Executive Order 13175. We have determined that this final rule does not contain policies that would have a substantial direct effect 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.

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov/.* Although FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, please note that websites are subject to change over time.

1. Laboratory Accreditation for Analyses of Foods, December 3, 2021. *https://www.govinfo.gov/content/pkg/FR-2021-12-03/pdf/2021-25716.pdf.* Accessed April 19. 2024.
2. FDA Foods Program Compendium of Analytical Laboratory Methods, 2024. *https://www.fda.gov/food/laboratory-methods-food/foods-program-compendium-analytical-laboratory-methods.* Accessed April 19, 2024.
3. FDA Laboratory Methods (Food), 2021. *https://www.fda.gov/food/science-research-food/laboratory-methods-food.* Accessed April 19, 2024.
4. Compliance Policy Guide Sec. 150.500 Analytical Methodology Used by FDA—Drugs, 2020. *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-150500-analytical-methodology-used-fda-drugs.* Accessed April 19, 2024.
5. FDA/Economics Staff, ''Revocation of Methods of Analysis Regulation, Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,'' 2020. *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.* Accessed April 19, 2024.
6. Food Compliance Programs, 2025. *https://www.fda.gov/food/compliance-enforcement-food/food-compliance-programs#food_ds.* Accessed August 29, 2025.

List of Subjects in 21 CFR Part 2

Administrative practice and procedure, Cosmetics, Drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 2, is amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

§ 2.19 [Removed and Reserved]

■ 2. Remove and reserve § 2.19.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–03285 Filed 2–18–26; 8:45 am]

BILLING CODE 4164–01–P