4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. FDA-2020-N-1383]

Revocation of Methods of Analysis Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to revoke the Methods of analysis regulation describing 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 proposing this action because the existing regulation is unnecessary.

DATES: Either electronic or written comments on the proposed rule must be submitted by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-N-1383 for "Revocation of Methods of Analysis Regulation." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information

you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, 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: Holli Kubicki, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Drive, Rockville, MD 20852, 240-402-4557.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

This proposed rule would revoke the Methods of analysis regulation, § 2.19 (21 CFR 2.19), describing 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 unnecessary.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule revokes § 2.19, which states that it is FDA policy to use the methods of analysis of the Association of Analytical Chemists (AOAC) International as published in the

1980 edition of "Official Methods of Analysis of the Association of Analytical Chemists" for FDA enforcement programs when the method of analysis is not prescribed in a regulation.

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

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

II. Background

A. Introduction

FDA's regulation concerning its policy on methods of analysis in enforcement programs dates back nearly 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 supplements thereto…." (see, e.g., 21 CFR 3.89 (1976 ed.). 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 part 51, and after to make several technical 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. FDA is now proposing to revoke the methods of analysis regulation as specified in this proposed rule.

B. Need for Regulation

The Agency believes that the regulation is unnecessary as a general matter. Absent specifying a method of analysis in a regulation, 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 Regulatory Affairs Laboratory Procedures Manual, FDA compliance programs, and other resources.

III. Legal Authority

FDA is issuing this proposed 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.

IV. Description of the Proposed Rule

The proposed rule revokes § 2.19, which states that it is FDA policy to use the methods of analysis of the AOAC International as published in the 1980 edition of "Official Methods of Analysis of the Association of Analytical Chemists" for FDA enforcement programs when the method of analysis is not prescribed in a regulation. Repeal of this regulation would eliminate an unnecessary policy.

FDA is proposing this action because a general reference to the 1980 edition of the "Official Methods of Analysis of the Association of Analytical Chemists" is unnecessary and because newer, updated methods of analysis may exist. Unless a method of analysis is specified in regulations, 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 Regulatory Affairs Laboratory Procedures Manual and other resources.

FDA is proposing to remove § 2.19 from the regulations.

V. Proposed Effective Date

FDA is proposing that any final rule based on this proposed rule become effective 30 days after the date of its publication in the *Federal Register*.

VI. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule does not add any new regulatory burden on the industry, we propose to certify that the proposed 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 an assessment of anticipated costs and benefits, before proposing "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 $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

We believe industry will largely maintain their current practices following the removal of § 2.19 Methods of analysis regulation. FDA will also maintain its current practices, similarly generating no quantifiable cost savings. Therefore, we expect this proposed rule to be cost neutral. Table 1 summarizes the estimated benefits and costs of the proposed rule, if finalized.

Table 1: Summary of Benefits, Costs and Distributional Effects of Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$0	$0	$0	2019	7%	10 years	
		$0	$0	$0	2019	3%	10 years	
	Annualized Quantified							
	Qualitative	There would no longer be any inefficiencies due to keeping unnecessary regulations on the books.						
Costs	Annualized Monetized $millions/year	$0	$0	$0	2019	7%	10 years	
		$0	$0	$0	2019	3%	10 years	
	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: None Small Business: None Wages: None Growth: None							

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule and at https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

VII. 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.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed 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.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed 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 proposed 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.

X. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that this proposed 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XI. Reference

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

1. FDA/Economics Staff, "Revocation of Methods of Analysis Regulation, Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis," 2020. (Available at: https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.)

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, FDA proposes that 21 CFR part 2 be amended as follows:

PART 2--GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

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

Authority: 15 U.S.C. 402, 409; 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]

2. Remove § 2.19.

Dated: July 11, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022-15109 Filed: 7/14/2022 8:45 am; Publication Date: 7/15/2022]