



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

[Docket No. FDA-2026-N-6404]

RIN 0910-AJ24

Amendment and Revocation of Organizational Information Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its regulations to direct the public to organizational and contact information available on the Agency’s website. FDA is also revoking certain regulations that are no longer necessary in light of this amendment. These changes are appropriate to provide the public with a uniform source of Agency organizational and contact information that can be readily updated as needed in the future.

DATES: This action is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4614, Brian.Pendleton@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

President Trump has directed the heads of executive departments and agencies to eliminate unnecessary and burdensome regulations (Executive Order 14192, “Unleashing Prosperity Through Deregulation” (90 FR 9065, February 6, 2025)). Independently, the Secretary of Health and Human Services (HHS) has expressed support for deregulatory

initiatives across all HHS components (see “Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again” (90 FR 20478, May 14, 2025)). This action is consistent with each of these directives.

Section 552(a)(1)(A) of the Administrative Procedure Act (APA) (5 U.S.C. 552(a)(1)(A)) requires each agency to separately state and currently publish in the *Federal Register*, for the guidance of the public, descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions. FDA has for many years published in the Code of Federal Regulations information on its organizational structure, public information offices, and relevant mailing addresses;¹ these regulations are currently set forth in part 5, subpart M, of Title 21 of the Code of Federal Regulations (21 CFR Part 5, subpart M).² This action streamlines these regulations while providing the public with a uniform source of Agency organizational and contact information that can be readily updated as needed in the future.

II. Description of the Action

As previously noted, subpart M of part 5 contains information on FDA’s organizational structure, public information offices, and relevant mailing addresses. Section 5.1100 provides FDA’s central and field organization with relevant mailing addresses in footnotes. Section 5.1105 specifies the mailing address of the Office of the Chief Counsel for FDA, and § 5.1110 states the names and contact information for FDA public information offices.

To centralize FDA organizational information and facilitate public access to information, this action amends part 5 by revoking §§ 5.1105 and 5.1110 and amending § 5.1100. As amended, § 5.1100 will now direct the public to information on FDA’s website at

¹ These regulations were originally published in the *Federal Register* in 1964 (see 29 FR 471, January 18, 1964)). They have since been amended and recodified on various occasions (see, e.g., “Delegations of Authority and Organization; Reorganization and Republication,” 66 FR 30992, June 8, 2001).

² Subpart M is the only active subpart of part 5, as subparts A through L have been reserved.

<http://www.fda.gov>. The regulation will specifically refer to information on FDA's organization, including the Agency's central and field offices, in FDA's Staff Manual Guides (available at <https://www.fda.gov/about-fda/staff-manual-guides/organizations-and-functions-volume-i-1000-1300>).

The regulation will also state that relevant contact information for FDA offices, including email addresses, is available on our website. Regulated entities and the general public typically contact FDA electronically at an Agency web address rather than by mail. Among other webpages, FDA's "Contact FDA" webpage provides website and email addresses for the Agency's offices. Revising § 5.1100 to reference FDA contact information, including email addresses, on the Agency's website will enable us to more effectively provide the public with information.

In light of these amendments to § 5.1100, we have determined that §§ 5.1105 and 5.1110 are no longer necessary. The direction to visit FDA's website will facilitate public access to a uniform source of Agency organizational and contact information that can be readily updated as needed in the future.

III. Notice and Public Comment

Under section 551(4) of the APA (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." Section 553(b)(A) of the APA (5 U.S.C. 553(b)(A)) exempts rules of agency organization, procedure, or practice from notice and comment rulemaking procedures. Under section 553(b)(B), rules are also exempt when an agency for good cause finds that notice and comment rulemaking procedures would be impracticable, unnecessary, or contrary to the public interest.

To the extent that this action is a rule, FDA has determined that it meets the notice and comment exemptions in section 553(b)(A) and (B) of the APA. We are amending regulations

describing the Agency's organizational structure, not any substantive requirements. In addition, we have determined that because these revisions are minor and insignificant in nature and impact, public comment is unnecessary. For these two independent reasons, notice and comment is not required.

Section 553(d)(3) of the APA allows an effective date less than 30 days after publication as provided by the agency for good cause found and published with a rule. A delayed effective date is unnecessary in this case because, to the extent this action is a rule, the amendments do not impose any new regulatory requirements. As a result, affected parties do not need time to "adjust to the new regulation" before it takes effect. *Am. Federation of Government Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981). Therefore, we find good cause for the amendments to become effective on the date of their publication.

IV. Economic Analysis of Impacts

A. Introduction

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 has determined that this action 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 action is not

an Executive Order 14192 regulatory action because it is not significant under Executive Order 12866.

B. Overview of Benefits, Costs, and Transfers

This action generates net cost savings which we discuss qualitatively. The cost savings accrue to FDA because we no longer have to devote resources to developing and publishing regulations to update the organizational structure after a reorganization. There are no costs associated with this rulemaking.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Action (millions of 2025 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized (\$millions/year)	\$0	\$0	\$0	2025	7%		
						3%		
	Annualized Quantified					7%		
						3%		
Qualitative								
Costs	Annualized Monetized (\$millions/year)	\$0	\$0	\$0	2025	7%		
						3%		
	Annualized Quantified					7%		
						3%		
Qualitative								
Transfers	Federal Annualized Monetized (\$millions/year)					7%		
						3%		
	Other Annualized Monetized (\$millions/year)	From:			To:			
						7%		
					3%			
		From:			To:			
Effects	State, Local or Tribal Government: None Small Business: None Wages: None Growth: None							

Note: Benefits encompass positive and negative benefits. Costs encompass costs and cost savings.

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 of this action.

Table 2. Executive Order 14192 Summary Table (millions of 2024 dollars, discounted over an infinite time horizon at a 7 percent discount rate)

	Primary Estimate	Low Estimate	High Estimate
Present Value of Costs	\$0		
Present Value of Cost Savings	\$0		
Present Value of Net Costs	\$0		
Annualized Costs	\$0		

Annualized Cost Savings	\$0		
Annualized Net Costs	\$0		

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

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(a) 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.

VI. Paperwork Reduction Act of 1995

FDA concludes that this action contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

We have analyzed this action in accordance with the principles set forth in Executive Order 13132. We have determined that it 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 action does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

VIII. Consultation and Coordination with Indian Tribal Governments

We have analyzed this action in accordance with the principles set forth in Executive Order 13175. We have determined that the action 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.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5 – ORGANIZATION

1. The authority citation for part 5 continues to read as follows:

Authority: 5 U.S.C. 552; 21 U.S.C. 301-397.

2. Revise § 5.1100 to read as follows:

§ 5.1100 Agency Organization Information.

Information about the organization of the Food and Drug Administration (including its central and field offices) is available on the Agency's website at <http://www.fda.gov>, including in FDA's Staff Manual Guides. Relevant contact information for Agency offices, including email addresses, is also available on the Agency's website.

§ 5.1105 [Removed]

3. Remove § 5.1105.

§ 5.1110 [Removed]

4. Remove § 5.1110.

Robert F. Kennedy, Jr.

Secretary, Department of Health and Human Services.

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