U.S. GOVERNMENT ACCOUNTABILITY OFFICE

**441 G St. N.W.**
**Washington, DC 20548**

B-337846

November 17, 2025

The Honorable Bill Cassidy
Chairman
The Honorable Bernard Sanders
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Brett Guthrie
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Medical Devices; Laboratory Developed Tests; Implementation of Vacatur*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Food and Drug Administration (FDA) entitled "Medical Devices; Laboratory Developed Tests; Implementation of Vacatur" (RIN: 0910-AJ05). We received the rule on September 19, 2025. It was published in the *Federal Register* on September 19, 2025. 90 Fed. Reg. 45134. The effective date of the rule is September 19, 2025.

According to FDA, this rule reverts the agency's regulatory definition of "in vitro diagnostic products" to the text as it existed prior to the effective date of a May 2024 rule that revised the definition.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). The 60-day delay in effective date does not apply, however, if the agency finds for good cause that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, and the agency incorporates the finding and a brief statement of its reasons in the rule. 5 U.S.C. §§ 553(b)(B), 808(2). Here, although FDA did not specifically mention CRA's delayed effective date requirement, the agency found good cause to waive notice and comment procedures and incorporated a brief statement of reasons. *See* 90 Fed. Reg. at 45134. Specifically, FDA determined that notice-and-comment rulemaking was impracticable, unnecessary, or contrary to the public interest because a court had vacated and set aside the previous FDA rule that revised the definition, and this rule is ministerial in nature and merely removes regulatory text to reflect the court's order. *Id.*

Enclosed is our assessment of FDA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Will Shakely, Acting Assistant General Counsel, at (202) 512-3363.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Department of Health and Human Services

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"MEDICAL DEVICES; LABORATORY DEVELOPED TESTS;
IMPLEMENTATION OF VACATUR"
(RIN: 0910-AJ05)

(i) Cost-benefit analysis

The Department of Health and Human Services, Food and Drug Administration (FDA) prepared an analysis of the costs and benefits for this rule. *See* 90 Fed. Reg. 45134, 45135 (Sept. 19, 2025). FDA estimated that the foregone annualized benefits from the previous rule no longer being in effect would be $3,723.39 million and $4,606.01 million at 7 and 3 percent discount rates, respectively, and the annualized cost savings would be $1,444.45 million and $1,539.50 million at 7 and 3 percent discount rates, respectively. *Id.*

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603–605, 607, and 609

Although FDA indicated in its submission to us that the agency both certified that this rule will not have a significant economic impact on a substantial number of small entities, and prepared a Final Regulatory Flexibility Analysis, the rule itself does not discuss the impacts on small entities. The rule includes a table summarizing the benefits and costs that includes a section for discussing the effects on small businesses, but that section is blank. *See* 90 Fed. Reg. 45134, 45136.

(iii) Agency actions relevant to sections 202–205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532–1535

FDA did not discuss the Act in this rule.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

The Act's notice-and-comment requirements do not apply if the agency finds for good cause that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, and the agency incorporates the finding and a brief statement of its reasons in the rule. 5 U.S.C. § 553(b)(B). FDA invoked the good cause exception for this rule, determining that notice-and-comment was impracticable, unnecessary, or contrary to the public interest because a court had vacated and set aside a previous FDA rule, and this rule is ministerial in nature and merely removes regulatory text to reflect the court's order. 90 Fed. Reg. 45134, 45135.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501–3520

FDA determined that this rule contains no information collection requirements under the Act.

Statutory authorization for the rule

FDA promulgated this rule pursuant to part 809 of title 21 of the *Code of Federal Regulations*.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA stated that this rule is significant under the Order. 90 Fed. Reg. 45134, 45135.

Executive Order No. 13132 (Federalism)

FDA indicated in its submission to us that the Order was not applicable to this rule.