U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

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January 14, 2025

Committee on Health, Education, Labor, and Pensions
United States Senate

Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Food Labeling: Nutrient Content Claims; Definition of Term "Healthy"*

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 "Food Labeling: Nutrient Content Claims; Definition of Term "Healthy"" (RIN: 0910-AI13). We received the rule on December 23, 2024. It was published in the *Federal Register* on December 27, 2024. 89 Fed. Reg. 106064. The stated effective date of the rule is February 25, 2025.

According to FDA, this rule updates the definition for the implied nutrient content claim ''healthy'' to be consistent with current nutrition science and Federal dietary guidance, especially the Dietary Guidelines for Americans, regarding how consumers can maintain healthy dietary practices. FDA stated that this rule revises the requirements for when the term ''healthy'' can be used as an implied nutrient content claim in the labeling of human food products to help consumers identify foods that are particularly useful as the foundation of a nutritious diet that is consistent with dietary recommendations.

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 rule was published in the *Federal Register* on December 27, 2024. 89 Fed. Reg. 106064. The House of Representatives received the rule on December 23, 2024. 170 Cong. Rec. H7432 (daily ed. Dec. 31, 2024). The Senate received the rule on December 30, 2024. 171 Cong. Rec. S66 (daily ed. Jan. 8, 2025). The rule has a stated effective date of February 25, 2025. Therefore, the stated effective date is less than 60 days from the date of receipt of the rule by Congress.

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 Charlie McKiver, Assistant General Counsel, at (202) 512-5992.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Samuel A. Shipley
Regulatory Team Lead
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
"FOOD LABELING: NUTRIENT CONTENT CLAIMS; DEFINITION OF TERM "HEALTHY""
(RIN: 0910-AI13)

(i) Cost-benefit analysis

The Department of Health and Human Services, Food and Drug Administration (FDA) prepared an economic analysis of the impacts of this rule. *See* 89 Fed. Reg. 106157–106159 (Dec. 27, 2024). FDA stated that the mean present value of costs is estimated at $403 million, or $27 million annualized, discounted at 3 percent over 20 years. FDA stated that the benefits of the rule include an estimated reduction over time in all-cause mortality stemming from consumers selecting and consuming more healthful foods. *Id*.

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

FDA certified that this rule will not have a significant economic impact on a substantial number of small entities. 89 Fed. Reg. 106157.

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

FDA estimated that this rule will result in an expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more, adjusted annually for inflation, in any one year. 89 Fed. Reg. 106157.

(iv) Agency actions relevant to the Administrative Pay-As-You-Go-Act of 2023, Pub. L. No. 118-5, div. B, title III, 137 Stat 31 (June 3, 2023)

Section 270 of the Administrative Pay-As-You-Go-Act of 2023 amended 5 U.S.C. § 801(a)(2)(A) to require GAO to assess agency compliance with the Act, which establishes requirements for administrative actions that affect direct spending, in GAO's major rule reports. In guidance to Executive Branch agencies, issued on September 1, 2023, the Office of Management and Budget (OMB) instructed that agencies should include a statement explaining that either: "the Act does not apply to this rule because it does not increase direct spending; the Act does not apply to this rule because it meets one of the Act's exemptions (and specifying the relevant exemption); the OMB Director granted a waiver of the Act's requirements pursuant to section 265(a)(1) or (2) of the Act; or the agency has submitted a notice or written opinion to the OMB Director as required by section 263(a) or (b) of the Act" in their submissions of rules to GAO under the Congressional Review Act. OMB, *Memorandum for the Heads of Executive Departments and Agencies,* Subject: Guidance for Implementation of the Administrative Pay-As-You-Go Act of 2023, M-23-21 (Sept. 1, 2023), at 11–12. OMB also states that directives in the memorandum that supplement the requirements in the Act do not apply to proposed rules that have already been submitted to the Office of Information and Regulatory

Affairs, however agencies must comply with any applicable requirements of the Act before finalizing such rules.

FDA did not discuss the Act in this rule. In its submission to us, FDA stated that the Act does not apply to the rule because it does not increase direct spending.

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

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

On September 29, 2022, FDA published a proposed rule. 87 Fed. Reg. 59168. FDA received approximately 400 comments on the proposed rule from a variety of entities including industry, trade organizations, consulting firms, law firms, academia, public health organizations, public advocacy groups, consumers, consumer groups, Congress, state and local governments, and other organizations. FDA summarized and responded to comments in the final rule. *See* 89 Fed. Reg. 106071.

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

FDA determined that this rule contains information collection requirements under PRA and submitted them to OMB for review. *See* 89 Fed. Reg. 106159.

Statutory authorization for the rule

FDA promulgated this rule pursuant to sections 321(n), 343(a), 343(r), and 371(a) of title 21 of the United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA stated that the Office of Information and Regulatory Affairs has determined that this rule is significant under the Order. 89 Fed. Reg. 106157.

Executive Order No. 13132 (Federalism)

FDA stated that the express preemption provision of section 403A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) does not preempt any state or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food; however, it is possible that such a requirement could be preempted on another basis. FDA determined that this rule creates requirements that fall within the scope of section 403A(a) of the FD&C Act. 89 Fed. Reg. 106161.