U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

B-330047

May 21, 2018

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Greg Walden
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: Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates*

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: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates" (RIN: 0910-AH92). We received the rule on May 4, 2018. It was published in the *Federal Register* as a final rule on May 4, 2018, with an effective date of July 3, 2018. 83 Fed. Reg. 19,619.

This final rule extends the compliance dates by approximately 1.5 years for the final rules. The final rules provide updated nutrition information on the label of food, including dietary supplements; define a single-serving container; require dual-column labeling for certain containers; update, modify, and establish certain reference amounts customarily consumed; and amend the label serving size for breath mints. FDA stated that it is taking this action because it determined that additional time would help ensure that all manufacturers covered by the final rules have guidance from FDA to address technical questions FDA received after publication of the final rules and that manufacturers have sufficient time to complete and print updated Nutrition Facts labels for their products before they are expected to be in compliance with the final rules.

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. Our review of the agency's submission to us indicates that FDA complied with the applicable requirements.

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 Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Kenneth Cohen
Director, Regulations Policy and Management Staff
Food and Drug Administration
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 ADMINISTRTION
ENTITLED
"FOOD LABELING: REVISION OF THE NUTRITION AND SUPPLEMENT FACTS LABELS AND SERVING SIZES OF FOODS THAT CAN REASONABLY BE CONSUMED AT ONE EATING OCCASION; DUAL-COLUMN LABELING; UPDATING, MODIFYING, AND ESTABLISHING CERTAIN REFERENCE AMOUNTS CUSTOMARILY CONSUMED; SERVING SIZE FOR BREATH MINTS; AND TECHNICAL AMENDMENTS; EXTENSION OF COMPLIANCE DATES"
(RIN: 0910-AH92)

(i) Cost-benefit analysis

The Department of Health and Human Services, Food and Drug Administration (FDA) summarized the benefits of the final rule. FDA estimates that this rule generates approximately $61 million in annualized cost savings discounted relative to year 2016 and using a 7 percent discount rate over a perpetual time horizon. Additionally, FDA estimates that the present value of the benefits of this final rule over the next 20 years is $1 billion using either a 3 percent or 7 percent discount rate. Furthermore, FDA estimates the forgone benefits of this final rule over the next 20 years is $0.9 billion using either a 3 percent or 7 percent discount rate. Finally, FDA estimates that the net benefits of this final rule are $0.1 billion using either a 3 percent or 7 percent discount rate.

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

FDA determined that this final rule will not have a significant economic impact on a substantial number of small entities.

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

FDA found that this final rule would not result in expenditures by state, local, or tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.

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

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

On October 2, 2017, FDA published a proposed rule. 82 Fed. Reg. 45,753. FDA received approximately 50,000 comments from individual consumers, consumer groups, industry, trade associations, academia, health professionals, and state/local government agencies. FDA responded to comments in the final rule.

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

FDA stated that this final rule contains no collection of information and therefore clearance by the Office of Management and Budget (OMB) is not required.

Statutory authorization for the rule

FDA stated that it promulgated this rule pursuant to sections 403(q), 403(a)(1), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and section 2(b)(1) of the Nutrition Labeling and Education Act.

Executive Order No. 12,866 (Regulatory Planning and Review)

FDA determined that this final rule is an economically significant regulatory action as defined by the Order.

Executive Order No. 13,132 (Federalism)

FDA stated that section 403A of the FD&C Act is an express preemption provision and that this final rule creates requirements that fall within the scope of section 403A(a) of the FD&C Act.