



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

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June 13, 2016

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

The Honorable Fred Upton
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*

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" (RIN: 0910-AF22). We received the rule on May 27, 2016. It was published in the *Federal Register* as a final rule on May 27, 2016. 81 Fed. Reg. 33,742.

The final rule amends the labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label in order to assist consumers in maintaining healthy dietary practices. FDA determined that the updated information is consistent with current data on the associations between nutrients and chronic diseases, health-related conditions, physiological endpoints, and/or maintaining a healthy dietary pattern that reflects current public health conditions in the United States, and corresponds to new information on consumer understanding and consumption patterns. The final rule updates the list of nutrients that are required or permitted to be declared; provides updated Daily Reference Values and Reference Daily Intake values that are based on current dietary recommendations from consensus reports; amends requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establishes nutrient reference values specifically for these population subgroups; and revises the format and appearance of the Nutrition Facts label.

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 procedural steps taken 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
Department of Health and Human Services

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: REVISION OF THE
NUTRITION AND SUPPLEMENT FACTS LABELS"
(RIN: 0910-AF22)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) developed one final regulatory impact analysis for both this final rule as well as the final rule entitled "Food Labeling: 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." FDA found that the two nutrition labeling rules have impacts, including the sign on net benefits that are characterized by substantial uncertainty. FDA's primary sensitivity analysis shows benefits having the potential to range between \$0.2 and \$2 or \$5 billion, and costs ranging between \$0.2, \$0.5 and \$0.8 billion (annualized over the next 20 years, in 2014 dollars, at 7 percent interest).

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

FDA determined that the final rules on nutrition labeling taken as a whole will 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 determined that the final rules on nutrition labeling when taken as a whole, includes a mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector of amounts in excess of the dollar threshold under the Act.

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

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

On March 3, 2014, FDA published a proposed rule. 79 Fed. Reg. 11,879. On May 27, 2014, FDA extended the comment period and on May 29, 2014, FDA announced a public meeting. 79 Fed. Reg. 30,055, 30,763. On July 27, 2015, FDA published a supplemental proposed rule. 80 Fed. Reg. 44,303. FDA received nearly 300,000 comments from consumers, foreign governments, industry, trade associations, professional societies, academia, health professionals, and other government agencies. FDA discussed issues raised in the comments in the final rule.

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

FDA determined that this final rule contains an information collection requirement under the Act entitled “Record Retention, Reporting, and Third-Party Disclosure Requirements for the Declaration of Added Sugars, Dietary Fiber, Soluble Fiber, Insoluble Fiber, Vitamin E and Folate/Folic Acid.” FDA estimated the total annual recordkeeping burden to be 187,942 hours, the total annual reporting burden to be 187,914, and the total annual third-party disclosure burden to be 1,626,716 hours with a total capital cost of \$2.47 billion.

Statutory authorization for the rule

FDA promulgated this final rule under the authority of sections 201(n), 403(a), 403(q), and 701(a) of the Federal Food, Drug, and Cosmetic Act and section 2(b)(1) of the Nutrition Labeling and Education Act of 1990. 21 U.S.C. § 321(n), 343(a), 343(q), 343 note, 371(a).

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

FDA determined that the final rules on nutrition labeling taken as a whole are economically significant under the Order.

Executive Order No. 13,132 (Federalism)

FDA determined that this final rule will create requirements that fall within the scope of an express statutory preemption provision.