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Washington, DC 20548

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June 10, 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: 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*

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: 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” (RIN: 0910-AF23). 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. 34,000.

The final rule defines a single-serving container; requires dual-column labeling for certain containers; updates, modifies, and establishes several reference amounts customarily consumed; amends the label serving size for breath mints; and makes technical amendments to various aspects of the serving size regulations. FDA stated that it is taking this action to provide consumers with more accurate and up-to-date information on serving sizes.

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  
"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"  
(RIN: 0910-AF23)

(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: Revision of the Nutrition and Supplement Facts Labels." 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 taken as a whole include 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. 11,989. On May 27, 2014, FDA extended the comment period for the proposed rule. 79 Fed. Reg. 30,056. FDA received more than 500 comments, mostly from individuals, but also from industry and trade associations, consumer and advocacy groups, academic organizations, state governments, and foreign government agencies. FDA responded to 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 “Third-Party Disclosure Requirements for Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying and Establishing Certain RACCs; Serving Size for Breath Mints; and Technical Amendments.” FDA estimated a total third-party disclosure burden of 673,600 hours and \$1.01 billion in capital costs. FDA submitted the information collection provisions of this final rule to the Office of Management and Budget for review.

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.