U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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Washington, DC 20548

B-329058

May 17, 2017

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; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments*

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; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments" (RIN: 0910-ZA48). We received the rule on May 2, 2017. It was published in the *Federal Register* as an "interim final rule; extension of compliance date; request for comments" on May 4, 2017. 82 Fed. Reg. 20,825.

The interim final rule extends the compliance date for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. On December 30, 2016, FDA stated that the compliance date for the final rule would be May 5, 2017. This interim final rule changes the compliance date to May 7, 2018.

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, FDA
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; NUTRITION LABELING OF STANDARD MENU ITEMS
IN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS;
EXTENSION OF COMPLIANCE DATE; REQUEST FOR COMMENTS"
(RIN: 0910-ZA48)

(i) Cost-benefit analysis

According to the Food and Drug Administration (FDA), the principal benefit of this interim final rule will be the reduction in costs to covered establishments associated with extending the compliance date by 1 year. FDA determined the total annualized benefit of this interim final rule, using a 3 percent discount rate over 20 years, would be from $2 to $6 million; with a 7 percent discount rate the annualized benefit would be $3 to $8 million. FDA also determined that the principal cost of this interim final rule will be the reduction in benefits to consumers associated with extending the compliance date by 1 year and calculated that the total annualized cost of this interim final rule, using a 3 percent discount rate over 20 years, would be from $5 to $15 million; with a 7 percent discount rate the annualized cost would be $6 to $19 million. FDA found that extending the compliance date by 1 year reduces the annualized net benefits (discounted at 3 percent) approximately 1 percent, from $506 million to $501 million. FDA also determined that while average annualized net benefits decrease by $5 million, they are still positive. FDA also recognized that there may be additional costs and benefits to both consumers and covered establishments that it did not have the data to quantify.

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

FDA certified that this interim 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 determined that this interim final rule would not result in expenditures by industry in any year that meets or exceeds $148 million ($100 million, adjusted for inflation).

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

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

FDA asserted that this interim final rule is exempt from notice and comment because it constitutes a rule of procedure. Alternatively, FDA asserted that, to the extent that the notice-and-comment and delayed effective date requirements applies to this rule, the implementation of this action without opportunity for public comment is based on the good cause exceptions. FDA stated that given the imminence of the compliance date and the fact that a number of

regulated establishments continue to raise numerous, complex questions about applicability of the menu labeling requirements and about how to implement them, FDA decided that providing an opportunity for public comment would be impracticable and contrary to the public interest. FDA reached this decision because it found that providing immediate notice to covered establishments of the additional time to come into compliance allows for more efficient planning and accounting for implementation of requirements, thus reducing regulatory burden and costs on affected entities. In addition, FDA found that providing immediate notice that there will be additional time to comply is necessary so that affected entities can avoid incurring immediate costs and efficiently plan and account for implementation of the requirements by the imminent compliance date. FDA determined that good cause exists to delay the compliance date without comment and to be effective immediately.

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

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

Statutory authorization for the rule

The December 1, 2014, final rule whose effective date is delayed by this final rule was promulgated under the authority of sections 201(n), 403(a)(1), 403(f), and 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, as well as under section 701(a) of the FD&C Act (21 U.S.C. § 371(a)), which gives FDA the authority to issue regulations for the efficient enforcement of the FD&C Act.

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

FDA estimated at least one type of impact of this interim final rule in at least 1 year to be greater than $100 million. Thus, FDA believes that this interim final rule is an economically significant regulatory action as defined by the Order.