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

B-326453

December 15, 2014

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

The Honorable Fred Upton
Chairman
The Honorable Henry Waxman
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*

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" (RIN: 0910-AG57). We received the rule on November 25, 2014. It was published in the *Federal Register* as a final rule on December 1, 2014. 79 Fed. Reg. 71,156.

The final rule implements the nutrition labeling provisions of the Patient Protection and Affordable Care Act of 2010 (PPACA) whereby the FDA is requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. PPACA, in part, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act), among other things, to require restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items to provide calorie and other nutrition information for standard menu items, including food on display and self-service food. According to FDA, providing accurate, clear, and consistent nutrition information, including the calorie content of foods, in restaurants and similar retail food establishments will make such nutrition information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

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

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"
(RIN: 0910-AG57)

(i) Cost-benefit analysis

The Patient Protection and Affordable Care Act (PPACA) requires nutrition labeling for standard menu items on menus and menu boards for certain restaurants and similar retail food establishments and calorie labeling for food sold from certain vending machines. FDA issued two separate final rules (one for menu labeling and one for vending machine labeling) to implement those labeling requirements. Taken together the labeling requirements are estimated to have benefits exceeding costs by $477.9 million on an annualized basis (over 20 years discounted at 7 percent). FDA provided a table in the rule summarizing the costs and benefits of menu labeling and vending machine rules in millions, but did not quantify or include the benefits for vending machine labeling in the table. The total for menu labeling over 20 years is estimated to have benefits exceeding costs by $510.99 million on an annualized basis (over 20 years discounted at 7 percent).

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

According to FDA's analysis, the final rule will have a significant economic impact on a substantial number of small entities. Accordingly, FDA analyzed regulatory options that would minimize the economic impact of the rule on small entities consistent with statutory objectives. FDA states that it crafted the final rule to provide flexibility for compliance. FDA also states that it has developed a detailed Regulatory Impact Analysis (RIA) that presents the benefits and costs of this final rule (Ref. 42), which is available at http://www.regulations.gov (enter Docket No. FDA–2011–F–0172). According to FDA, the full economic impact analyses of FDA regulations are no longer (as of April 2012) published in the *Federal Register* but are submitted to the docket and are available at http://www.regulations.gov. FDA has also posted the full economic impact analyses of FDA regulations at the following web site: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

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

FDA states that the current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA determined that this final rule has met this threshold under the Unfunded Mandates Reform Act of 1995. Their analysis under this statute is included in the RIA (Ref. 42).

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

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

On April 6, 2011 (76 Fed. Reg. 19,192), FDA issued a proposed rule to implement the requirements of section 4205 of PPACA for the nutrition labeling of standard menu items in certain restaurants and similar retail food establishments. FDA requested public comments on the proposed requirements and some alternatives by June 6, 2011. In the *Federal Register* of May 24, 2011 (76 Fed. Reg. 30,050), FDA issued a document correcting errors in the proposed rule. In the *Federal Register* of May 24, 2011 (76 Fed. Reg. 30,051), FDA extended the comment period until July 5, 2011. In the proposed rule, FDA described both the provisions that became requirements upon enactment and the provisions that depend on FDA to issue rules before they can become effective (76 Fed. Reg. 19,192 at 19,194). FDA received approximately 900 comments on the proposed rule each containing one or more issues. FDA received comments from Congress, federal agencies, state agencies, local government agencies, consumers, consumer groups, trade organizations, industry (including restaurants, entertainment venues, food service operations, and grocery stores), public health organizations, public advocacy groups, contractors, and other organizations. FDA described and responded to the comments in the final rule.

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

The final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under PRA. A description of these provisions is given with estimates of the annual reporting, recordkeeping, and third-party disclosure burden. Included in each burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. The reporting requirements include one that affects restaurants and similar retail food establishments that voluntarily elect to be subject to the federal requirements of the rule by registering with FDA. A table estimating the annual reporting burden associated with voluntary registration is included in the rule. FDA estimates that 5 percent of such establishments may voluntarily register to become subject to the final requirements, or 10,678 non-covered restaurants, non-covered grocery, convenience, and general merchandise stores. FDA estimates a burden of approximately 2 hours per initial registration, which yields a total burden of 21,356 hours (10,678 establishments × 1 initial registration per establishment × 2 hours per registration). FDA annualized this number over 3 years, yielding a rounded 7,118 hours per year (10,678 establishments/3 years × 1 initial registration per establishment × 2 hours per registration). (10,678 establishments/3 years = 3,559 establishments per year.) FDA expects that renewal registrations after the first year will require substantially less time because establishments are expected to be able to affirm or update the existing information in an online account in a way similar to other FDA firm registration systems. Therefore, FDA estimated that reregistration will take 0.5 hours for each registrant. This would indicate that biennial registration would impose a burden of 5,340 hours (10,678 establishments × 0.5 hours) every 2 years, or 2,670 hours every year (10,678 establishments/2 years × 0.5 hours).

FDA also stated that the preamble to the proposed rule provided an estimate of the recordkeeping burden, which consisted of the burden associated with nutrition analysis and the burden associated with generating, providing, or maintaining records. Upon further consideration, FDA omitted the burden estimate associated with generating, providing, or maintaining records previously estimated in the proposed rule because the rule does not require restaurants and similar retail food establishments to generate or maintain records. FDA

included a table in the rule of the estimated recordkeeping burden. FDA estimated the total recordkeeping burden for the initial nutrition analysis to be 17,254.25 hours (= 69,017 records × 0.25 hours per record). FDA estimated the total recurring recordkeeping burden for the nutrition analysis to be 7,515 hours [(26,899 records for new/reformulated standard menu items under existing chains + 3,155 records for items under new chains) × 0.25 hours per record)]. The total burden hours are therefore estimated to be 24,769.

FDA stated that there are five types of third-party disclosure burdens related to: initial nutrition analysis, initial menu replacement, chain-level written nutrition information, establishment-level nutrition information, recurring nutrition analysis, and recurring menu replacement. FDA included a table in the rule summarizing the estimated third-party disclosure burden. The third-party disclosure burdens are estimated and broken down in detail in table 3 of the rule—estimating a total burden of 463,951 total hours and total operating and maintenance costs of $249,296,000.

FDA states that in compliance with PRA, it has resubmitted the information collection provisions of this final rule to OMB for review, because the final rule provides an additional modification to section 101.11 of the regulation. FDA states that these requirements will not be effective until FDA obtains OMB approval.

Statutory authorization for the rule

FDA states that it issued this final rule under 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 concluded that the final rule is an economically significant regulatory action as defined by Executive Order 12,866.

Executive Order No. 13,132 (Federalism)

FDA states that the final rule creates requirements for nutrition labeling of food under section 403(q) of the FD&C Act that would preempt certain non-identical state and local nutrition labeling requirements. FDA invited and responded to comments on the preemption issues in the proposed rule. FDA explained that section 4205 of PPACA included a Rule of Construction regarding preemption issues and that it interprets the provisions of section 4205 of PPACA related to preemption to mean that states and local governments may not impose nutrition labeling requirements for food sold in a covered establishment that must comply with the federal requirements of section 403(q)(5)(H) of the FD&C Act, unless the state or local requirements are identical to the federal requirements. In other words, FDA states that states and localities cannot have additional or different nutrition labeling requirements for food sold either in: (1) chain retail food establishments or (2) restaurants and similar retail food establishments not subject to the requirements of section 403(q)(5)(H) of the FD&C Act that voluntarily elects to be subject to those requirements by registering biannually under section 403(q)(5)(H)(ix) of the FD&C Act. Otherwise, for certain food that is not subject to the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act, states and localities may establish or continue to impose nutrition labeling requirements. Under FDA's interpretation of the Rule of Construction in section 4205(d)(1) of PPACA, nutrition labeling for food sold from such establishments would

not be ‘‘nutrient content disclosures of the type required under section 403(q)(5)(H)(viii) [of the FD&C Act]’’ and, therefore, would not be preempted. According to FDA, under this interpretation, states and localities would be able to continue to require nutrition labeling for food sold from establishments that are exempt from nutrition labeling under section 403(q)(1) to (q)(4) of the FD&C Act and not subject to nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act. FDA states that the express preemption provisions of section 403(A)(a)(4) of the FD&C Act do 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. FDA also provided an alternative interpretation of the preemption provisions described in the proposed rule. FDA concluded that this interpretation, which involves a petitioning process for state or local requests for exemption, would create a regulatory gap that would be inconsistent with the purposes of section 4205 of PPACA, in addition to imposing restrictions and burdens on the states and localities that would be inconsistent with the Federalism principles expressed in the Executive Order 13,132.