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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; Calorie Labeling of Articles of Food in Vending Machines*

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; Calorie Labeling of Articles of Food in Vending Machines" (RIN: 0910-AG56). 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. 71,259.

The final rule implements the vending machine food labeling provisions of the Patient Protection and Affordable Care Act of 2010 (PPACA) whereby FDA is establishing requirements for providing calorie declarations for food sold from certain vending machines. This final rule will ensure that calorie information is available for certain food sold from a vending machine that does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article, or does not otherwise provide visible nutrition information at the point of purchase. According to FDA, the declaration of accurate and clear calorie information for food sold from vending machines will make calorie information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. This final rule applies to certain food from vending machines operated by a person engaged in the business of owning or operating 20 or more vending machines. Vending machine operators not subject to the rules may elect to be subject to the federal requirements by registering with FDA.

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; CALORIE LABELING OF ARTICLES OF
FOOD IN VENDING MACHINES"
(RIN: 0910-AG56)

(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. For this rule on vending machines alone, FDA states that the expected annualized costs are \$37.9 million (over 20 years discounted at 7 percent), while the benefits have not been quantified. Taken together, the mean estimated benefits of the labeling requirements (menu labeling and vending machine labeling rules combined) exceed costs by \$477.9 million on an annualized basis (over 20 years discounted at 7 percent; not including net benefits from this final rule on vending machine labeling, which are not quantified). 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 from the vending machine labeling rule in the table.

(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 states that it has developed a detailed Regulatory Impact Analysis (RIA) that presents the benefits and costs of this final rule (Ref. 1), which is available at <http://www.regulations.gov> (enter Docket No. FDA-2011-F-0171). 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 does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

(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. 19,238), FDA published a proposed rule that would establish requirements for calorie declarations for certain articles of food sold from vending machines to implement section 403(q)(5)(H)(viii) and (q)(5)(H)(ix) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). FDA proposed definitions, requirements for calorie labeling for certain food sold from vending machines, and requirements for voluntary registration by a vending machine operator that is not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act to elect to be subject to such requirements. FDA provided a 90-day comment period that ended on July 5, 2011. FDA received approximately 250 comments on the proposed rule each containing one or more issues. FDA states that it received comments from Congress, federal agencies, state agencies, local government agencies, consumers, consumer groups, trade organizations, the vending machine industry, public health organizations, and other organizations. FDA described and responded to the comments in the final rule. On July 23, 2010, FDA published in the *Federal Register* (75 Fed. Reg. 43,182), a notice specifying the terms and conditions for implementation of voluntary registration, pending issuance of regulations.

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 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 vending machine operators 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 vending machine operators with fewer than 20 machines may voluntarily register to become subject to the final requirements, or 38 operators. FDA estimates a burden of approximately 2 hours per initial registration, which yields a total burden of 76 hours (38 total operators × 2 hours per response). FDA annualized this number over 3 years, which yields a rounded 13 respondents per year (5 percent × 757 operators/3 years). With an annualized estimate of 13 vending machine operators and one registration per vending machine operator at 2 hours per registration, FDA estimates the initial hourly burden for these operators is 26 hours. FDA expects that renewal registrations after the first year will require substantially less time because operators 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 19 hours (38 operators × 0.5 hours) every 2 years, or 9.5 hours every year (18 operators every year × 0.5 hours).

FDA also stated that the preamble to the proposed rule (76 Fed. Reg. 19,238 at 19,249–19,251) provided an estimate of the recordkeeping burden, which consisted of the burden associated with calorie 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 provided in table 3 of the proposed rule because the rule does not require vending machine operators to generate, provide, or maintain records.

FDA included a burden estimate for calorie analysis as part of the two types of third-party disclosure burden, since the “total time, effort, or financial resources expended by [covered vending machine operators]” (5 C.F.R. § 1320.3(b)) to declare calories for covered vending

machine food likely includes time, effort, or financial resources to determine the calorie content of such food. The second type of third-party disclosure burden is for the activities involved with calorie declaration signs. Both of the third-party disclosure burdens are estimated and broken down in detail in table 2 of the rule—estimating a total burden of 1,507,753 total hours and total capital costs of \$4,671,047.

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 101.8 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 from vending machines 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: (1) from vending machines that are operated by a person engaged in the business of owning or operating 20 or more vending machines subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act or (2) from vending machines operated by a person not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act who 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 food sold from vending machines not subject to the nutrition labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act, states and localities may 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 these vending machines 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 vending machines that are exempt from nutrition labeling under section 403(q)(5) of the FD&C Act. FDA believes this interpretation is consistent with the fact that Congress included vending machine operators in the voluntary registration provision of section 403(q)(5)(H)(ix) of the FD&C Act. FDA states that there would have been no need to include vending machine operators in the provision that allows opting into the federal requirements if states and localities could not otherwise require non-identical nutrition labeling for food sold from any vending machines.