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May 25, 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: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*

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 "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (RIN: 0910-AG38). We received the rule on May 10, 2016. It was published in the *Federal Register* as a final rule on May 10, 2016. 81 Fed. Reg. 28,974.

The final rule extends FDA's "tobacco product" authorities to all other categories of products that meet the statutory definition of tobacco product, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of covered tobacco products to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages, and in advertisements. The requirements that will apply to the products deemed to be tobacco products include establishment registration and product listing, ingredient listing, harmful or potentially harmful testing and reporting, premarket submissions prior to the introduction of new products, and labeling requirements. Free samples of newly deemed tobacco products will also be prohibited.

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
Food and Drug Administration
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
“DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO
THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED
BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT;
RESTRICTIONS ON THE SALE AND DISTRIBUTION OF TOBACCO PRODUCTS
AND REQUIRED WARNING STATEMENTS FOR TOBACCO PRODUCTS”
(RIN: 0910-AG38)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) analyzed the costs and benefits of this final rule. FDA stated that the direct benefits of this final rule are difficult to quantify, and it could not predict the size of these benefits. Among other effects, new products will be subject to an evaluation to ensure they meet the appropriate public health standard for the pathway before they can be marketed, labeling cannot contain misleading statements, and FDA will be made aware of the ingredients in newly deemed tobacco products. If, without the final rule, new products would pose substantially greater health risks than those already on the market, the premarket requirements made effective by this final rule would keep such products from appearing on the market and worsening the health effects of tobacco product use. FDA expects the warning statements required by this final rule will help consumers better understand and appreciate the risks and characteristics of tobacco products.

FDA calculated lower bounds, primary estimates, and upper bounds for the costs of this final rule at 3 percent and 7 percent discount rates over 20 years for both the government and the private sector. At a 3 percent discount rate, the lower bound, primary estimate, and upper bound annualized value of total costs were \$48.5 million, \$66.4 million, and \$88.3 million, respectively. At a 7 percent discount rate, the lower bound, primary estimate, and upper bound annualized value of total costs were \$56.3 million, \$77.1 million, and \$102.5 million, respectively. FDA concluded that the benefits of the final rule justify the costs.

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

FDA determined that this final rule will have a significant economic impact on a substantial number of small entities. FDA prepared a Final Regulatory Flexibility Analysis for this rule, which included a description and number of affected small entities and the economic effects on those small entities. FDA also noted that it announced a compliance policy for small-scale tobacco product manufacturers for this rule.

(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 final rule will result in a 1-year expenditure that meets or exceeds the statutory threshold of \$144 million (\$100 million adjusted for inflation). FDA prepared an

Unfunded Mandates Reform Act Analysis for this final rule which included an assessment of anticipated costs and benefits of the rule.

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

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

On April 25, 2014, FDA issued a proposed rule. 79 Fed. Reg. 23,142. FDA received over 135,000 comments on the proposed rule from tobacco product manufacturers, retailers, academia, medical professionals, local governments, advocacy groups, and consumers. 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 information collection requirements under the Act. FDA estimates that the total burden for these new collections of information in this rule is 1,621,212 reporting hours and 12,342 recordkeeping hours for a total of 1,633,554 burden hours. The information collection provisions in this final rule have been submitted to the Office of Management and Budget (OMB) for review.

Statutory authorization for the rule

FDA promulgated this final rule under the authority of sections 701(a), 901, 903, and 906(d)(1) of the Food, Drug, and Cosmetic Act, as amended. 21 U.S.C. §§ 371(a), 387a, 387c, 387f(d)(1).

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

FDA determined that this final rule is significant under the Order.

Executive Order No. 13,132 (Federalism)

FDA determined that this final rule does not contain policies that have federalism implications as defined in the Order.