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July 26, 2011

The Honorable John D. Rockefeller IV
Chairman
The Honorable Kay Bailey Hutchison
Ranking Member
Committee on Commerce, Science, and Transportation
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Required Warnings for Cigarette Packages and Advertisements*

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 "Required Warnings for Cigarette Packages and Advertisements" (RIN: 0910-AG41). We received the rule on July 12, 2011. It was published in the *Federal Register* as a final rule on June 22, 2011. 76 Fed. Reg. 36,628.

The final rule amends FDA's regulations to add a new requirement for the display of health warnings on cigarette packages and in cigarette advertisements. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics, depicting the negative health consequences of smoking, to accompany nine new textual warning statements required under the Tobacco Control Act. The final rule specifies the color graphic images that must accompany each of the nine new textual warning statements required by the Tobacco Control Act.

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: Edwin V. Dutra, Jr.
Director, Regulations Policy and
Management Staff
Food and Drug Administration
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
"REQUIRED WARNINGS FOR CIGARETTE PACKAGES
AND ADVERTISEMENTS"
(RIN: 0910-AG41)

(i) Cost-benefit analysis

FDA performed a cost-benefit analysis of the final rule. FDA stated that its estimate of the benefits of the rule is based on the predicted reduction in the number of U.S. smokers and the consequent reduction in the number of people who will ultimately become ill or die from diseases caused by smoking. FDA's estimated costs include costs to manufacturers of changing cigarette labels, administrative and recordkeeping costs to manufacturers of ensuring equal and random display of the nine different warning labels over time, the costs to large manufacturers of market-testing new cigarette package labels, and the costs to manufacturers and retailers of removing point-of-sale advertising that does not comply with the rule. FDA stated that the rule will also lead to private costs in the form of reduced revenues for many firms, but that these costs cannot be counted as social costs because they are, for the most part, distributional effects.

FDA estimated that the rule will produce annualized benefits over 20 years of approximately $630.5 million at a 3-percent discount rate and $221.5 million at a 7-percent discount rate. FDA estimated that the rule will produce annualized costs over 20 years of $29.1 million at a 3-percent discount rate and $37 million at a 7-percent discount rate.

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

FDA determined that the final rule will have a significant impact on a substantial number of small entities. Accordingly, FDA prepared a regulatory flexibility analysis for the 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 the final rule contains mandates that will impose spending costs on state, local, or tribal governments in the aggregate, or by the private

sector, in excess of the current statutory threshold--approximately $136 million. FDA incorporated the final rule's cost-benefit analysis to meet the Act's requirements, as allowed under 2 U.S.C. § 1532(c).

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

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

FDA published a notice of proposed rulemaking on November 12, 2010. 75 Fed. Reg. 69,524. FDA received over 1,700 comments on the proposed rule. FDA responded to those comments in the final rule. 76 Fed. Reg. 36,628.

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

FDA determined that the required warning disclosures under this rule are not within the scope of the Paperwork Reduction Act because they are the "public disclosure of information originally supplied by the Federal government to the recipient for th[at] purpose" pursuant to 5 CFR 1320.3(c)(2).

Statutory authorization for the rule

The final rule is authorized by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), Pub. L. 111-31, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Federal Cigarette Labeling and Advertising Act (FCLAA).

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

FDA found that the final rule constitutes an economically significant regulatory action under Executive Order 12,866.

Executive Order No. 13,132 (Federalism)

According to FDA, the FCLAA, as amended by the Tobacco Control Act, expressly preempts state and local rules regarding statements relating to smoking and health, other than the statements required by the FCLAA, and any state and local requirements or prohibitions based on smoking and health with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of the FCLAA. The FDA also states that the FD&C Act expressly preempts state or local requirements that are different from, or in addition to, any requirement under Chapter IX of the FD&C Act relating to, among other things, misbranding and labeling. The FDA states, however, that the express preemption provision does not apply to requirements relating to, among other things, the sale, distribution, access to, or the advertising and promotion of tobacco products.