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April 7, 2010

The Honorable Tom Harkin  
Chairman  
The Honorable Michael B. Enzi  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Henry A. Waxman  
Chairman  
The Honorable Joe L. Barton  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration:  
Regulations Restricting the Sale and Distribution of Cigarettes and  
Smokeless Tobacco To Protect Children and Adolescents*

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 “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents” (RIN: 0910-AG33). We received the rule on March 24, 2010. It was published in the *Federal Register* as a final rule on March 19, 2010, with an effective date of June 22, 2010. 75 Fed. Reg. 13,225.

The FDA is reissuing a final rule restricting the sale, distribution, and use of cigarettes and smokeless tobacco. As required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), FDA is issuing a final rule that is identical to the provisions of the final rule on cigarettes and smokeless tobacco published by FDA in 1996, with certain required exceptions. The rule prohibits the sale of cigarettes and smokeless tobacco to individuals under the age of 18 and imposes specific marketing, labeling, and advertising requirements. The FDA is issuing an advance notice of proposed rulemaking to obtain information related to the regulation of outdoor advertising of cigarettes and smokeless tobacco.

Specifically, the rule requires retailers to verify a purchaser's age by photographic identification and limits the advertising and labeling to which children and adolescents are exposed to a black-and-white, text-only format. The final rule also prohibits free samples of cigarettes and free samples of smokeless tobacco, except in qualified adult-only facilities. It also prohibits the sale of cigarettes and smokeless tobacco products through vending machines and self-service displays, except in facilities where individuals under the age of 18 are not present or permitted at any time. Additionally, the final rule prohibits the sale or distribution of brand-identified promotional non-tobacco items such as hats and tee shirts and prohibits sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permits such sponsorship in a corporate name.

Enclosed is our assessment of the 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: Kennon M. Smith  
Deputy 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  
"REGULATIONS RESTRICTING THE SALE AND  
DISTRIBUTION OF CIGARETTES AND SMOKELESS  
TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS"  
(RIN: 0910-AG33)

(i) Cost-benefit analysis

In its current submission to the Comptroller General, the FDA did not include a cost-benefit analysis of the final regulations under this Act.

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

In its current submission to the Comptroller General, the FDA did not include a regulatory flexibility analysis of the final regulations under this Act.

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

In its current submission to the Comptroller General, the FDA did not include an analysis of the final regulations under this Act.

(iv) Other relevant information or requirements under Acts and Executive orders

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

FDA states that under section 102(a)(1)(B) of the Tobacco Control Act, the rule issued under this section is, "deemed to be in compliance with all applicable provisions of chapter 5, title 5, United States Code, and all other provisions of law related to rulemaking procedures."

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

FDA states that this final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. §§ 3501–3520). The 1995 proposed rule provided a 90-day comment period (extended to 144 days in the *Federal Register* of October 16, 1995 (60 Fed. Reg. 53,560)). The information collection provisions in the

proposed rule were approved under OMB control number 0910–0312. FDA states that it will be submitting the information collection provisions of the final rule to OMB for reinstatement. Prior to the effective date of this final rule, FDA notes that it will publish a notice in the *Federal Register* of OMB’s decision to approve, modify, or disapprove the information collection provisions in the final rule.

#### Statutory authorization for the rule

FDA states that section 102 of the Tobacco Control Act directs the Secretary to issue a final rule identical in its provisions to the final rule issued on August 28, 1996 (61 Fed. Reg. 44,615 to 44,618), with certain exceptions. 21 U.S.C. § 301 *et seq.*, Sec. 102, Pub. L. 111–31, 123 Stat. 1776. Under section 102(a)(1)(B), the rule issued under this section is, “deemed to be in compliance with all applicable provisions of chapter 5, title 5, United States Code, and all other provisions of law related to rulemaking procedures.” 21 U.S.C. § 387a-1.

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

This rule has been determined to be economically significant for the purposes of Executive Order 12,866 and, therefore, it has been reviewed by the OMB. Because section 102 of the Tobacco Control Act directs the Secretary to issue a final rule identical in its provisions to the final rule issued on August 28, 1996 (61 Fed. Reg. 44,615 to 44,618), OMB has not required a Regulatory Impact Analysis beyond that done at that time (see 61 Fed. Reg. 44,568 to 44,606).

#### Executive Order No. 13,132 (Federalism)

In its current submission to the Comptroller General, the FDA did not include an analysis of the final regulations under this Order.