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September 27, 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:
Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug
Products for Over-the-Counter Human Use*

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 “Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use” (RIN: 0910-AF69). We received the rule on September 13, 2016. It was published in the *Federal Register* as a final rule on September 6, 2016, with an effective date of September 6, 2017. 81 Fed. Reg. 61,106.

The final rule establishes that certain active ingredients used in over-the-counter antiseptic products are not generally recognized as safe and effective and are misbranded. This rule amends the 1994 tentative final monograph for over-the-counter antiseptic drug products that was published in the *Federal Register* of June 17, 1994. 59 Fed. Reg. 31,402.

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
“SAFETY AND EFFECTIVENESS OF CONSUMER ANTISEPTICS;
TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR
OVER-THE-COUNTER HUMAN USE”
(RIN: 0910-AF69)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) summarized the costs and benefits resulting from this final rule. FDA estimated that the overall economic cost over 10 years is \$23.6 million at a 3 percent discount rate and \$27.6 million at a 7 percent discount rate. FDA notes that these costs include the one-time costs of relabeling and reformulation. These one-time costs range from \$106.3 million to \$402.6 million. FDA further estimates that each pound of reduced exposure to antiseptic active ingredients will cost \$12.97-\$14.28 at a 3 percent discount rate and \$16.36-\$18.02 at a 7 percent discount rate.

FDA determined that the primary benefit of this final rule is reduced exposure to antiseptic active ingredients by 2.2 million pounds per year. However, FDA acknowledged that there is limited data available that characterizes the health effects of long-term exposure to antiseptic active ingredients. According to FDA, this prevented it from translating the estimated reduced exposure into monetary equivalents of health effects.

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

FDA examined the impacts of this final rule under the RFA. FDA found that this rule will have a significant economic impact on a substantial number of small entities, and FDA developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. FDA provides a summary of this analysis in the final 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 this final rule will impose a mandate of over \$146 (\$100 million adjusted for inflation) in any one year, as defined in title II of the Act. In its submission to GAO, FDA stated that it prepared a written statement under section 202 of the Act.

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

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

On December 17, 2013, FDA published a proposed rule. 78 Fed. Reg. 76,444. FDA invited interested parties to submit comments on the proposed rule by June 16, 2014. Additionally, interested parties had until December 16, 2014, to submit new data or information to the docket.

FDA provided 2 additional months for interested parties to submit comments on any new data or information submitted. FDA received approximately 40 comments from drug manufacturers, trade associations, academia, testing laboratories, consumer groups and health professionals, as well as over 1,800 comments filed by individuals. FDA responded to comments in the final rule.

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

This final rule contains no collections of information. Therefore, FDA found that clearance by the Office of Management and Budget under PRA is not required.

Statutory authorization for the rule

FDA stated that they promulgated this final rule under the authority of 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 360hh–360ss, 361(a), 371, 374, 375, 379e, 379k-l, and 42 U.S.C. 216, 241, 242(a), 262.

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

FDA determined that this final rule is economically significant under the Order. This rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

FDA identified section 751 of the Federal Food, Drug, and Cosmetic Act as giving preemptive effect to this final rule. 21 U.S.C. § 379r. However, FDA determined that this rule complies with the requirements set out in the Order.