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May 5, 2005

The Honorable Michael B. Enzi
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Joe Barton
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration:
Use of Ozone-Depleting Substances; Removal of Essential-Use Designations*

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 "Use of Ozone-Depleting Substances; Removal of Essential-Use Designations" (RIN: 0910-AF18). We received the rule on April 21, 2005. It was published in the Federal Register as a final rule on April 4, 2005. 70 Fed. Reg. 17168.

The final rule amends FDA's regulation on the use of ozone-depleting substances (ODSs) in self-pressurized containers to remove the essential use designations for albuterol used in oral pressurized metered-dose inhalers (MDIs). The albuterol MDIs that do not use ODS have been marketed for more than 3 years. FDA has determined that the two non-ODS MDIs will be satisfactory alternatives to albuterol MDIs containing ODSs and is removing the essential-use designation for albuterol MDIs as of December 31, 2008. Albuterol MDIs cannot be marketed after that date.

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 indicates that FDA complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation work relating to the subject matter of the rule is Marjorie Kanof, Managing Director, Health Care. Ms. Kanof can be reached at (202) 512-7101.

signed

Kathleen E. Wannisky
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

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"USE OF OZONE-DEPLETING SUBSTANCES;
REMOVAL OF ESSENTIAL-USE DESIGNATIONS"
(RIN: 0910-AF18)

(i) Cost-benefit analysis

FDA performed a cost-benefit analysis of the final rule. The rule will remove approximately 96 million to 430 million albuterol chlorofluorocarbons (CFC) MDIs from the market depending on whether generic albuterol MDIs become available in 2010 or 2017, the expiration dates of the current patents.

Assuming generic albuterol hydrofluoroalkane (HFA--substitute for ODS) MDIs enter the market at the end of 2010, the removal of albuterol CFC MDIs will eliminate competition from low-cost generic drugs during the period between December 2008 and December 2010, thereby raising prices and increasing spending on albuterol MDIs by about \$2.1 billion, assuming a 3-percent discount rate, or \$1.7 billion, assuming a 7-percent discount rate (present value in 2005).

If the generics enter the market in 2017, the increased spending would be about \$8.3 billion (3-percent discount rate) or \$6.2 billion (7-percent discount rate).

The reduction in CFC emissions is expected to be 1,200 metric tons annually.

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

FDA performed a Final Regulatory Flexibility Analysis in connection with the final rule that complies with the requirements of the Act, including the number of small entities impacted by the rule. Because of insufficient data, FDA could not certify that the final rule would not have a significant economic impact on a substantial number of small entities.

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

The final rule does not contain either an intergovernmental or a private sector mandate, as defined in title II, of more than \$100 million in any one year.

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

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

The final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On June 16, 2004, FDA published a Notice of Proposed Rulemaking in the Federal Register. 69 Fed. Reg. 33602. In response, 75 comments were received and are discussed in the preamble to the final rule.

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

The final rule does not contain any information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Statutory authorization for the rule

The final rule is promulgated under the authority 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; and 42 U.S.C. 7671 *et seq.*

Executive Order No. 12866

The final rule was reviewed by OMB and found to be an “economically significant” regulatory action under the order.

Executive Order No. 13132 (Federalism)

FDA has determined that the final rule does not have sufficient federalism implications to warrant the preparation of a federalism impact statement.