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May 3, 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: Use of Ozone-Depleting Substances; Removal of Essential-Use Designation (Flunisolide, etc.)*

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 Designation (Flunisolide, etc.)" (RIN: 0910-AF92). We received the rule on April 16, 2010. It was published in the *Federal Register* as a final rule on April 14, 2010. 75 Fed. Reg. 19,213. The rule has stated effective dates ranging from June 14, 2010, to December 31, 2013.

The final rule amends FDA's regulations on the use of ozone-depleting substances (ODSs) in self-pressurized containers to remove the essential-use designations for flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil used in oral pressurized metered-dose inhalers (MDIs). FDA has concluded that there are no substantial technical barriers to formulating these products so that they do not release ODSs, and therefore they will no longer be essential uses of ODSs as of the effective dates of this rule. MDIs for these active moieties containing an ODS may not be marketed after the relevant effective date. With this rule, FDA removes the last remaining essential-use designations for chlorofluorocarbons (CFCs) used in MDIs for the treatment of asthma and chronic obstructive pulmonary disease.

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
"USE OF OZONE-DEPLETING SUBSTANCES;
REMOVAL OF ESSENTIAL-USE DESIGNATION
(FLUNISOLIDE, ETC.)"
(RIN: 0910-AF92)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) analyzed the costs and benefits of this final rule. According to FDA, the benefits of this rule include environmental and public health improvements from protecting stratospheric ozone by reducing chlorofluorocarbons (CFCs) emissions. FDA also expect the benefits to include expectations of increased returns on investments in environmentally friendly technology and continued international cooperation to comply with the spirit of the Montreal Protocol, thereby potentially reducing future emissions of ozone-depleting substances (ODSs) throughout the world.

FDA determined that the costs of the final rule would include increased spending for needed medicines used to treat asthma and Chronic Obstructive Pulmonary Disease (COPD). FDA determined that the social costs of the final rule include the health benefits lost through decreased use of medicines that may result from increased prices. FDA was unable to quantify the economic costs of reducing the variety of marketed products from which consumers, and their doctors, can choose. FDA estimated that, depending on whether asthma and COPD patients use the most or least expensive of alternatives, private, third-party, and public expenditures on inhaled medicines would increase by roughly $90 million to $280 million per year.

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

FDA determined that this final rule will 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

FDA determined that this final rule includes a federal mandate that may result in the expenditure by state, local, or tribal governments, in the aggregate, or by the private

sector, of $100 million ($133 million adjusted for inflation at 2008 levels) or more in any one year. FDA stated that it examined the impacts of this rule under the Act.

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

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

On June 11, 2007, FDA published a proposed rule. 72 Fed. Reg. 32,030. FDA received over 4,000 comments in response to the proposed rule and held an open public meeting on the rule on August 2, 2007. Comments were submitted by consumers, health care providers, patient advocacy groups, manufacturers, a congressional caucus, and industry organizations. FDA responded to these comments in the final rule.

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

FDA determined that this final rule contains no information collection requirements under the Act.

Statutory authorization for the rule

FDA promulgated this final rule under the authority of sections 402 and 409 of title 15; sections 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, and 374 of title 21, and sections 7671–7671q of title 42, United States Code.

National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321–4370f

FDA concluded that this final rule will not have a significant impact on the human environment and that an environmental impact statement is not required.

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

FDA determined that this final rule is an economically significant rule under the Order. The Office of Management and Budget reviewed this rule.

Executive Order No. 13,132 (Federalism)

FDA determined that this final rule does not contain policies that have substantial direct effects on the states, on the relationship between the national governments and the states, or on the distribution of power and responsibilities among the various levels of government.