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B-296630

June 23, 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: Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components*

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 "Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components" (RIN: 0910-AC34). We received the rule on June 16, 2005. It was published in the Federal Register as a final rule on June 10, 2005. 70 Fed. Reg. 33998.

The final rule amends the federal performance standard for diagnostic x-ray systems and their major components. FDA is taking this action to update the performance standard to account for changes in technology and use of radiographic and fluoroscopic x-ray systems and to fully utilize the International System of Units to describe radiation-related quantities and their units when used in the performance standard.

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

ENCLOSURE

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
"ELECTRONIC PRODUCTS; PERFORMANCE STANDARD FOR
DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS"
(RIN: 0910-AC34)

(i) Cost-benefit analysis

FDA conducted a cost-benefit analysis of the final rule that found that the rule had an annual cost of $30.8 million during the first 10 years using a 7-percent annual discount rate and $30.1 million using a 3-percent discount rate. The estimated benefits of the rule are average annual amortized pecuniary savings in the first 10 years of at least $320 million, with an estimated 90 percent confidence interval spanning a range between $88.3 million and $1.160 billion using a 7-percent discount rate. Using a 3-percent discount rate results in annualized benefits of $715 million, with a 90-percent confidence interval of between $197.4 million and $2.593 billion.

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

FDA prepared an Initial Regulatory Flexibility Analysis in connection with the proposed rule and no comments were received concerning the analysis so FDA adopted the initial analysis as its Final Regulatory Flexibility Analysis. The analysis complies with the requirements of the Act and discusses the alternatives considered to reduce the impact on 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 states that the final rule does not contain either an intergovernmental or private sector mandate, as defined in title II, of more than $115 million ($100 million adjusted for inflation) 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 December 10, 2002, FDA published a Notice of Proposed Rulemaking in the

Federal Register. 67 Fed. Reg. 76056. Twelve comments were received in response to the notice and are discussed in the preamble to the final rule.

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

The final rule contains an information collection that is subject to review by the Office of Management and Budget under the Paperwork Review Act. The preamble to the final rule contains the required information regarding the collection. OMB has reviewed and approved the collection and assigned OMB Control No. 0910-0564 with an expiration date of December 31, 2006.

Statutory authorization for the rule

The final rule is promulgated pursuant to the authority found at 21 U.S.C. 351, 352, 360e-360j, 360gg-360ss, 371, and 381.

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 states that the final rule is consistent with the federalism principles expressed in the order. The rule only preempts state law to the extent required by statute and only on the limited aspects of performance of fluoroscopic and radiographic x-ray systems covered by the rule. FDA is not aware of any existing state or local requirements that will be displaced by the rule.