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United States Government Accountability Office  
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B-295520

December 22, 2004

The Honorable Judd Gregg  
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:  
Establishment and Maintenance of Records Under the Public Health  
Security and Bioterrorism Preparedness and Response Act of 2002*

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 "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (RIN: 0910-AC39). We received the rule on December 9, 2004. It was published in the Federal Register as a final rule on December 9, 2004. 69 Fed. Reg. 71562.

The final rule requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to help address credible threats of serious adverse health consequences or death to humans and animals.

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 Ms. 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: Ann Stallion  
Regulations Coordinator  
Department of Health and  
Human Services

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE  
ISSUED BY  
DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
FOOD AND DRUG ADMINISTRATION  
ENTITLED  
"ESTABLISHMENT AND MAINTENANCE OF RECORDS UNDER THE  
PUBLIC HEALTH SECURITY AND BIOTERRORISM  
PREPAREDNESS AND RESPONSE ACT OF 2002"  
(RIN: 0910-AC39)

(i) Cost-benefit analysis

FDA performed a cost-benefit analysis of the final rule. The estimated annual costs for recordkeeping consist of \$85,082,000 for learning, \$205,239,000 for records redesign, \$114,701,000 for additional records maintenance, and \$8,508,000 for learning for new firms. Over a 20-year time horizon (assuming a 7-percent discount rate) the total costs are \$1,406,356,000.

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

FDA conducted a Final Regulatory Flexibility Analysis that shows that the final rule will have a significant economic impact on a substantial number of small entities. One alternative used by FDA to reduce the burden on small entities is an extended compliance date.

(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 contains a mandate on the private sector of more than \$112,300,000 (\$100 million adjusted for inflation) in any one year. Therefore, the FDA has prepared the required statement including the rule's effects of future costs and exports.

(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 May 9, 2003, the FDA published a Notice of Proposed Rulemaking in the Federal Register. 68 Fed. Reg. 25188. In response, FDA received 212 comments, which are discussed in the preamble to the final rule.

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

The final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. FDA has submitted the required information to OMB including the estimated burden hours. FDA expects the recordkeeping burden for the first and second years the rule is effective to be 7,763,000 hours, which includes learning and record redesign. In subsequent years, the burden is estimated to be 3,359,000.

Statutory authorization for the rule

The final rule is promulgated under the authority found in 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

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)

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