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B-296182

April 14, 2005

The Honorable Arlen Specter  
Chairman  
The Honorable Patrick J. Leahy  
Ranking Minority Member  
Committee on the Judiciary  
United States Senate

The Honorable F. James Sensenbrenner, Jr.  
Chairman  
The Honorable John Conyers, Jr.  
Ranking Minority Member  
Committee on the Judiciary  
House of Representatives

Subject: *Department of Justice, Drug Enforcement Administration: Electronic Orders for Controlled Substances*

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 Justice, Drug Enforcement Administration (DEA), entitled "Electronic Orders for Controlled Substances" (RIN: 1117-AA60). The Senate and the House of Representatives received the rule on March 30, 2005. It was published in the Federal Register as a final rule on April 1, 2005. 70 Fed. Reg. 16902.

The final rule provides an electronic equivalent to the Drug Enforcement Agency official form that is required for all distributions involving Schedule I and II controlled substances. The rule allows, but does not require, registrants to order Schedule I and II substances electronically and maintain records of these orders electronically.

Enclosed is our assessment of the DEA'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 DEA 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 Norman Rabkin, Managing Director, Homeland Security and Justice. Mr. Rabkin can be reached at (202) 512-8777.

signed

Kathleen E. Wannisky  
Managing Associate General Counsel

Enclosure

cc: William J. Walker  
Deputy Assistant Administrator  
Office of Diversion Control  
Drug Enforcement Administration  
Department of Justice

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE  
ISSUED BY THE  
DEPARTMENT OF JUSTICE,  
DRUG ENFORCEMENT ADMINISTRATION  
ENTITLED  
"ELECTRONIC ORDERS FOR CONTROLLED SUBSTANCES"  
(RIN: 1117-AA60)

(i) Cost-benefit analysis

DEA estimates that electronic orders will reduce the annualized cost of Schedule I and II orders by \$284 million. The annualized cost of digital certificates is estimated to be \$20 million. Therefore, the annualized net benefit of the rule, according to DEA, is \$264 million.

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

DEA has certified that the 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

The final rule does not contain either an intergovernmental or 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 27, 2003, DEA published a Notice of Proposed Rulemaking in the Federal Register. 68 Fed. Reg. 38558. In response, DEA received 11 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. The preamble to the final rule contains the information submitted to OMB for approval of the two collections including the annual burden hours.

Statutory authorization for the rule

The final rule is promulgated pursuant to the authority found at 21 U.S.C. 821, 828, 829, 871(b), 958(e), and 965.

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)

DEA states that the final rule does not contain sufficient federalism implications to warrant the preparation of a federalism impact statement.