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United States Government Accountability Office
Washington, DC 20548

B-298911

October 10, 2006

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

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

Subject: *Department of Justice, Drug Enforcement Administration: Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products*

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 “Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products” (RIN: 1117-AB05). We received the rule on September 25, 2006. It was published in the Federal Register as an “interim final rule with request for comment” on September 26, 2006. 71 Fed. Reg. 56008.

The interim final rule implements the provisions of the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which establishes new requirements for retail sales of over-the-counter (nonprescription) products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The three chemicals can be used to manufacture methamphetamine illegally. The rule establishes daily and 30-day limits on the sales of scheduled listed chemical products to individuals and requires recordkeeping for most sales.

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: Joseph T. Rannazzisi
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
"RETAIL SALES OF SCHEDULED LISTED CHEMICAL PRODUCTS;
SELF-CERTIFICATION OF REGULATED SELLERS OF
SCHEDULED LISTED CHEMICAL PRODUCTS"
(RIN: 1117-AB05)

(i) Cost-benefit analysis

DEA performed a cost-benefit analysis but cannot estimate the cost impact accurately because it is difficult to predict how sales of the listed products will be impacted and how many outlets may stop selling the items. If the value of the existing market is \$500 million, the additional costs, including transaction costs would be considerably lower than \$100 million. If the value of the market is \$1.5 billion, the cost could exceed \$100 million.

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

Since the interim final rule was not preceded by a notice of proposed rulemaking, the provisions of the Regulatory Flexibility Act do not apply. However, DEA has reviewed the impacts of the rule and found that it will not have a substantial 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 interim final rule does not contain either an intergovernmental or private sector mandate, as defined in title II, of more than \$118 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.

DEA has found "good cause" to forego the notice and comment requirements of 5 U.S.C. 553. CMEA requires that the sellers self-certify by September 30, 2006, to continue to sell the listed products. In addition, the sales limit and blister pack requirements became effective on April 8, 2006, under the provisions of CMEA.

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

The interim final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. DEA has submitted the required information to OMB for its review, including the estimated annual burden of 4,548,500 hours.

Statutory authorization for the rule

The interim final rule is promulgated under the authority found at 21 U.S.C. 802, 830, 842, 871(b), 875, and 877.

Executive Order No. 12866

The interim 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 interim final rule does not have sufficient federalism implications to warrant the preparation of a federalism impact analysis.