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United States General Accounting Office  
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February 26, 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 W.J. "Billy" Tauzin  
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:  
Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids  
Adulterated Because They Present an Unreasonable Risk*

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 "Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk" (RIN: 0910-AA59). We received the rule on February 12, 2004. It was published in the Federal Register as a final rule on February 11, 2004. 69 Fed. Reg. 6788.

The final rule declares dietary supplements containing ephedrine alkaloids adulterated under the Federal Food, Drug, and Cosmetic Act because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use.

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 the 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: 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 THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
FOOD AND DRUG ADMINISTRATION  
ENTITLED  
"FINAL RULE DECLARING DIETARY SUPPLEMENTS  
CONTAINING EPHEDRINE ALKALOIDS ADULTERATED  
BECAUSE THEY PRESENT AN UNREASONABLE RISK"  
(RIN: 0910-AA59)

(i) Cost-benefit analysis

FDA performed a cost-benefit analysis on the final rule and estimates that the option chosen for removing the dietary supplement from the market will generate estimated benefits of between \$43 million and \$132 million per year. The analysis also discusses the costs and benefits of the other options considered by FDA during the rulemaking process.

(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 found that the final rule would have a significant economic impact on a substantial number of small entities. The analysis discusses the various impacts on manufacturers and distributors and the options that were considered.

(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 \$113 million (\$100 million adjusted annually 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 June 4, 1997, FDA published a Notice of Proposed Rulemaking in the Federal Register. 62 Fed. Reg. 30678. This proposed rule was followed by numerous other notices published in the Federal Register by FDA that withdrew portions of the 1997 proposed rule and advised of the availability of additional information regarding the drug. See 62 Fed. Reg. 44247 (August 20, 1997), 63 Fed. Reg. 23633

(April 29, 1998), 65 Fed. Reg. 17474 and 17509 (April 3, 2000), and 68 Fed. Reg. 10417 (March 5, 2003). FDA received over 48,000 comments in response to the various notices and the relevant comments are discussed in the preamble to the final rule.

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

The final rule does not contain any information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Statutory authorization for the rule

The final rule is promulgated pursuant to the authority contained in 21 U.S.C. 321, 342, 343, and 371.

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 evaluated the final rule in accordance with the order. It found that the rule would have a preemptive effect on state and local laws that concern ephedrine alkaloids, such as labeling requirements, because the FDA rule prohibits the introduction into interstate commerce. The preamble to the final rule contains the contacts that the FDA had with state and local authorities and the comments the FDA received from state authorities.