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July 6, 2007

The Honorable Edward M. Kennedy
Chairman
The Honorable Michael B. Enzi
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable John D. Dingell
Chairman
The Honorable Joe Barton
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration:
Current Good Manufacturing Practice in Manufacturing, Packaging,
Labeling, or Holding Operations for Dietary Supplements*

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 “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements” (RIN: 0910-AB88). We received the rule on June 22, 2007. It was published in the *Federal Register* as a final rule on June 25, 2007. 72 Fed. Reg. 34,752.

The final rule establishes the minimum current good manufacturing practice (CGMP) necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplements. The final rule is effective on August 24, 2007, 60 days after it was published in the *Federal Register*. The compliance date is June 25, 2008. However, for businesses employing fewer than 500, but 20 or more full-time equivalent employees, the compliance date is June 25, 2009, and for businesses that employ fewer than 20 full-time equivalent employees, the compliance date is June 25, 2010. FDA also issued an interim final rule, published in the *Federal Register* on June 25, 2007, that sets forth a procedure for requesting an exception to a CGMP requirement in the final rule. 72 Fed. Reg. 34,959. This interim final rule is not a major rule under section 804(2) of title 5, United States Code.

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 Michael R. Volpe, Assistant General Counsel, at (202) 512-8236. 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) 512-7114.

signed

Robert J. Cramer
Associate General Counsel

Enclosure

cc: Ann Stallion
Regulations Coordinator
Department of Health and
Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"CURRENT GOOD MANUFACTURING PRACTICE IN
MANUFACTURING, PACKAGING, LABELING, OR
HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS"
(RIN: 0910-AB88)

(i) Cost-benefit analysis

FDA performed a cost-benefit analysis of the final rule. FDA estimated that, once fully implemented, the quantifiable annual benefits from the final rule will be about \$44 million. The benefits able to be quantified are generated by more consistently produced dietary supplements that will increase product safety, which reduces the number of acute illnesses and product recalls. FDA also noted that the final rule may generate benefits that cannot be quantified, such as the reduction in the number of chronic illnesses and conditions. Moreover, FDA estimated that the final rule will cost about \$16 million in the first year, \$120 million in the second year, and \$190 million in the third year. FDA determined that the benefits of the final rule justify the costs.

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

FDA estimated that the final rule will have a significant economic effect on small businesses. FDA estimated that the final rule will cost, annually, about \$46,000 for an establishment with fewer than 20 employees and \$184,000 for an establishment with 20-499 employees. For this reason, FDA prepared a Final Regulatory Analysis. The analysis complies with the requirements of the Act, including the steps taken to reduce the economic impact on small entities. For example, FDA provided a longer compliance period for businesses with fewer than 500 employees.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

FDA's compliance with the Act's documentary requirements regarding costs, benefits, and alternatives considered are contained in FDA's cost-benefit analysis, which was prepared for compliance with Executive Order 12,866. Section 202 of the Unfunded Mandates Reform Act of 1995 authorizes such use of other analysis for compliance.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

FDA promulgated this final rule using the notice and comment procedures found in the Administrative Procedure Act, 5 U.S.C. § 553. FDA published an Advance Notice of Proposed Rulemaking (ANPRM) in the *Federal Register* on February 6, 1997. 62 Fed. Reg. 5700. FDA received more than 100 comments in response to the 1997 ANPRM. FDA evaluated these comments and, during 1999, conducted a number of outreach activities related to dietary supplements. FDA published a proposed rule in the *Federal Register* on March 13, 2003. 68 Fed. Reg. 12,157. FDA addressed the comments to the ANPRM in the proposed rule. FDA conducted additional outreach activities related to dietary supplements after the proposed rule was published. FDA received approximately 400 comments in response to the proposed rule, to which they responded in the final rule.

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

The final rule contains information collection requirements that have been submitted for review by the Office of Management and Budget (OMB) as required by the Act. FDA stated that, prior to the effective date of the final rule, FDA will publish a document in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule.

Statutory authorization for the rule

The Dietary Supplement Health and Education Act (DSHEA), Pub. L. No. 103-417, was enacted on October 25, 1994. Among other things, DSHEA amended the Federal Food, Drug, and Cosmetic Act by adding section 402(g) (codified in 21 U.S.C. § 342(g)). Section 402(g) provides that the Secretary of Health and Human Services may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g) also stipulates that such regulations shall be modeled after CGMP regulations for food.

Executive Order No. 12,866

The final rule was reviewed by OMB and found to be an “economically significant” regulatory action under the order.

Executive Order No. 13,132 (Federalism)

FDA concluded that the final rule does not have federalism implications, *i.e.*, FDA determined that the final rule will not have a substantial impact on states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.