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July 22, 2003

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: Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims*

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 "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims" (RIN: 0910-AB66). We received the rule on July 11, 2003. It was published in the Federal Register as a final rule on July 11, 2003. 68 Fed. Reg. 41434.

The final rule amends the FDA's regulations on nutrition labeling to require that *trans* fatty acids be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fatty acids.

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 William Scanlon, Managing Director, Health Care. Mr. Scanlon can be reached at (202) 512-7114.

signed

Kathleen E. Wannisky
Managing Associate General Counsel

Enclosure

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

ENCLOSURE

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
"FOOD LABELING: *TRANS* FATTY ACIDS IN NUTRITION LABELING,
NUTRIENT CONTENT CLAIMS, AND HEALTH CLAIMS"
(RIN: 0910-AB66)

(i) Cost-benefit analysis

FDA performed a cost-benefit analysis of the final rule. FDA estimates the total testing costs of the affected products could range from a low of $40,298,000 to a high of $57,282,000 and relabeling costs ranging from a low of $85,964,00 to a high of $204,986,000.

FDA utilized two methods of valuing statistical life years to estimate the benefits of the final rule, and the methods are discussed in detail in the preamble to the final rule. After 20 years, one method estimates the cumulative benefits at $13,130 million and the second method estimates the cumulative benefits at $26,757 million.

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

The FDA performed a Final Regulatory Flexibility Analysis of the final rule, which contains the information required by the Act including the number and types of small entities affected, the costs to small entities, and the regulatory options that were considered to ease the burden on small entities. The options that were considered included delaying the effective date and exempting small entities. Both of these options were found by FDA to be unfeasible since they would delay or reduce the benefits of the final rule.

(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, as defined in title II, of more than $100 million in any one year on the private sector. FDA has included the required statement in the preamble to the final rule, which discusses, among other items, future costs; particular regions, communities, or industrial sectors affected; 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. The FDA published a Notice of Proposed Rulemaking in the Federal Register on November 17, 1999. 64 Fed. Reg. 62746. Following several reopenings of the comment period, FDA has received over 1,700 letters in response to the proposal. The comments are discussed in the preamble to the final rule.

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

The final rule contains an information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The preamble to the final rule contains the required information regarding the collection including the burden associated with the collection. FDA estimates that the reporting burden will be 615,200 hours at an operating cost of $171.7 million.

Statutory authorization for the rule

The final rule is promulgated pursuant to the authority contained in 15 U.S.C. 1453, 1454, 1455, and 21 U.S.C. 321, 331, 342, 343, 348, 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 has analyzed the final rule in accordance with the order and found that, while the rule has a preemptive effect on state law since states are preempted from imposing any nutritional labeling requirements that are not identical to those imposed by the final rule, the rule is consistent with the order.