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The Honorable Nancy Landon Kassebaum
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Labor and Human Resources
United States Senate

The Honorable Thomas J. Bliley, Jr.
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives

Subject: Department of Health and Human Services - Food and Drug Administration: Food Labeling; Nutrition Labeling, Small Business Exemption

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by Department of Health and Human Services - Food and Drug Administration (FDA), entitled "Food Labeling; Nutrition Labeling, Small Business Exemption" (RIN: 0910-AA19). We received the rule on August 6, 1996. It was published in the Federal Register as a final rule on August 7, 1996. 61 Fed. Reg. 40,963.

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.

The rule is in response to the Nutrition Labeling and Education Act Amendments of 1993, Pub. L. 103-80. The Nutrition Labeling and Education Act of 1990, Pub. L. 101-535, established the requirement that with limited exceptions, a food, including both conventional foods and dietary supplements must have a label bearing certain nutrition labeling in order not to be considered misbranded. Among the exceptions to this nutrition labeling requirement was one for small business based upon the

value of their gross sales. The 1993 amendments to the Act established another exemption from the nutrition labeling requirement for low-volume food products of small businesses. The Act defines low volume by the number of units sold in a year, and what constitutes a small business by the number of full-time equivalent employees of the company. The rule issued by the FDA is intended to provide an understanding of how the small business nutrition labeling exemptions operate.

If you have any questions about this report, please contact Alan Zuckerman, Assistant General Counsel, at (202) 512-4586. The official responsible for GAO evaluation work relating to the Department of Health and Human Services - Food and Drug Administration is Thomas E. Slomba, Assistant Director. Mr. Slomba can be reached at (202) 512-9910.

Robert P. Murphy
General Counsel

Enclosure

cc: The Honorable Donna E. Shalala
The Secretary 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; NUTRITION LABELING, SMALL BUSINESS EXEMPTION"
(RIN: 0910-AA19)

(i) Cost-benefit analysis

In its publication of the proposed rule, 59 Fed. Reg. 11,872, March 14, 1994, the FDA included an economic impact analysis wherein it found that the only "significant economic effect of this rule is the benefit that it creates by reducing labeling costs for newly exempted companies." The FDA noted that the benefit provided was the result of the statutory provisions, and not FDA discretion. The actual costs to small business for applying for the exemption and the government for administering the rule was estimated to be less than $4 million annually.

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

Section 603-605

The agency prepared an initial regulatory flexibility analysis in it proposed rulemaking published on March 14, 1994, supra. Our review of that analysis indicates that the agency complied with the requirements of section 603(1)-(4). Prior to the publication of the proposed rule on March 14, 1994, the FDA published a complete regulatory impact analysis on the final rule to amend the food labeling regulations. 58 Fed Reg. 2927, January 6, 1993. Included in that analysis is the economic impact on small business and the saving estimated for the exemptions available to small business prior to the passage of the Nutrition Labeling and Education Act Amendments of 1993, Pub. L. 103-80. An FDA representative indicated that the Administration did not separately send a copy of the initial regulatory flexibility analysis to the Chief Counsel, Small Business Administration, because it has a longstanding informal agreement with the SBA that publication was sufficient transmission to the Chief Counsel.

In its publication of this final rule, the FDA noted that "because the rule will not have any adverse effect on small business, the agency believes that under the Regulatory Flexibility Act, the rule will not have a significant impact on a substantial number of small entities." Nonetheless, the agency stated that its discussion of costs and cost savings to small business would constitute a final regulatory flexibility analysis in accordance with the requirements of section 604.

The agency noted also that no comments were received and that it was aware of no information which would serve as a basis for significantly increasing the costs or decreasing the benefits estimated in the analysis. The Administration's report does not show that it invoked any of the special procedures authorized by section 605 in preparing the analysis.

Section 607

The rule fully analyzes the economic impact anticipated as a result of the rule. The FDA expects a maximum of 10,000 small business firms to file for the exemption at a total first year cost for all respondents of approximately $3,312,000, while the savings for small businesses that are exempted from the labeling requirement are estimated to be between $275 and $360 million.

Section 609

Although there is no indication in the publication that the Administration made any special efforts to involve small entities in this current rulemaking process, an FDA representative reports that extensive informal efforts were made. For example, the agency mailed copies of the proposed rule to 100 food industry associations which include small business members and to a number of small business firms directly. In addition, the FDA has participated in a series of public forums that had been scheduled by the U. S. Department of Agriculture to discuss the small business issues under the Nutrition Labeling and Education Act of 1990, Pub. L. 101-535. That act established the requirement for nutrition labeling.

The background discussion for this rule noted that the 1993 amendments establishing the exemption for nutrition labeling for low-volume foods of small business were self-effectuating, but that it concluded that rulemaking would be useful in providing a common understanding of how the exemption provisions operate.

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

Our review indicates that the rule will not result in annual expenditures of $100 million or more by State, local or tribal governments in the aggregate, or by the private sector. Sections 202 and 205 of the Unfunded Mandates Reform Act of 1994 are thus inapplicable. In addition, the final rule does not affect small governments or contain a significant intergovernmental mandate. Accordingly, sections 203 and 204 of the Act are also inapplicable. An agency representative confirmed this analysis.

(iv) Other relevant information or requirements under Acts and Executive orders

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

The rule was promulgated through the general notice of proposed rulemaking procedures of the Act, 5 U.S.C. § 553. The proposed rulemaking 59 Fed. Reg. 11,872, March 14, 1994, afforded interested persons the opportunity to comment on the proposed rule, and this final rule addresses those comments.

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

The final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB). FDA received OMB's approval for a 90-day period, OMB control No. 0910-0324. FDA notes that because of the limited approval, it is taking steps to obtain a regular approval. Nonetheless, the FDA notes that the 1993 amendments require that small businesses file a notice with the FDA if they desire to avail themselves of the food labeling exemption, and that these provisions take precedence over the Paperwork Reduction Act. The FDA notes that without the requisite notice, a non-labeled food product will be misbranded regardless of whether OMB has approved the information requirements included in the final rule.

Statutory authorization for the rule

The rule is promulgated under the authority of the Fair Packaging and Labeling Act, 15 U.S.C. §§ 1453, et seq., and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321, 331, 342, 343, 348, 371.

Executive Order No. 12866

The rule was determined to be a significant regulatory action within the meaning of Executive Order 12866. The FDA supplied the necessary documentation to the Office of Information and Regulatory Affairs which cleared the rule after some suggested modifications.

The FDA has not identified any other statutes or executive orders imposing requirements relative to this rule.