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April 1, 1999

The Honorable James M. Jeffords
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
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: Over-the-Counter Human Drugs; Labeling Requirements

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 "Over-the-Counter Human Drugs; Labeling Requirements" (RIN: 0910-AA79). We received the rule on March 19, 1999. It was published in the Federal Register as a final rule on March 17, 1999. 64 Fed. Reg. 13254.

The final rule establishes a standardized format and standardized content requirements for the labeling of over-the-counter drug products.

The final rule has an announced effective date of April 16, 1999, which is less than the 60-day delay in a major rule's effective date required by the Small Business Regulatory Enforcement Fairness Act of 1996. 5 U.S.C § 801(a)(3). The FDA gives no reason in the rule's preamble as to why the 60-day delay provision was not met. While the rule has varying compliance dates that are much later than the announced effective date of the rule (some previously approved products covered by the rule have several years to become compliant with the labeling requirement), we do note

that products which have drug marketing applications approved on or after April 16, 1999, must comply upon approval.

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, with the exception of the failure to allow the 60-day delay, 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 Department of Health and Human Services, Food and Drug Administration, is William Scanlon, Director, Health Financing and Public Health Issues. Mr. Scanlon can be reached at (202) 512-7114.

Robert P. Murphy
General Counsel

Enclosure

cc: Ms. Jackie White
Deputy Executive Secretariat
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
"OVER-THE-COUNTER HUMAN DRUGS; LABELING REQUIREMENTS"
(RIN: 0910-AA79)

(i) Cost-benefit analysis

The FDA performed a cost-benefit analysis of the final rule. The analysis estimates that the one-time costs of the rule to be about $58 million with annual recurring costs of about $11.5 million.

The health benefits could not be quantified by the FDA, but FDA believes the benefits to be substantial. If the rule prevents 5 percent of the hospitalizations associated with the unintended consequences of self-medication, the economic savings could be $39 million annually in direct benefits and $52 million annually from indirect benefits. In addition, the rule is expected to produce more efficient consumer search activities which could lead to time savings valued at $19 million to $38 million per year. Based on the above, the total benefits of the rule range from $110.5 million to $129.6 million per year.

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

The preamble to the final rule contains the Final Regulatory Flexibility Analysis conducted by the FDA.

Using the Small Business Administration's size designation for this industry of fewer than 750 employees, FDA estimates that 70 percent of the 400 firms in the industry would be considered small entities.

FDA finds that the one-time cost of compliance for each product, estimated to be $600, should be manageable for small entities even if they manufacture 10 to 20 products that require relabeling at a cost of $6,000 to $12,000.

The analysis also discusses the alternatives considered such as different compliance dates and the reasons for the alternative selected.

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

FDA has found that the final rule will not impose a mandate on either state, local, or tribal governments or the private sector in any one year of $100 million or more.

(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 February 27, 1997, the FDA published a Notice of Proposed Rulemaking in the Federal Register. 62 Fed. Reg. 9024. The FDA received over 1,800 comments and discusses the comments and the changes it made to the proposed rule in the preamble to the final rule.

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

The final rule contains information collections which are subject to review by the Office of Management and Budget under the Paperwork Reduction Act.

The preamble to the final rule contains the information required by the Act, including a description of the collection, the reason for the collection, and an estimate of the annual burden hours imposed.

FDA estimates that the total burden hours annually will be 120,578 with 51,336 hours being a one-time burden. The burden hours are not higher because, with the varied compliance dates for the labeling, many manufacturers will be able to change the labels as part of the usual and customary business practice of redesigning the labels and therefore no additional burden is incurred.

Statutory authorization for the rule

The final rule was issued pursuant to the authority of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act as codified at 21 U.S.C. §§ 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e and 42 U.S.C. §§ 216, 241, 262, and 264.

Executive Order No. 12866

The final rule was reviewed by the Office of Management and Budget and determined to be an economically significant regulatory action and approved as complying with the order.