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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: Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation

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, entitled "Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation" (RIN: 0910-AA09). We received the rule on October, 11, 1996. It was published in the Federal Register as a final rule on October 7, 1996. 61 Fed. Reg. 52601.

The final rule revises existing current good manufacturing practice requirements for medical devices and incorporates them into a quality system regulation. The quality system regulation includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices intended for human use. The rule adds preproduction design controls and is intended to achieve consistency with quality system requirements worldwide.

Enclosed is our assessment of the Food and Drug Administration's compliance with the procedural steps required by sections 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review indicates that the Food and Drug Administration complied with the applicable requirements.

If you have any questions about this report, please contact James Vickers, Senior Attorney, 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 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
"MEDICAL DEVICES; CURRENT GOOD MANUFACTURING PRACTICE (CGMP) FINAL RULE; QUALITY SYSTEM REGULATION"
(RIN: 0910-AA09)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) performed a cost and benefit analysis evaluating the economic impact of the final rule.

The estimated total annual incremental cost to the industry is $81.9 million. The majority of the costs ($57.5 million) represent the establishment of design controls for new products. Most of the remaining costs are attributable to extending the quality system and requiring appropriate documentation, evaluating suppliers and contractors and management review.

The benefits to the public health are estimated to be 36 to 44 fewer deaths per year and 484 to 677 fewer serious injuries per year attributable to design-related device failures. FDA assumed an economic value of $5 million per fatality avoided, so that the monetary savings per year would be $180 to $220 million per year. These figures do not include any monetary savings associated with the reduction in serious injuries. Additionally, the FDA states that the rule will result in fewer product recalls and better product quality.

Finally, since the final rule is designed to harmonize with the international standards, device manufacturers will not have to maintain two different quality systems to compete both nationally and internationally.

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

The FDA has concluded that the rule will have a significant economic impact on a substantial number of small entities because almost all medical device establishments are classified as small under the Small Business Administration's definition of size. An initial regulatory flexibility analysis and a final regulatory flexibility analysis have been prepared and included in the preambles to the proposed rule and the final rule notice, respectively, as required by sections 603 and 604. The analyses comply with the informational requirements of the sections

including the classes of small entities subject to the rule and alternatives considered to reduce the burden on the small entities.

The FDA, in drafting the rule to ease the burden on small entities, has not applied the design requirements to all Class I devices and component suppliers have been removed from the rule's coverage. Also, the requirement for traceability of components has been limited to where the agency believes it is necessary to protect the public health. In addition, other revisions were made to make the final rule less prescriptive and to allow establishments greater flexibility in meeting the requirements. Finally, the FDA will conduct workshops, issue guidance manuals and videotapes, and hold teleconferences to aid small entities in complying with the rule.

The analyses use both quantifiable and general descriptions of the effects of the rule on small entities as required by section 607 and numerous small entities participated in the rulemaking as required by section 609 by submitting comments on the proposed rule and by attending an open public meeting in August 1995 and the September 1995 meeting of the Good Manufacturing Practice Advisory Committee.

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

The FDA examined the final rule as prescribed by the Act and found that no mandate will be imposed on State, local or tribal governments and it believes that the burden on the private sector will be below the $100 million annual expenditure level to require compliance with the Act. However, while the cost estimated by the FDA on the private sector is $81.9 million, in view of the uncertainties in the estimates, FDA has followed the requirements of the Act.

As required by section 205, FDA considered regulatory alternatives to the requirements of the rule but determined that the provisions of the final rule constituted the most cost-effective and least burdensome alternative that would meet the objective of the rule.

To ease the regulatory burden, the FDA has extended the effective date of the rule to June 1, 1997, and will not take regulatory action for an additional year on the design control requirement. Also, FDA exempted almost all Class I devices. However, FDA rejected suggestions that low-risk devices be exempted because the cost of implementation will exceed the public health benefits gained. FDA found that all Class II and III devices, even those devices from firms with excellent past records, should be covered because their failure could adversely affect public health.

(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 using the notice and comment procedures of 5 U.S.C. § 553 and the procedures contained at 21 U.S.C. § 360j(f)(3) concerning the establishment of an advisory committee to advise and submit recommendations to the Secretary regarding regulations concerning good manufacturing practices.

Meetings of the Device Good Manufacturing Practice Advisory Committee (GMP Advisory Committee) were announced by Federal Register publication on April 25, 1990 (55 Fed. Reg. 17502) and April 17, 1991 (56 Fed. Reg. 15626). An advance notice of proposed rulemaking was published on June 15, 1990 (55 Fed. Reg. 24544), and the proposed rule was published in the Federal Register on November 23, 1993 (58 Fed. Reg. 61952), soliciting comments from the public. In addition, various papers and working drafts of the rule were made available to the public and an open public meeting on the rule was held.

The preamble to the final rule discusses the comments which were received and the changes which were made to the rule based on such comments.

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

The final rule contains information collections that are subject to review by the Office of Management and Budget and include device master records, device history records, quality system records and complaint files. The FDA solicited comments on these requirements in the notice of proposed rulemaking and has evaluated and responded to them in the preamble to the final rule.

The preamble to the final rule contains an explanation of the need for the information and the burden estimates relating to each section of the rule. The information collections associated with the final rule contain 3,527,901 burden hours which include 1,433,579 burden hours for a one time start up expenditure for 7,237 manufacturers and 2,094,321 burden hours expended annually by 7,237 manufacturers.

The FDA solicits comments on the information collections contained in the final rule until December 6, 1996, regarding the necessity of the collection, the estimate of the burden hours and ways to minimize the burden including electronic submission of responses. After receipt of these comments, FDA will publish a notice in the Federal Register when the agency is submitting the collections to OMB for approval and again when OMB makes a decision on approval, modification or disapproval. The information collections in the rule will not become effective until OMB approval is obtained and an OMB control number has been issued.

Statutory authorization for the rule

The Safe Medical Devices Act of 1990 (Pub. L. 101-629, November 28, 1990), amended section 520(f) of the Federal Food, Drug and Cosmetic Act providing the FDA with the authority to add preproduction design controls to the Current Good Manufacturing Practices regulation. 21 U.S.C.§ 360j(f)(1)(A).

Executive Order No. 12866

The rule was determined to be an "economically significant regulatory action" under Executive Order No. 12866 requiring review by the Office of Management and Budget, Office of Information and Regulatory Affairs (OIRA). OIRA approved the final rule as complying with the requirements of the Order based on information supplied by the FDA, including a planned regulatory action document describing the reason for the rule and an assessment of the costs and budgetary impact of the rule.

Executive Order No. 12875 (Intergovernmental Partnership)

The FDA has reviewed the rule under Executive Order No. 12875 and finds that the Order does not apply because the rule is not applicable to government facilities but to finished device manufacturers. However, regarding consultation with State, local and tribal governments, the FDA notes that there were two state government representatives who were members of the Good Manufacturing Practices Advisory Committee in 1995 which explored the need to revise the Current Good Manufacturing Practices regulation.