

September 9, 1999

Stephen P. Rhodes  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

Re: FDA Final Rule on Effective Date of Requirement for Pre-market Approval of the Silicone Inflatable Breast Prosthesis; 64 Fed. Reg. 45,1555 (August 19, 1999).

Dear Mr. Rhodes:

The Office of the Chief Counsel for Advocacy of the U.S. Small Business Administration was created in 1976 to represent the views and interests of small business in federal policy making activities.<sup>1</sup> The Chief Counsel participates in rulemakings when he deems it necessary to ensure proper representation of small business interests. The Chief Counsel also reports to Congress annually on federal agency compliance with the Regulatory Flexibility Act (RFA),<sup>2</sup> and works with federal agencies to ensure that their rulemakings demonstrate an analysis of the impact that their decisions will have on small businesses.

On August 19, 1999, FDA published a final rule designating the effective date for requiring the filing of a pre-market approval application (PMA) or a notice of completion of product development protocol (PDP) for the silicone inflatable breast prosthesis. Under the regulation, commercial distribution of the device must cease unless a manufacturer or importer has filed with FDA a PMA or PDP within 90 days of the effective date of the regulation, or approximately November 18, 1999. A proposed rule was published in 1993 to require the filing of PMAs or PDPs. During the interim between the proposed and final rules, FDA examined emerging research on the issue. FDA has decided to pursue these requirements in lieu of banning the product or issuing a recall as recommended by some commenters/consumers.

FDA expects up to seven manufacturers to submit a PMA or PDP for the devices at a cost of up to \$1 million per submission. FDA certified, pursuant to the RFA, that the rule would not have a significant economic impact on a substantial number of small entities because the industry has long been aware that PMAs or PDPs would be required and therefore have had an opportunity to develop information in support of a PMA or PDP. In addition, the agency says that it has worked with manufacturers to assist them in preparing for the submission of PMAs and PDPs.

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<sup>1</sup> Pub. L. No. 94-305 (codified as amended at 15 U.S.C. §§ 634a-g, 637).

<sup>2</sup> Regulatory Flexibility Act, 5 U.S.C. § 601, as amended by the Small Business Regulatory Enforcement Fairness Act, Pub. L. No. 104-121, 110 Stat. 866 (1996). The RFA requires federal agencies to assess and analyze the impact of their regulations on small entities and asks agencies to consider less burdensome alternatives that do not interfere with the agencies' policy or regulatory objectives.

Section 605(b) of the RFA requires agencies to state a factual basis for their certifications. The certification provided by FDA provides no information about the number of small entities affected, nor does it fully explain why there will not be a significant economic impact associated with paying \$1 million per submission. While some might assume that the regulation was an inevitability and prepare accordingly, over the course of six years (the time between the proposed and final rules), some might also expect that the regulation could be withdrawn or altered significantly. The latter assumption could be supported by the most recent research which indicates that “there is no definitive evidence linking breast implants to cancer, immunological diseases, neurological problems, or other systemic diseases.”<sup>3</sup> In other words, the assumption that the industry is prepared and therefore will not face significant costs is not a forgone conclusion—and therefore may not suffice as a factual basis for RFA purposes.

A more complete analysis could reveal that FDA’s certification may in fact be accurate. However, the agency has not provided a factual basis for its conclusions regarding the impact of the regulation. The Office of Advocacy recommends that FDA republish the final regulation with a factually based certification. An improper certification is judicially reviewable under section 611(a)(1) of the RFA. An adversely affected or aggrieved small business might view an improper certification as an opportunity to sue the FDA.

Thank you for your attention to this important matter. Please do not hesitate to contact our office if you have any questions, 202-205-6533.

Sincerely,

Jere W. Glover  
Chief Counsel for Advocacy

Shawne Carter McGibbon  
Asst. Chief Counsel for Advocacy

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<sup>3</sup> 64 Fed. Reg. at 45,156, *citing* a report of the Institute of Medicine released on June 2, 1999.