

December 11, 2009

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Regulation of Tobacco Products, FDA-2009-N-0294

To Whom It May Concern:

On July 1, 2009, the Food and Drug Administration (FDA) published a notice¹ in the *Federal Register* requesting comments regarding the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).² The Office of Advocacy (Advocacy) applauds the FDA for seeking public input on the implementation of the Tobacco Control Act and submits this comment letter in response to the notice.

The FDA's responsibilities under the Tobacco Control Act include setting performance standards, reviewing premarket applications for new and modified risk tobacco products, and establishing and enforcing advertising and promotion restrictions.³ Pursuant to Section 901(e) of the Tobacco Control Act, on August 19, 2009, the FDA launched the new Center for Tobacco Products (Center) to oversee the implementation of the Tobacco Control Act. Section 901(f) provides that the FDA must establish an Office to assist Small Tobacco Manufacturers. As of the date of this comment letter, the FDA and the Center have set-up a webpage and email address for small businesses to consult.⁴

Advocacy appreciates the efforts of the FDA and the Center to assist small businesses and urges the agency to continue to consider the impact on small businesses when issuing rules implementing the Tobacco Control Act.

¹ 74 Fed. Reg. 31457 (Jul. 1 2009).

² Pub. L. No. 111-31, 123 Stat. 1776 (2009)

³ *Id.*

⁴ <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ForIndustry/ucm189635.htm>.

Office of Advocacy

Advocacy was established by Congress under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within SBA, so the views expressed by Advocacy do not necessarily reflect the views of SBA or the Administration. Section 612 of the Regulatory Flexibility Act (RFA) also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.⁵

RFA Considerations

Section 901(d) of the Tobacco Control Act provides that the Center's rulemakings will be subject to the Administrative Procedure Act and the RFA. As a threshold matter, under the RFA, the FDA and the Center will have to determine whether a proposed rule implementing the Tobacco Control Act will have a significant economic impact on a substantial number of small entities. Section 900(16) of the Tobacco Control Act defines "small tobacco manufacturer" as a business that "employs fewer than 350 employees".

Should the FDA and the Center determine that a proposed rule will not have such an impact, the agency may certify to that under section 605(b) of the RFA. Section 605(b) requires that the agency provide a factual basis in support of the certification. At a minimum the factual basis should include: (1) identification of the regulated small entities; (2) the estimated number of regulated small entities; (3) a description of the economic impact of the rule on small entities; and (4) an explanation of why either the number of small entities is not substantial and/or the economic impact is not significant under the RFA.⁶

Alternatively, if the FDA and the Center cannot properly certify a proposed rule, then an initial regulatory flexibility analysis (IRFA) must be developed and published in the *Federal Register* with a period for notice and comment. An IRFA must contain: (1) a description of the reasons why the regulatory action is being taken; (2) the objectives and legal basis for the proposed regulation; (3) a description and estimated number of regulated small entities; (4) a description and estimate of compliance requirements, including any differential for different categories of small entities; (5) identification of duplication, overlap, and conflict with other rules and regulations; and (6) a description of significant alternatives to the rule.⁷

For purposes of complying with the RFA, Advocacy stands ready to assist the FDA and the Center gather information regarding how any proposed rule that the agency is contemplating will impact small businesses. Advocacy regularly disseminates information to, and solicits comments from, small businesses regarding proposed Federal rules affecting them. Advocacy takes its direction from small businesses. In order to

⁵ Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat. 857 (1996). 5 U.S.C. § 612(a).

⁶ 5 USC § 605(b)

⁷ 5 USC § 603.

understand the effect a particular proposal will have on small businesses within an industry Advocacy holds stakeholder roundtables as one means of gathering information, and can provide the agencies with sources of information on the small business impacts of rules in general, and these requirements in particular.

In addition, Advocacy is required by Executive Order 13272 to provide training to the federal agencies on how to comply with the RFA.⁸ We would be happy to schedule such a training for the FDA and the Center at your earliest convenience.

We look forward to working with the FDA and the Center to help reduce the burdens facing small businesses that produce and market tobacco products. If you have any questions or require additional information please contact Assistant Chief Counsel for Dillon Taylor at (202) 401-9787 or by email at Dillon.Taylor@sba.gov.

Sincerely,

/s/

Susan M. Walthall
Acting Chief Counsel for Advocacy
Chief Counsel for Advocacy

⁸ Proper Consideration of Small Entities in Agency Rulemaking, 67 Fed. Reg. 53461 (Aug. 16, 2002).