

Advocacy Comments on FDA Proposed Deeming Rule

On June 11, 2014, the Office of Advocacy (Advocacy) submitted a comment letter to the Food and Drug Administration (FDA) in response to the agency's proposed rule, Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act. The FDA proposed rule would deem formerly unregulated or uncovered products subject to FDA regulation, including premium cigars, e-cigarettes, and hookah tobacco, and would subject these products to regulatory requirements currently only applicable to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. These requirements include general controls, health warnings, sales and marketing restrictions, and premarket authorization.

- Small business owners that manufacture or market previously uncovered products have been in contact with Advocacy to provide feedback about the proposed rule. Advocacy has heard from small businesses that market and sell tobacco products as well as previously uncovered products, small businesses in the “little cigar” industry, small businesses in the “premium cigar” industry, small businesses in the e-cigarette industry, and small businesses in the hookah industry.
- Based on input from small business stakeholders, Advocacy is concerned that the Initial Regulatory Flexibility Analysis (IRFA) contained in the proposed rule lacks essential information required under the Regulatory Flexibility Act (RFA).
- The IRFA does not discuss the quantitative or qualitative costs of the proposed rule on many potentially affected small entities. Additionally, the IRFA does not adequately consider or explain significant alternatives which accomplish the stated FDA objectives while minimizing the significant economic impact of the proposal on small entities.
- Advocacy recommends that the FDA publish for public comment a Supplemental IRFA before proceeding with this rulemaking. Advocacy encourages the FDA to revise the IRFA to provide a more accurate description of the costs of the proposed rule by including a quantitative analysis of all product categories that are manufactured or marketed by small businesses. Advocacy also recommends that the FDA take into consideration small business stakeholders' suggested alternatives to minimize the proposed rule's potential impact.

For more information, as well as a complete copy of Advocacy's letter to the FDA, please visit Advocacy's website at <http://www.sba.gov/advocacy/816> or contact Assistant Chief Counsel Dillon Taylor by email at dillon.taylor@sba.gov or by telephone at 202-401-9787.