July 25, 2018

VIA ELECTRONIC SUBMISSION

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Regulation of Premium Cigars, Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 12901 (March 26, 2018) (Doc. No. FDA-2017-N-6107).

Dear Commissioner Gottlieb:

On March 26, 2018, the Food and Drug Administration (FDA) published an advance notice of proposed rulemaking entitled: *Regulation of Premium Cigars*.[1] The U.S. Small Business Administration's Office of Advocacy (Advocacy) appreciates the FDA's solicitation for more information related to the regulation of premium cigars and welcomes the opportunity to provide input on behalf of small business stakeholders. Advocacy recommends the agency consider and explain all significant alternatives in order to minimize the significant economic impact of any proposal on small entities.

The Office of Advocacy

Congress established Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),[2] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[3] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant

[1] *See* Food and Drug Admin.; *Regulation of Premium Cigars*, Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 12901 (March 26, 2018).
[2] *See* 5 U.S.C. § 601 et seq.
[3] *See* Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.).

economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

Background

On June 22, 2009 the Tobacco Control Act was enacted and provided the FDA with authority to regulate the manufacture, distribution, and marketing of tobacco products to "protect the public health."[4] The Tobacco Control Act further provides that other tobacco-related products can be subject to regulation if the FDA deems them to be regulated products under a rulemaking process referred to as the "deeming regulation."

On April 24, 2014 the FDA issued a proposed deeming regulation that would deem formerly unregulated or uncovered products subject to FDA regulation, including premium cigars.[5] On, June 11, 2014, Advocacy submitted comments on the proposed rule, citing concerns that the proposed rule's Initial Regulatory Flexibility Act Analysis (IRFA) did not adequately consider or explain significant alternatives which could accomplish the stated FDA objectives while minimizing the significant economic impact of the proposal on small entities.[6] A copy of the letter is attached. The deeming rule became final on May 10, 2016.[7] While one of the proposed rule's options contained an exemption for premium cigars, the final rule ultimately included premium cigars within the scope of the final rule.[8] On July 28, 2017, the FDA announced a new comprehensive plan for regulating tobacco and nicotine.[9] Pursuant to these efforts, on March 26, 2018, the FDA published an advance notice of proposed rulemaking seeking additional information related to the regulation of premium cigars.

Small Businesses are Concerned about the Impacts of Premium Cigar Regulation

In its June 11, 2014 letter, Advocacy voiced concerns the proposed deeming rule's IRFA was deficient, and therefore the public had not been adequately informed about the possible impact of the proposal on small entities and whether there were less burdensome significant alternatives to the proposed rule that would meet the FDA's objectives. Many of the small business concerns cited in Advocacy's previous letter still remain – including concerns related to the cost of premarket submissions and the potentially extensive costs of complying with any regulatory proposal.

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[4] *See* Tobacco Control Act of 2009 (Pub. L. 111-31) amending FD&C Act, § 901, 21 U.S.C. 387a.
[5] *See* 79 Fed. Reg. 23142 (April 25, 2014).
[6] *See* SBA Office of Advocacy, *Letter re: 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, Docket No. FDA-2014-N-0189* (June 11, 2014), https://www.sba.gov/advocacy/61114-deeming-tobacco-products-be-subject-federal-food-drug-and-cosmetic-act-amended-family.
[7] *See* 81 Fed. Reg. 28974 (May 10, 2016).
[8] *See id.* at 29020.
[9] *See* Food and Drug Admin., *News Release: FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death* (July 28, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm.

Advocacy's Recommendations

Advocacy expects that any regulation of the premium cigar industry under the deeming rule would include a more robust economic analysis of the rule's impact on small businesses, and a description of significant alternatives that would minimize that impact. As we pointed out in our 2014 letter, the Regulatory Flexibility Act itself provides guidance on alternatives that the FDA should consider as a minimum: (1) the establishment of different compliance or reporting requirements for small entities or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements for small entities; (3) use of performance rather than design standards; and (4) exemption for certain or all small entities from coverage of the rule, in whole or in part.[10]

Advocacy is encouraged that FDA has taken this step to acquire information that it would need to evaluate these alternatives and the significant alternatives that have been put forward by small businesses in the industry. Advocacy expects that in any proposed rulemaking FDA will include a full analysis of all significant alternatives and a fully explained rationale for its preferred alternative.

Conclusion

In response to the agency's notice, Advocacy submits the above comments and resubmits its previous comments to assist the agency as it prepares its proposed rulemaking and any related RFA analysis. Advocacy recommends that the agency consider and explain all significant alternatives in order to minimize the significant economic impact of any proposal on small entities. If you have any questions or require additional information please contact me or the Director of the Office of Interagency Affairs, Charles Maresca, at (202) 205-6978 or by email at charles.maresca@sba.gov.

Sincerely,

Major L. Clark, III
Acting Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Charles A. Maresca
Director of the Office of Interagency Affairs
Office of Advocacy
U.S. Small Business Administration

[10] *See* 5 U.S.C. § 603(c).

June 11, 2014

VIA ELECTRONIC SUBMISSION

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Room 2217
Silver Spring, MD 20993
http://www.regulations.gov

Re: 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, Docket No. FDA-2014-N-0189

Dear Commissioner Hamburg:

The Office of Advocacy (Advocacy) offers the following comment to the Food and Drug Administration (FDA) in response to the above-referenced proposed rule issued on April 24, 2014.[1] The FDA issued the proposed rule to implement provisions of the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act)[2]. Since the passage of the Tobacco Control Act, small businesses that manufacture or market tobacco products have been in contact with Advocacy in anticipation of this rulemaking. After the FDA promulgated this proposal, small business owners continued to contact and meet with Advocacy to convey feedback about the proposed rule. 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)[3]. Specifically, the IRFA does not discuss the quantitative or qualitative costs of the proposed rule on many potentially affected small entities. Moreover, given the extent of the anticipated costs of this proposal, 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. For this reason, Advocacy recommends that the FDA republish for public comment a Supplemental IRFA before proceeding with this rulemaking.

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[1] 79 Fed. Reg. 23,142 (April 25, 2014). Proposed rule available at: https://www.federalregister.gov/articles/2014/04/25/2014-09491/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the.

[2] 21 U.S. Code § 387a.

[3] 5 U.S.C. § 601 et seq.

Office of Advocacy

Advocacy was established pursuant to 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 the SBA or the Administration. The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[4] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small business and to consider less burdensome alternatives.

The RFA requires agencies to give every appropriate consideration to comments provided by Advocacy. The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.[5]

Background

The Tobacco Control Act authorizes the FDA to regulate the manufacture, distribution, and marketing of tobacco products to "protect public health." The Tobacco Control Act provides that other tobacco-related products can be subject to FDA regulation if the agency deems them to be regulated products under a rulemaking process referred to as the "deeming regulation."

On April 24, 2014, the FDA Center for Tobacco Products issued a proposed rule that would deem formerly unregulated or uncovered products subject to FDA regulation, including premium cigars, e-cigarettes, and hookah tobacco. In the release, the FDA proposes and requests comment on an option where it would not deem (i.e., the agency would exempt) premium cigars. The FDA is considering this option because "it has been suggested that different kinds of cigars may have the potential for varying effects on public health, based on possible differences in their effects on dual use, youth initiation and frequency of use by youth and young adults."[6]

The deeming regulations would subject newly covered 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, and sales and marketing restrictions. Additionally, under the proposal, a previously uncovered product would be subject to FDA premarket authorization before it may be marketed in the United States if the product is "new." A tobacco product is considered "new" if it was not being marketed as of February 15, 2007 (the "Grandfather Date") or if any modification has been made to the product that was on the market before the Grandfather Date. If the FDA treats a product as "new," the product manufacturer must submit to the FDA either a Premarket Tobacco Application, a Substantial Equivalence (SE) Report, or request a Minor Modification Exemption. For purposes of an SE report, a business must cite a predicate product that was commercially marketed as of the

[4] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.).
[5] 5 U.S.C. § 601 et seq.
[6] See proposed rule at page 8.

Grandfather Date, and contain detailed information about the cited predicate product, including complete specifications, ingredient and component information, manufacturing information, and product testing data.

In the proposal, the FDA observes that "approximately 90 percent of domestic entities affected by this rule are estimated to be small." The FDA estimates that upfront costs for small businesses will measure approximately $390,000 - $759,000 and that annual compliance costs for small businesses will measure approximately $450,000 - $541,000.[7] The FDA notes that the annual costs of the proposed rule are expected to be greater than 10 percent of sales for small manufacturers / producers. However, the FDA's Preliminary Regulatory Impact Analysis (PRIA) and IRFA[8] suggest that there is uncertainty around these cost estimates. In several portions of its analysis, the FDA concedes that it has not accurately quantified all of the costs and burdens associated with extending its authority to regulate previously uncovered products.[9]

Since the passage of the Tobacco Control Act, small businesses that manufacture or market previously uncovered products have been in contact with Advocacy in anticipation of this rulemaking. After the FDA issued the proposal, small business owners have continued to contact Advocacy to convey concerns related specifically to 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.

The Proposed Rule's IRFA is Deficient

Because it does not adequately describe the impacts on all types of newly covered small entities and because it does not adequately explain significant alternatives that might reduce those impacts, Advocacy believes that the IRFA contained in the proposed rule is deficient, and for this reason, the FDA should republish a Supplemental IRFA for additional public comment before proceeding with this rulemaking. Under the RFA, 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.[10] Advocacy is concerned that because the proposed rule's IRFA is deficient, the public has not been adequately informed about the possible impact of the proposal on small entities and whether there are less burdensome significant alternatives to the proposed rule that would meet the FDA's objectives.

Given the scope of the proposal and the number of small entities that would be impacted by it, the IRFA should include more data and analysis to provide the public with sufficient information on the economic impact of the proposed rule. However, the IRFA contained in the proposed rule

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[7] See proposed rule at page 191.
[8] PRIA and IRFA available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM394933.pdf.
[9] See, e.g., PRIA at pages 7, 12, 25, and 41.
[10] 5 USC § 603.

does not adequately describe and estimate the costs the proposal would impose on small entities by both omitting a substantive discussion of costs that accrue to products with many small entities and understating compliance costs. As described above, the FDA does not quantify many of the costs and burdens associated with the proposed rule in the IRFA even for product categories where the agency estimates there are a sizeable number of small manufacturers. Instead, the FDA presents data and analysis only for cigar manufacturers and uses a limited dataset that does not measure burgeoning marketplaces such as online sales.

Many small businesses have expressed concern to Advocacy regarding costs related to premarket submissions that the proposed rule would require. These small businesses have explained to Advocacy that the cost estimates in the IRFA may be understated because the FDA does not account for differences in the way that small business will comply with the proposed rule. As an example, the FDA does not recognize that the proposal may be disproportionately burdensome to small entities that do not have the legal resources of larger businesses.

Additionally, many small businesses have told Advocacy that they will have trouble utilizing the less burdensome SE premarket submission process. Because businesses in industries for newly covered products would not be able to obtain marketing orders as many of these industries, such as e-cigarettes, were not in existence as of the Grandfather Date, or they rely on proprietary technologies. Small businesses have even confided to Advocacy that the costs associated with the proposal's premarket submission requirements could force many of them to exit the market and cease operating.

Taking into account the potentially extensive costs of the proposal, the IRFA does not fully consider significant alternatives which accomplish the stated FDA objectives and which minimize the significant economic impact of the proposal on small entities. All of the alternatives currently considered in the IRFA would only make marginal changes to the overall compliance costs to small entities, such as exempting products from labeling changes. Therefore, Advocacy encourages the FDA to further consider alternatives that may be able to more greatly decrease the regulatory burden on small business while still allowing the FDA to meet its regulatory goals.

The RFA provides guidance on this issue and it instructs agencies that when faced with economic impacts as significant as those estimated by the FDA, agencies should consider alternatives such as: (1) the establishment of different compliance or reporting requirements for small entities or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements for small entities; (3) use of performance rather than design standards; and (4) exemption for certain or all small entities from coverage of the rule, in whole or in part.[11] Advocacy believes that all of these categories of alternatives would be relevant and useful to consider as a part of this rulemaking.

Notably, the proposed rule considers some of these alternatives for one specific product category: premium cigars. In the proposal, the FDA provides detailed data showing why the agency is considering this alternative and the cost savings that exempting premium cigars would yield. While Advocacy appreciates this example of an alternative that could meet regulatory goals while significantly reducing regulatory burdens, the FDA however does not provide an analysis related

[11] See 5 U.S.C. § 603(c).

to this alternative in the IRFA for premium cigars or any other product. Advocacy is unsure of why the FDA would not consider this significant alternative in the proposal's IRFA. Further, Advocacy is concerned that the FDA did not discuss and consider other alternatives in the IRFA that would yield similar significant cost savings as exempting premium cigars would, and that the agency did not perform a similar level of analysis on the alternatives listed in the IRFA as the agency did do elsewhere in the rule related to premium cigars. Advocacy recommends that FDA extend the analysis done on premium cigars to more product types so that the FDA can ensure that it is proposing the most effective and efficient regulation possible.

Recommendations

Advocacy recommends that the FDA 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. Specifically, although the FDA notes in the proposed rule that it expects the proposal to directly impact small businesses that market or manufacture cigars, pipe tobacco, hookah, and e-cigarettes, the FDA does not provide a detailed analysis of the potential impact on many of the small entities for newly covered products. As described above, the FDA provides a detailed analysis for only one alternative – not deeming premium cigars – that would yield significant cost savings for certain small businesses. Advocacy encourages the FDA to apply this analysis elsewhere in the IRFA so that not deeming other product categories can be considered and comprehensively discussed. The FDA should develop an alternative to consider regarding not deeming other "premium" products that are similarly marketed, designed, and used as premium cigars. The FDA should also provide additional data and analysis to illustrate why the benefits of deeming some of these products outweigh the substantial costs.

Advocacy also believes that even if an alternative is discussed elsewhere in the proposed rule, for purposes of the RFA analysis, it should be discussed in the IRFA portion of the proposal to allow for more substantive public comment and improved transparency around the FDA's analysis. Moreover, to improve the quality of comments received by the public and to ensure a comprehensive review under the RFA where FDA chooses to reject an alternative, the FDA should provide a policy or economic justification as to why it did not adopt each particular alternative considered.

Advocacy also recommends that the FDA should take into consideration small business stakeholders' suggested alternatives to minimize the proposed rule's potential impact. Small business representatives in contact with Advocacy observe that the FDA could still achieve its stated purposes for the premarket submission process in the deeming proposal through the use and enforcement of statutes and regulations already in effect. As an example, small business representatives note that under 21 U.S.C. § 387d(a)(1) and § 387d (c), manufacturers and importers of regulated tobacco products are required to submit (and update) specific information about the ingredients in each marketed product. Similarly, 21 U.S.C. § 387e mandates the registration of all domestic tobacco product manufacturing establishments and product listings for all regulated tobacco products manufactured at such establishments. Advocacy encourages the FDA to review and discuss statutes and regulations currently in effect as suggested by small

business stakeholders that may already achieve the purposes of the premarket submission process in the deeming proposal.

Finally, Advocacy would like the FDA to provide at least a 90-day comment period for the proposed rule given the large economic impact that it is estimated it will have on small business. Small business will need sufficient time to analyze the potential impact of this proposed rule.

Conclusion

Advocacy is concerned that the FDA's proposed rule and IRFA lack essential information needed to properly inform the agency's decision making. Specifically, the IRFA does not adequately describe the costs of the proposed rule on small entities, and the IRFA does not set forth, consider, and discuss significant alternatives which accomplish the stated FDA objectives and which minimize the significant economic impact of the proposal on small entities. For this reason, Advocacy recommends that the FDA republish for public comment a Supplemental IRFA before proceeding with this rulemaking.

By republishing a Supplemental IRFA, small businesses will have more adequate data to assess the potential impact of the proposed rule. The FDA will further gain valuable insight into the effects of the proposed rule on small business and be more transparent in explaining and justifying the choices that it made in the proposal. Advocacy also believes that the FDA should take into consideration small business representatives' suggested alternatives that may minimize the proposed rule's potential impact.

Advocacy is committed to helping the FDA comply with the RFA in the development of the proposed rule. Therefore, Advocacy stands ready to assist the FDA in the completion of a Supplemental IRFA. Advocacy looks forward to working with the FDA. If you have any questions or require additional information please contact me or Assistant Chief Counsel Dillon Taylor at (202) 401-9787 or by email at Dillon.Taylor@sba.gov.

Sincerely,

Winslow Sargeant

Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy

Dillon Taylor
Assistant Chief Counsel Advocacy

Copy to: The Honorable Howard Shelanski, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget