U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
REGULATION • RESEARCH • OUTREACH

September 27, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Re: Requirements for Tobacco Product Manufacturing Practice (Docket No. FDA-2013-N-0227; 88 Fed. Reg. 15,174).

Dear Commissioner Califf:

On March 10, 2023, the Food and Drug Administration (FDA) published a proposed rule titled "Requirements for Tobacco Product Manufacturing Practice."[1] The proposed rule would establish a compliance framework related to the manufacture, preproduction design validation, packing, and storage of all types of finished and bulk tobacco products.[2] This letter constitutes the Office of Advocacy's (Advocacy) public comments on the proposed rule.

Advocacy is concerned that FDA's proposed rule will impose significant costs on small businesses without sufficient evidence that the requirements will minimize risks associated with their final products. Although the "umbrella" framework is designed to allow flexibility in the establishment of procedures, major elements of the proposed requirements may not be appropriate for the broad spectrum of covered products, including those that are produced following traditional farming and manufacturing practices.

Moreover, Advocacy is concerned that the initial regulatory flexibility analysis (IRFA)[3] contained in the proposed rule lacks essential information required under the Regulatory

[1] Requirements for Tobacco Product Manufacturing Practice, 88 Fed. Reg. 15,174 (Mar. 10, 2023) (to be codified at 21 C.F.R. pt. 1120).
[2] *Id*. at 15,174. The proposed rule defines "finished tobacco products" as tobacco products, including any component or part, sealed in final packaging. "Bulk tobacco products" are defined as tobacco products not sealed in final packaging but otherwise suitable for consumer use as a tobacco product. *See id.* at 15,188.
[3] Food & Drug Admin., *Requirements for Tobacco Product Manufacturing Practice, Docket No. FDA-2013-N-0227, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis*, 151-60 (Mar. 10, 2023), https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/requirements-tobacco-product-manufacturing-practice-proposed-rule-preliminary-regulatory-impact [hereinafter IRFA].

Flexibility Act (RFA).[4] Specifically, the IRFA does not adequately discuss the costs of the proposed rule on many potentially affected small entities. Furthermore, given the extent of the anticipated costs of this proposal, the IRFA does not adequately consider or explain significant alternatives which could accomplish FDA's stated objectives while minimizing the significant economic impact of the proposal on small entities. For these reasons, Advocacy recommends that FDA prepare and make available for public comment a supplemental IRFA.

I. Background

A. The Office of Advocacy

Congress established the Office of 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 SBA or the Administration. The RFA,[5] as amended by the Small Business Regulatory Enforcement Fairness Act,[6] 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, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[7] The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, unless the agency certifies that the public interest is not served by doing so.[8]

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."[9]

B. The Proposed Rule

The Family Smoking Prevention and Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide FDA with the authority to regulate and to identify through regulation the tobacco products that it deems to be subject to the agency's regulation.[10] Chapter IX of the FD&C Act provides FDA with tools and funds to regulate tobacco products and imposes obligations on tobacco product manufacturers, importers, distributors, and retailers.[11]

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[4] 5 U.S.C. § 601 et seq.
[5] *Id.*
[6] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).
[7] Small Business Jobs Act of 2010, Pub. L. 111-240, §1601.
[8] *Id.*
[9] *Id.*
[10] Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 (June 22, 2009).
[11] 21 U.S.C. §§387-387u. Following passage of the Family Smoking Prevention and Tobacco Control Act, FDA published a rule "deeming" a series of products to be subject to FDA regulation, including electronic nicotine delivery systems, e-liquids, and premium cigars. *See* 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

On March 10, 2023, FDA published a notice of proposed rulemaking in the *Federal Register* that would establish tobacco product manufacturing practice (TPMP) requirements for manufacturers of finished and bulk tobacco products.[12] The proposed rule intends to ensure that tobacco products comply with Chapter IX of the FD&C Act, and thereby minimize additional risks associated with their use.[13] If finalized, the rule would provide an "umbrella" procedural framework for product manufacturers of all types of finished and bulk tobacco products.[14] Major components of the proposed framework include:

1) Establishing product design and development controls.
2) Ensuring that manufacture conforms with established specifications.
3) Minimizing the likelihood of the manufacture and distribution of nonconforming products.
4) Requiring investigation and identification of nonconforming products, including those that have been distributed, to enable manufacturers to institute appropriate corrective actions.
5) Requiring manufacturers to take appropriate measures to prevent contamination of tobacco products.
6) Establishing traceability to account for all components or parts, ingredients, additives, and materials, as well as each batch of finished or bulk tobacco product.[15]

Generally, the final rule would have an effective date two years after its publication in the *Federal Register*.[16] FDA proposes to delay the compliance date for small tobacco product manufacturers until four years after the effective date of the final rule.[17]

The proposed rule includes a link to a related initial small entity analysis that, combined with other sections of the economic analysis, serves as its initial regulatory flexibility analysis under the RFA.[18] The IRFA identifies 130 small tobacco manufacturing firms and 1,240 small tobacco wholesalers that will be impacted by the regulation.[19] The IRFA does not attempt to identify or estimate economic impacts to small tobacco farmers, product designers, retailers, or other indirectly impacted entities.

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the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,973 (May 10, 2016).

[12] Requirements for Tobacco Product Manufacturing Practice, 88 Fed. Reg. 15,174 (March 10, 2023) (to be codified at 21 C.F.R. pt. 1120). For purposes of the proposed rule, a tobacco product manufacturer is defined as "any person(s), including any repacker or relabeler, who: manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States. Tobacco product manufacturer includes any person(s) who establishes the specifications for a tobacco product." *Id*. at 15,190.

[13] *See id*. at 15,175.

[14] *Id*. at 15,175, 15,183.

[15] *Id*. at 15,175.

[16] *Id*. at 15,239.

[17] *Id*.

[18] *See* IRFA, *supra* note 3.

[19] *Id*. at 153. FDA uses the category for Tobacco and Tobacco Product Merchant Wholesalers as a proxy for domestically-located tobacco importers in the IRFA. *Id*. at 152 n.69.

II. The IRFA Included in the Proposed Rule is Deficient

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.
6) A description of significant alternatives to the rule.[20]

Advocacy believes that the IRFA included in the proposed rule is deficient for two reasons. Advocacy is concerned that the IRFA does not adequately describe the regulated small entities and underestimates potential impacts to those entities. Advocacy further believes the IRFA does not adequately discuss specific alternatives that might reduce that economic impact to small entities.

A. FDA Underestimates the Economic Impact of the Proposed Rule to Small Entities

The IRFA found in the proposed rule does not adequately estimate the economic impact to small entities. As noted by FDA, the "Statistics of U.S. Businesses data from 2017 indicate that 96 percent of 'tobacco manufacturing' businesses with employees are small…[and]…96 percent of 'tobacco and tobacco product merchant wholesalers' qualify as small."[21] Given the scope of the proposal and the number of small entities that would be directly and indirectly impacted, the IRFA should include more data and analysis to provide the public with sufficient information on the economic impact of the proposed rule. To that end, Advocacy has identified several deficiencies in the small entity analysis.

First, many small entities are likely to face significant upfront, one-time compliance costs associated with the regulation. Reducing these burdens should receive greater emphasis in the IRFA and they should be assessed for significance and alternative approaches. FDA's IRFA emphasizes assessment of annualized cost estimates over a 10-year period and underappreciates upfront, one-time compliance costs which inform a full understanding the rule's impact on small entities.[22]

Second, the IRFA does not adequately analyze the relative impact of costs to small entities. FDA's discussion of the burden on small entities is limited to calculating estimated costs to the average small business.[23] As acknowledged by FDA, "average small-entity impacts are likely to hide a significant amount of heterogeneity in small-entity impacts across manufacturers of

[20] 5 U.S.C. § 603.
[21] IRFA *supra* note 3, at 152.
[22] *Id.* at 156.
[23] *Id*. at 157-58.

different sizes."[24] For purposes of RFA analysis, small tobacco manufacturers may have up to 1,500 employees. Focusing on the smallest small businesses reveals a much higher relative cost burden for those firms. For example, the 46 (29%) smallest firms with fewer than five employees would face a burden of between 1.9% and 4.5% of annual revenue in the year they face both one-time and recurring costs.[25] The 23 (14%) firms with between five and nine employees would also see high burdens of between 0.7% and 1.6% of annual revenue.[26]

In preparing these comments, Advocacy spoke with trade representatives and small manufacturers and retailers from the premium cigar and the electronic nicotine delivery systems (ENDS) industries.[27] Small manufacturers told Advocacy that the compliance costs associated with the proposed rule's recordkeeping requirements will be particularly onerous. These firms report that they will need to hire new staff to manage and maintain sufficient records over the four-year retention period,[28] a relatively high-cost measure for the smallest firms. Small manufacturers have also expressed concern regarding the additional cost burden associated with gathering and retaining the required records from qualifying product designers, suppliers, and other third parties, particularly when those parties are located in foreign countries where English is not the primary language.[29] In addition, small firms have expressed apprehension that FDA will consider tobacco products adulterated based solely on paperwork errors, resulting in unnecessary product recalls. These firms note that the proposed rule does not discuss opportunities to remedy paperwork and other recordkeeping errors to avoid corrective measures.

Third, the IRFA omits a meaningful discussion of costs borne by industry segments where the regulation would require novel or comparatively complex compliance measures. Small premium cigar firms have expressed particular concern with the proposed rule because tobacco cultivation and manufacturing for their products are artisanal processes. Unlike mass-market tobacco products, premium cigars are primarily produced in small, traditional tobacco farms and factories, often in developing countries. As such, compliance with the regulations would require substantial investment in new equipment, training, and personnel. Small entities in the industry have told Advocacy that infrastructure does not exist to support the TPMP requirements, and that compliance with certain requirements may be infeasible. Despite the unique manufacturing processes associated with premium cigars, FDA has not analyzed specific industry impacts or discussed the industry's capacity to comply with the proposed regulations.[30]

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[24] *Id*. at 157.

[25] This burden estimate was calculated by adding the undiscounted one-time and recurring estimated costs found on p. 157 of the IRFA and comparing the sum to the average receipts by firm size as reported on p. 158. *See id.* at 157-58.

[26] *Id*.

[27] The proposed rule applies to manufacturers of all finished and bulk tobacco products that are subject to Chapter IX of the FD&C Act, including deemed products. Advocacy notes that on August 9, 2023, the U.S. District Court of the District of Columbia issued a final Memorandum Opinion vacating FDA's decision to deem premium cigars. *See Cigar Ass'n of Am. v. U.S. Food & Drug Admin*., Case No. 1:16-cv-01460-APM (D.D.C. Aug. 9, 2023).

[28] The proposed rule would require that documents and records be maintained and be made readily accessible to FDA for inspection and reproduction during a 4-year retention period. *See* 88 Fed. Reg. 15,174 at 15,234.

[29] The proposed rule would require that all documents and records be written or accurately translated into English. *See id*.

[30] For example, the process of drying whole-leaf tobacco generally occurs in an open-air environment. This factor would make it difficult to ensure environmental controls, or that facility grounds are "maintained in a condition to

Small ENDS manufacturers have told Advocacy that despite the broad reach of the proposed rule, FDA has not addressed many issues related to their products' complex development and manufacturing processes. Specifically, ENDS manufacturers are apprehensive that FDA's involvement in product design and development could have implications for intellectual property rights. Further, ENDS manufacturers are concerned that, without features like a preapproved list of ingredients, FDA's approval process will lack the agility necessary in a competitive market.

Finally, Advocacy is concerned that FDA has not considered the impacts of the proposal to indirectly regulated small entities. Although it is not required by the RFA, Advocacy believes that it is good public policy for agencies to examine the reasonably foreseeable effects of regulations on small entities that purchase products or services from, sell products or services to, or otherwise conduct business with directly regulated entities.[31] FDA is indirectly affecting tobacco farmers, product designers, and other third parties by mandating that manufacturers implement environmental, safety, and design controls, recordkeeping procedures, and other processes which affect these third parties' operations. Further, the proposed rule will likely also impact tobacco retailers. These small entities are numerous and may face higher costs due to the indirect effects of the regulation.

B. FDA Failed to Adequately Consider Significant Regulatory Alternatives

The RFA requires that an IRFA consider significant, feasible alternatives for small entities that accomplish an agency's objectives. In view of the potentially high costs associated with the rule, the IRFA does not adequately consider significant alternatives which minimize the significant economic impact of the proposal on small entities.

The proposed rule first focuses on a case-by-case application for exemption or variance from the regulation in its discussion of regulatory alternatives.[32] Here, because section 906(e)(2) of the FD&C Act allows any person subject to a final regulation to petition for exemption or variance, it is unclear how application for exemption or variance can be considered a regulatory alternative under the RFA. Additionally, although small entities may apply for exemption or variance, they will still be expected to comply with the regulation while waiting for a determination. In the interim, small entities would be required to make significant investments and incur

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prevent contamination and to control the water used in the manufacturing process." 88 Fed. Reg. at 15,175-76. FDA has not addressed how environmental, sanitation, tracking, and other controls would apply to tobacco grown and manufactured using traditional processes. In contrast, the proposed rule specifically considers how certain portions of the manufacturing framework would apply to hand-rolled cigars. For instance, all tobacco products would be required to undergo verification processes to ensure a standardized product. Examples of verification activities for hand-rolled cigars include conducting a laboratory analysis of a pH level to confirm it is within a specified range and performing a visual comparison of a finished cigar against a standard or approved model. *Id.* at 15,191. FDA has suggested that model samples for hand-rolled cigars should define the type and size of tobacco leaf to be used for the wrapper, the type and amount of filler tobacco to be used, the brand label to be applied, and the size/shape/length/diameter of the finished, rolled cigar. *Id.* at 15,220. Premium cigar manufacturers have told Advocacy that this level of standardization in a hand-rolled, boutique product is unnecessary.

[31] *See* U.S. Small Bus. Admin., Off. of Advocacy, *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act*, 23 (Aug. 2017), https://advocacy.sba.gov/resources/the-regulatory-flexibility-act/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/.

[32] IRFA, *supra* note 3, at 158.

administrative costs with no guarantee of a positive outcome. For these reasons, Advocacy believes that case-by-case application for exemption or variance should not be discussed as a regulatory alternative in the IRFA.

The proposed rule then discusses two regulatory alternatives that FDA believes would specifically alleviate the burden to small entities: (1) an extended compliance period for small entities and (2) an exemption of a small subset of manufacturers.[33] Although Advocacy appreciates these examples of alternatives that could reduce regulatory burdens, FDA does not provide an analysis of the cost savings associated with either option. A more detailed analysis of the cost savings associated with a regulatory alternative can provide the public and small entities with sufficient information about the viability of that alternative and the ways it may reduce the regulation's economic burden.

Advocacy is also concerned that the proposed rule did not specifically consider an exemption for premium cigars. In a Memorandum Opinion and Order issued on July 5, 2022, the U.S. District Court of the District of Columbia ruled that FDA's decision to deem premium cigars was arbitrary and capricious.[34] On August 9, 2023, the court issued a final Memorandum Opinion vacating FDA's decision to deem premium cigars.[35] Given the court's July 2022 decision and its impact on FDA's jurisdiction to regulate premium cigars, it is notable that the proposed rule did not reference or analyze the costs savings associated with exemption for the premium cigar industry. Advocacy believes that a thorough discussion of an exemption for the premium cigar industry would be warranted in any case, given the traditional manufacturing practices associated with the product and the financial and administrative burdens the regulations would place on an industry principally composed of small businesses.

C. Advocacy's Recommendations

Advocacy is concerned that, because of deficiencies in the IRFA, the public has not been adequately informed about the possible impact of the proposed rule on small entities. Small entities have also not been given sufficient information regarding less burdensome significant alternatives to the proposed rule that would meet FDA's objectives.

For these reasons, FDA must prepare and make available for public comment a supplemental IRFA. The supplemental IRFA should adequately describe the regulated small entities and estimate potential impacts to those entities. FDA should provide detailed information that will allow the agency to analyze the relative impact of costs based on entity size. FDA should also analyze costs borne by industry segments where the regulation would require novel or complex compliance measures. Further, the supplemental IRFA must include specific alternatives which accomplish FDA's objectives for the rulemaking, as required by the RFA. Advocacy encourages FDA to provide a detailed analysis of each potential alternative and to discuss how that alternative may reduce the economic burden on small entities.

[33] *Id*. at 159.
[34] *See* Cigar Ass'n of Am. v. U. S. Food & Drug Admin., 2022 WL 2438512 (D.D.C. July 5, 2022).
[35] *See* Cigar Ass'n of Am. v. U.S. Food & Drug Admin., Case No. 1:16-cv-01460-APM (D.D.C. Aug. 9, 2023).

III. Conclusion

Advocacy is concerned that the proposed rulemaking and IRFA lack essential information required by the RFA. FDA must provide an adequate description of the affected small entities and a detailed analysis of the impact of the proposed rule to those small entities before proceeding to a final rule. FDA must also provide detailed analysis of specific regulatory alternatives that might reduce the significant economic impact to small entities. This analysis should be published in a supplemental IRFA to provide small entities an opportunity to comment.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Meagan Singer at (202) 921-4843 or by email at meagan.singer@sba.gov.

Sincerely,

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

/s/
Meagan E. Singer
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: The Honorable Richard L. Revesz, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget