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

November 27, 2019

VIA ELECTRONIC SUBMISSION

Admiral Brett P. Giroir, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

RE: Premarket Tobacco Product Applications and Recordkeeping Requirements Proposed Rule, Docket No. FDA-2019-N-2854

Dear Admiral Giroir:

On September 25, 2019, the Food and Drug Administration (FDA) published a proposed rule titled *Premarket Tobacco Product Applications and Recordkeeping Requirements*.[1] This letter constitutes the Office of Advocacy's (Advocacy) public comments on the proposed rule. Advocacy is concerned that the agency's certification that the rule will not have a significant economic impact on a substantial number of small entities lacks an adequate factual basis. This certification improperly assumes that the compliance costs of the proposed rule's requirements for deemed products are due to the agency's 2016 rule, *Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements* (Deeming Rule).[2] The FDA did not detail all requirements for Premarket Tobacco Product Applications (PMTA), nor adequately assess PMTA costs for the Deeming Rule. Because the PMTA requirements are detailed in the proposed rule, Advocacy recommends that the agency prepare

[1] 84 Fed. Reg. 50,566 (Sept. 25, 2019).
[2] 81 Fed. Reg. 28,974 (May 10, 2016). The FDA promulgated the Deeming Rule with a notice of proposed rulemaking (79 Fed. Reg. 23,142 (April 25, 2014)). Advocacy submitted written comments on the notice of proposed rulemaking, raising concerns about the adequacy of the Initial Regulatory Flexibility Analysis and the failure to consider "significant regulatory alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities." (5 U.S.C. § 603(c)).

and make available for public comment an initial regulatory flexibility analysis (IRFA) that adequately assesses the costs associated with the PMTA requirements in the proposed rule incurred by small entities and that would include consideration of significant alternatives to the proposed rule that will accomplish the stated objectives of applicable statutes while minimizing the proposed rule's economic impact on small entities.

I. Background

The 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 the U.S. Small Business Administration (SBA), so the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),[3] 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, the RFA requires federal agencies to assess the impact of the proposed rule on small business and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to Advocacy's comments.[5] The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to Advocacy's submitted written comments on the proposed rule, unless the agency certifies that the public interest is not served by doing so.[6] 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."[7]

The Deeming Rule

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provides FDA with the authority to regulate tobacco products and provides FDA the authority to identify through regulation the tobacco products that it deems to be subject to FDA regulation. Once "deemed" to be subject to FDA regulation, the Tobacco Control Act generally requires a new tobacco product to undergo premarket review by FDA before it may be introduced or delivered for introduction into interstate commerce.

On May 10, 2016, FDA published the Deeming Rule, "deeming" a series of products to be subject to FDA regulation, including electronic nicotine delivery systems (ENDS), e-liquids, and premium cigars. These deemed products became, by action of the Tobacco Control Act, subject

[3] 5 U.S.C. § 601 et seq.
[4] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.).
[5] Small Business Jobs Act of 2010 (PL 111-240) § 1601.
[6] *Id.*
[7] 5 U.S.C. § 601 note 7.

to PMTA requirements. All manufacturers and importers of ENDS and e-liquids, as well as all retailers that mix e-liquids, who are considered manufacturers, are subject to these requirements. Additionally, the proposed rule will affect manufacturers of premium cigars that entered the market after February 15, 2007, the statutorily determined "grandfather date." The Deeming Rule itself, however, included no specific requirements on the procedure or information to be included in a PMTA, and details of the PMTA are only briefly explained in an appendix to the rule. Where specifics are described, such mentions are prefaced by inconclusive terms such as "may," "might," or "will likely be necessary." For example, the Deeming Rule Final Regulatory Impact Analysis (FRIA) states: "[t]he types of studies that applicants *may* need to supplement existing data *might* be specific to the perception and actual use of their product. These could be in the form of survey or observational studies. A range of small surveys or set of focus group studies to more expansive behavioral use studies *might* be conducted."[8]

The analysis accompanying the Deeming Rule listed four main categories of PMTA costs: (1) composition, design, and manufacturing; (2) toxicology studies; (3) human studies; and (4) administrative staff hours.[9] Based on these categories, the FDA estimated that PMTA costs would be between $28,566 and $2,595,224 per ENDS unit, with an average cost of $466,563, and between $12,112 and $398,324 per e-liquid used in such devices, with an average cost of $131,643.[10] These estimates, however, are significantly caveated: "[w]e cannot predict the costs or benefits of future rulemaking before the contents of the rules themselves have been established[,]"[11] anticipating future rulemaking to flesh out the PMTA requirements.

The PMTA Proposed Rule

On September 25, 2019, the FDA published the PMTA proposed rule, which details the requirements of what must be included in a PMTA, the recordkeeping requirements associated with a PMTA, as well as the FDA's guidelines for review of PMTAs. The proposed rule requires each PMTA to have the following requirements: (1) general information, (2) descriptive information, (3) product samples, (4) labeling, (5) statement of compliance with 21 C.F.R. part 25, (6) a summary, (7) product formulation, (8) manufacturing, (9) health risk investigations, and (10) a certification.[12] The details of these ten requirements are discussed over the next 37 pages of the proposed rule.[13] These PMTA requirements in the proposed rule are more exacting than the four main categories of cost described in the Deeming Rule mentioned above.

[8] Food and Drug Administration, Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements, Final Regulatory Impact Analysis, Docket No. FDA-2014-N-0189, page 151 (2016) [hereinafter Final Regulatory Impact Analysis] (emphasis added).
[9] *Id.* at 87.
[10] *Id.* at 91.
[11] *Id.* at 55.
[12] 84 Fed. Reg. at 50,577.
[13] *Id.* at 50,577-50,614.

The FDA states that the sector of the tobacco industry that will be most affected by the proposed rule are manufacturers, importers, and retailers of ENDS products.[14] The FDA also states that the proposed rule generates negligible costs for most affected small entities.[15] Further, the FDA has certified that the rule will not have a significant economic impact on a substantial number of small entities because the agency assumed the costs associated with a PMTA were accounted for in the Deeming Rule FRIA, which includes the agency's Final Regulatory Flexibility Analysis (FRFA).

II. The Proposed Rule Will Have a Significant Economic Impact on a Substantial Number of Small Entities and the FDA Must Consider Alternatives

Small businesses drive the ENDS industry. While the Census Bureau's Statistics of U.S. Businesses does not publish data specifically on the vaping industry, the data shows that well over 90 percent of Tobacco Stores (NAICS 453991) are small. According to industry sources, there are approximately 14,000 ENDS firms located across the country,[16] and there are over 20,000 establishments listed under "Vape Shops & Electronic Cigarettes" in the Yellow Pages.[17] Additionally, over 2,000 establishments with "vap," "liq," or "juice" in the establishment name have registered with the FDA.[18] The FDA cannot certify the proposed rule because it imposes significant costs on small entities that the agency did not contemplate in the Deeming Rule. Therefore, the agency must prepare and make available for public comment an IRFA and consider alternatives that would accomplish the stated objectives of applicable statutes while minimizing the rule's impact on small entities.

A. The Agency Lacks an Adequate Factual Basis to Certify That the Proposed Rule Will Not Have a Significant Economic Impact on a Substantial Number of Small Entities, As Required by the RFA

Under § 605(b) of the RFA, an agency may avoid the requirements of an initial and final regulatory flexibility analysis, including a discussion of significant, burden-reducing alternatives, if the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities.[19] Any such certification must be accompanied by a statement of the factual basis for the certification. An agency's improper certification is subject to judicial review, which could delay implementation of the rule.[20] Agency actions, including improper RFA

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[14] In the Deeming Rule, the FDA estimated that no premium cigars would use the PMTA marketing pathway. *See* Final Regulatory Impact Analysis *supra* note 8 at 16. Advocacy does not agree that no premium cigars will use the PMTA marketing pathway.

[15] *Id.* at 50,629.

[16] The Vapor Industry Economic Impact Study, pg. 6, https://vaportechnology.org/wp-content/uploads/2019/09/Vapor-Industry-Economic-Impact-Study-by-Dunham-Associates-2019-Updated.pdf (last visited November 13, 2019).

[17] Represents a count of establishments in the "Vape Shops & Electronic Cigarettes" category in each of the 50 states and the District of Columbia as listed at https://www.yellowpages.com/.

[18] Establishment Registration & Tobacco Product Listing, https://ctpocerl.fda.gov/rlapp/home.html (last visited October 20, 2019).

[19] 5 U.S.C. § 605(b).

[20] *Id.* §§ 611(a)(1), 701 *et seq.*; *see also, White Eagle Coop. Ass'n v. Conner*, 553 F.3d 467, 480 (7th Cir. 2009) (small entities directly regulated by a proposed rule may challenge an agency's RFA analysis or certification).

certifications, are reviewed under the arbitrary and capricious standard of the Administrative Procedure Act.[21] Failure to provide a factual basis for a certification may result in the rule being returned to the agency.[22] Advocacy is concerned that the certification in the current rule lacks a factual basis and, thus, is improper.

In the proposed rule, the FDA states: "we anticipate that the level of effort required to gather information and prepare the PMTA aligns with the effort described in the final regulatory impact analysis for the Deeming Rule."[23] No evidence is provided to support this statement, and it is at odds with the FDA statement in the Deeming Rule that "[w]e cannot predict the costs or benefits of future rulemaking before the contents of the rules themselves have been established."[24] In the proposed rule, the FDA is relying on its inadequate assessment of the costs of the Deeming Rule to certify the PMTA proposed rule.[25] Because the costs of the PMTA process have yet to be accounted for, all the costs attributable to the PMTA requirement must be accounted for in this rule.

Advocacy has heard from several small businesses in the industry who have stated that the costs associated with the PMTA process are excessive and the PMTA requirements are overly burdensome. Indeed, Reynolds American Inc. (RAI), best known as RJ Reynolds, one of the largest tobacco manufacturers, submitted a PMTA in October 2019 that consisted of over 150,000 pages of documents.[26] RAI's Executive Vice President James Figlar stated that RAI's PMTA was "a culmination of years of hard work across multiple teams, involving more than 100 individuals, including dozens of Ph.D. team members collaborating every day, with a substantial financial investment."[27] The majority of ENDS manufacturers do not have the resources or revenue to comply with the PMTA requirements. According to small businesses in the industry, most ENDS manufacturers generally have hundreds of stock keeping units (SKU) that will have to be approved through a PMTA. Submitting those SKUs individually or bundled for approval through the PMTA process will be too onerous a cost for many small businesses in the industry. One small business reported to Advocacy that it had closed three of its 14 stores, laid off 15 employees, and lost over $2 million in revenue in anticipation of complying with the PMTA proposed rule.

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[21] 5 U.S.C. §§ 611(a), 701 *et seq*.; *see also*, *North Carolina Fisheries Ass'n v. Daley*, 27 F. Supp. 2d 650, 658 (U.S. Dist. Ct. E.D. Va 1998).

[22] *North Carolina Fisheries Ass'n v. Daley*, 16 F. Supp. 2d 647, 658 (U.S. Dist. Ct. E.D. Va 1997).

[23] Premarket Tobacco Product Applications and Recordkeeping Requirements, Initial Regulatory Impact Analysis, Docket No. FDA - _____, page 14.

[24] Final Regulatory Impact Analysis, *supra* note 8 at 55.

[25] Moreover, the FDA assumed in the Deeming Rule that public dockets of research would be available to assist in the development of PMTAs, "potentially reducing the time for preparation of a particular application." Final Regulatory Impact Analysis, *supra* note 8 at 56. These resources, however, do not appear to be available. If available, the FDA should direct stakeholders to these resources. If these resources are unavailable, the agency should take this into account when developing a more detailed analysis of the proposed rule's impacts on small entities.

[26] https://vaping360.com/vape-news/85364/the-first-vape-pmta-has-been-submitted-to-the-fda/ (last visited November 20, 2019).

[27] *Id.*

Additionally, the FDA cannot even fully account for the proposed rule's cost because all the required regulations to which any entity submitting a PMTA must adhere have not been drafted. For example, the proposed rule states that entities submitting a PMTA must account for "a full description of the methods used in, and the facilities and controls used for, the design (including design validation and design verification, to assess whether the tobacco product, as manufactured, performs in accordance with design specifications), manufacture, packing, and storage of the tobacco product in sufficient detail to demonstrate whether the product meets manufacturing specifications, can be manufactured in a manner consistent with the information submitted in the application, and conforms to the requirements of any regulations issued under section 906(e) of the Federal Food, Drug, and Cosmetic Act."[28] But to date, the FDA "has not yet issued a regulation under section 906(e) of the FD&C Act."[29]

Because of the numbers of small entities regulated by this rule, and because of the economic impact attributable to this rule, Advocacy concludes that the agency has failed to state a factual basis upon which to certify that the PMTA proposed rule will not have significant economic impact on a substantial number of small entities. The rule cannot be certified under § 605(b)(2), and the agency must publish an IRFA as required by § 603 of the RFA.

B. The Agency Should Prepare and Make Available for Public Comment an IRFA Before Going Forward with This Rule

Advocacy urges the FDA to prepare and make available for public comment an IRFA for the proposed rule that includes a detailed quantitative analysis of the costs to small entities of the FDA's requirements and expectations for a successful PMTA. A proper IRFA must describe the impact of the proposed rule on small entities and contain the following information: (1) a description of the reasons why the agency's action is being considered; (2) a succinct statement of the objectives of, and the legal basis for, the proposed rule; (3) a description – and, where feasible, an estimate of the number – of small entities to which the rule will apply; (4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the types of professional skills necessary for preparation of the report or record; and (5) an identification, to the extent practicable, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.[30]

Although foreshadowed in the Deeming Rule, a detailed analysis of costs of individual requirements for PMTAs has never been published. There is a significant amount of specificity in this proposed rule that was not addressed in the analysis in the Deeming Rule.
Small entities have not had any opportunity to comment on specific burdens of the PMTA pathway or to suggest alternatives that may be less burdensome. The FDA should compare the estimated quantitative costs per small entity in an IRFA for the proposed rule to the costs per small entity published in the Deeming Rule to assess the incremental costs or cost savings of the PMTA proposed rule. Examples of compliance costs of requirements that FDA should specifically identify in an IRFA include preparation and submission of marketing plans, which

[28] 84 Fed. Reg. at 50,650.
[29] *Id.* at 50,597.
[30] 5 U.S.C. § 603(b).

were not specifically quantified in the Deeming Rule; specific costs of testing, which were mentioned in the Deeming Rule but with little detail; and the costs of specific requirements for an environmental assessment, which were mentioned in the Deeming Rule but with no detail. Estimates of individual requirements of the proposed rule are necessary for a meaningful evaluation of alternatives for small entities.

C. The FDA Must Consider Significant Alternatives to the Proposed Rule that Accomplish the Stated Objectives of Applicable Statutes While Minimizing the Rule's Economic Impact on Small Entities

The FDA needs to present significant alternatives for regulatory relief as part of an IRFA as required by § 603(a). At a minimum, the agency should consider: (1) the establishment of different compliance or reporting requirements for 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.[31] Additionally, the FDA should consider significant alternatives proposed by stakeholders whose comments are published on the proposed rule's public docket.

III. Conclusion

Advocacy is concerned that the agency's certification that the proposed rule will not have a significant economic impact on a substantial number of small entities lacks an adequate factual basis. The certification improperly assumes that the compliance costs of the proposed rule's requirements for deemed products are due to the agency's 2016 Deeming Rule. Advocacy recommends that the agency prepare and make available for public comment an IRFA that would: (1) adequately assess the costs associated with the PMTA requirements in the proposed rule incurred by small entities and (2) include consideration of significant alternatives to the proposed rule that will accomplish the stated objectives of applicable statutes while minimizing the proposed rule's economic impact on small entities.

[31] *Id.* § 603(c).

If you have any questions or require additional information, please do not hesitate to contact me or Assistant Chief Counsel Charles G. Jeane at (202) 205-7168 or by email at charles.jeane@sba.gov.

Sincerely,

/s/
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/s/
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