U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
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FACT SHEET

Advocacy Suggests FDA's Certification is Improper and that the Agency Should Prepare and Publish and Initial Regulatory Flexibility Analysis for Its Premarket Tobacco Product Application Proposed Rule

On November 27, 2019, the Office of Advocacy sent a letter to the Food and Drug Administration (FDA) asserting that the agency improperly certified the *Premarket Tobacco Product Applications and Recordkeeping Requirements* proposed rule. A copy of Advocacy's letter may be accessed at https://advocacy.sba.gov.

- On September 25, 2019, the Food and Drug Administration (FDA) published a proposed rule titled *Premarket Tobacco Product Applications and Recordkeeping Requirements*. (84 Fed. Reg. 50,566).

- The proposed rule sets out the form of and content for a premarket tobacco product application (PMTA). The rule also describes the FDA's PMTA review process and the recordkeeping requirements for those who submit a PMTA for review.

- For purposes of the Regulatory Flexibility Act, the FDA certified that the proposed rule will not have a significant economic impact on a substantial number of small entities. The agency's stated basis for its certification is that the rule will have negligible costs for small entities that manufacture or import deemed tobacco products because the PMTA costs were already accounted for in the Deeming Rule's Final Regulatory Flexibility Analysis (FRFA) (81 Fed. Reg. 28,974 (May 10, 2016)). By the agency's own estimation, the PMTA process will cost between $28,566 and $2,595,224 per electronic nicotine delivery system (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. The FDA estimated that no premium cigars will use the PMTA marketing pathway.

- Advocacy cautioned the FDA that its certification was improper because there was no factual basis supporting it. PMTA costs are not negligible, and the Deeming Rule's FRFA was inadequate and not a proper basis for certification of the PMTA proposed rule.

- Advocacy recommended that the FDA prepare and make available for public comment an Initial Regulatory Flexibility Analysis and consider significant alternatives for small entities in the industry.

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