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

November 7, 2019

VIA ELECTRONIC SUBMISSION

The Honorable Norman Sharpless
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

RE: Request for Extension of Comment Period for Premarket Tobacco Product Applications and Recordkeeping Requirements Proposed Rule (Docket No. FDA-2019-N-2854)

Dear Acting Commissioner Sharpless:

On September 25, 2019, the Food and Drug Administration (FDA) published a proposed rule titled *Premarket Tobacco Product Applications and Recordkeeping Requirements*, with a comment period ending on November 25, 2019.[1] For the reasons stated below, the Office of Advocacy (Advocacy) respectfully requests that the FDA extend the comment period for the above-referenced rule by 60 days, to Friday, January 24, 2020.

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),[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 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.[4] 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

[1] 84 Fed. Reg. 50,566 (Sept. 25, 2019).
[2] 5 U.S.C. § 601 et seq.
[3] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.).
[4] Small Business Jobs Act of 2010 (PL 111-240) § 1601.

the public interest is not served by doing so.[5] 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."[6]

Advocacy commends the FDA for holding a public meeting on October 28-29, 2019, to discuss the Premarket Tobacco Product Application (PMTA) process and the FDA's expectations on how that process will work, as well as the information industry must provide in a PMTA. Advocacy notes, however, that the meeting was held less than one month before the close of the proposed rule's comment period. The amount of information provided over the two-day meeting was voluminous and both enhanced the information included in the proposed rule and provided further context.

At the meeting, the FDA announced that the presentation slides and a transcript of the meeting would not be available until 30 to 60 days after the date of the meeting. Even if the FDA were to make the presentation slides and meeting transcript available on November 28, 2019, 30 days after the public meeting, the PMTA proposed rule's comment period will have already closed on November 25, 2019. The information disseminated at the public meeting would be extremely helpful to small businesses drafting comment letters; the comment period should be extended for those businesses to review the new information and incorporate it into their comment letters to the agency.

For this reason, Advocacy respectfully requests that the FDA extend the PMTA proposed rule comment period 60 days, to Friday, January 24, 2020. 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/
Major L. Clark, III
Acting Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/
Charles G. Jeane
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: Paul Ray, Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget

[5] *Id.*
[6] 5 U.S.C. § 601 note 7.