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Captain Serina Hunter-Thomas
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: May 18, 2023, TPSAC Meeting Related to Tobacco Product Manufacturing Practice

Dear Captain Hunter-Thomas:

As the large manufacturer industry representative, I write to share some suggestions for the May 18, 2023, meeting of the Tobacco Products Scientific Advisory Committee ("TPSAC") related to Tobacco Product Manufacturing Practice ("TPMPs"). After consultation with others in the industry, we agree that it would be helpful for the Center for Tobacco Products ("CTP") to direct the TPSAC agenda and conversation to the following key areas and questions where further clarification is needed:

- **Accounting for Product Differences:** The proposed rule seeks to establish TPMPs for different categories of tobacco products without necessarily differentiating between and among those products, and without clearly accounting for the unique aspects of manufacturing and processing agriculturally-based conventional tobacco products such as cigarettes, cigars and moist smokeless tobacco. Given these differences, should the TPMPs be more fit for purpose so that manufacturers can comply with requirements like product design and development, verification and validation and sampling?
- **Complaint Investigations:** The proposed rule's complaint management and risk management process sections would require manufacturers to identify and investigate every complaint associated with adverse experiences. Given the fact that the health effects of tobacco products are well-known and many of the adverse events from their use are expected, would it make more sense for the investigation requirement to only be triggered if the adverse event frequency or severity crosses a threshold determined by historical data and current procedures used by manufacturers?
- **Exemption and Variance Petitions:** The proposed rule provides that FDA can refer petitions for an exemption or variance from a TPMP requirement to the TPSAC. Can manufacturers get a better understanding of the process, how it will be managed, potential timelines, the TPSAC's role, and examples of circumstances for which an exemption or variance would be permitted?

- **Implementation:** The proposed rule describes requirements that may necessitate upgrades to buildings and facilities, IT systems and more than cannot be done in parallel and have to be sequenced over time. Given these challenges, should manufacturers be given more time to fully comply with the TPMP requirements, including a transition period?

We believe a robust discussion of these topics at the TPSAC meeting will help provide additional clarification to regulated industry, the general public, and other interested parties.

Thank you for your consideration, and please let me know if you have any questions.

Vice President and Chief Scientific Officer
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