PMI | U.S.

August 4, 2025

Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Building 71, Room G335
Silver Spring, MD 20993-0002

ATTENTION:
Benjamin Apelberg, Deputy Director for Regulatory Science, Office of Science

Submitted via CTP Portal
Cc: Anab Kemal, Regulatory Health Project Manager, via email

Subject: Amendment to MR0000254.PD1, MR0000254.PD3, MR0000254.PD5 – MR0000254.PD7

To Whom It May Concern,

PMI US Corporate Services, Inc.[1] (PMI US), on behalf of Philip Morris Products S.A. (PMP S.A.), submits this amendment to provide new scientific evidence demonstrating that IQOS consumables do not meet the cigarette definition set forth in section 900(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). As such, we request removal of the three required smoking-related warnings[2] for the IQOS consumables subject of this review. We do not request removal of, and remain committed to ensuring that the IQOS consumable labeling contains, the *nicotine is addictive* warning conditioned in the April 29, 2019, PMTA Technical Project Lead (TPL) review.[3]

While FDA considers this request, it should be guided by the following four salient facts:

1. **IQOS consumables do not meet the statutory definition set forth in section 900(3) of the FD&C Act.**
2. **Product-specific evidence confirms that consumers do not perceive IQOS consumables to be cigarettes.**
3. **Imposing smoking-related warnings on IQOS consumables (which are classified by FDA as HTPs) is scientifically inaccurate and misleading to consumers.**

[1] PMI US Corporate Services Inc. is a services company for the Philip Morris International (PMI) family of companies.
[2] SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.
SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.
[3] See Page 87 of TPL Review for PM0000424.PD-PM0000426.PD1 and PM0000479.PD1

4. **The Administrative Procedure Act (APA) requires that FDA decisions be based on substantial evidence.**

Both FDA and PMI US share the common goal of moving U.S. adult smokers away from combusted cigarettes. To effectively achieve this goal, it is essential that regulatory decisions are informed by rigorous science and communicate the relative risks across tobacco products.

Requiring IQOS consumables to bear the same warnings as combusted cigarettes is not supported by currently available scientific evidence, nor FDA decisions concluding that the products were appropriate for the protection of public health and modified risk tobacco products. In fact, treating IQOS products as equally harmful as combusted cigarettes, despite scientific evidence to the contrary, misleads and confuses U.S. adult smokers looking for better alternatives.

As FDA weighs this decision, we reiterate that imposing smoking-related warnings on FDA-authorized IQOS consumables only delays efforts to transition current U.S. adult smokers down the continuum of risk and away from the most harmful form of tobacco.

Sincerely,

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Sarah Amyot (Aug 4, 2025 15:15:33 CDT)

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