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July 12, 2021

Mr. Mitchell Zeller
Director, Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2021-N-0408

Modified Risk Tobacco Product Application: Application for the IQOS 3 System Holder and Charger Submitted by Philip Morris Products S.A.

Dear Mr. Zeller:

I am writing on behalf of UCSF TCORS in response to the notice of availability for public comment on the supplemental modified risk tobacco product application (sMRTPA) for the IQOS 3 System Holder and Charger posted by FDA on May 14, 2021 and the subsequent Message from CTP posted on July 1, 2021 announcing that public comments on the sMRTPA would be due by August 2, 2021 and providing a link to the application materials.

The May 14, 2021 notice stated:

> FDA will post the application documents, **including those cross-referenced from prior submissions previously authorized** and those contained in any amendments, for public comment in batches on a rolling basis as they are redacted in accordance with applicable laws. In this document, FDA is announcing the availability of the first batch of application documents for public comment. FDA intends to establish a closing date for the comment period that is both at least 45 days after the date this notice publishes and **at least 30 days after the final documents from the application are made available for public comment**. FDA will announce the closing date at least 30 days in advance.

Per FDA's May 14 notice, the application materials posted on July 1, 2021 include a link to a zip file to the IQOS 3 System Holder and Charger Supplemental Premarket Tobacco Product Application (PMTA). The IQOS 3 Supplemental PMTA materials are available here: https://digitalmedia.hhs.gov/tobacco/hosted/mrtpa/pmi/Cross-referenced%20PMTA%20Submission%20%28PM0000364%29.zip

Included among these materials is the m2.2 Index, part of the Module 2: Table of Contents, which lists the new documents organized by Module and Section Number. This index lists 47 Perception and Behavior Assessment (PBA) Studies that are supposed to be provided with the

Module 7: Scientific Studies and Analyses. However, ***none of these PBA studies have been posted and made available for review.***

Family Smoking Prevention and Tobacco Control Act section 911(g)(2)(B) requires the applicant seeking a reduced exposure MRTP order to demonstrate, among other things, that "testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product (I) is or has been demonstrated to be less harmful; or (II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products." Perception and Behavior Assessment studies are among the most important studies that FDA and the public need to evaluate the proposed reduced exposure MRTP claim. These studies are also among only a very few new studies that PMPSA is using to support its application beyond the studies originally submitted with its IQOS 2.4 PMTA and MRTP applications. While the studies may not be new to FDA given its review and authorization of the Supplemental PMTA for IQOS 3, the public has not yet been afforded the opportunity to review them. In order for scientists and the public to adequately assess and comment on the IQOS 3 sMRTPA, it is essential that they have the opportunity to review these Perception and Behavior Studies. We and other interested persons have no way to analyze the merit of PMPSA's evidence and claims without these essential documents.

FDA is required by section 911(e) of the Family Smoking Prevention and Tobacco Control Act to make the MRTPA publicly available, and section 911(g)(4)(E) requires FDA to take into account comments, data, and information submitted by interested persons in making its determination of whether to issue an MRTP marketing order. As FDA stated in its May 14 notice, it intended to provide ***a closing date of at least 30 days after the final documents from the application are made available for public comment,*** and that it would announce the closing date at least 30 days in advance. However, as of July 12, 2021, FDA has not posted the underlying Perception and Behavior Studies, which are essential to adequately comment on the IQOS 3 sMRTPA. We respectfully request that FDA extend the comment period at least an additional 30 days after it posts all of the application documents, including the Perception and Behavior Studies listed in the Module 2.2 index of the IQOS 3 Supplemental PMTA, and ensure that all of the posted documents are searchable.

Thank you.

Lauren Kass Lempert
UCSF TCORS