

July 16, 2021

Mr. Mitchell Zeller  
Director, Center for Tobacco Products  
U.S. 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 Director Zeller:

I write in support of the July 12, 2021 request by the University of California, San Francisco Tobacco Center for Regulatory Science (UCSF TCORS) for a change in the announced comment period for the supplemental modified risk tobacco product application in the above-referenced docket.

When FDA announced on May 14, 2021 that the IQOS supplemental modified risk application was being made available for public comment, the agency indicated that FDA would post the application documents, including those cross-referenced from prior submissions previously authorized. The agency also signaled that FDA would establish a closing date for the comment period that is at least 30 days after the final documents from the application are made available for public comment. However, several of the documents in Philip Morris Products S.A.'s cross-referenced prior submission for its IQOS 3 sPMTA, including 47 Perception and Behavior Studies that are indexed in the m2.2 Index in Module 2 and are supposed to be provided within Module 7, have not been posted and made available for public review.

Because the Perception and Behavior Studies are critically important to a determination of whether the IQOS 3 supplemental Modified Risk Tobacco Product (sMRTP) is appropriate for the protection of the public health, FDA should revise its current comment period. Whether Philip Morris Products S.A. has met its statutory burden under Section 911(g)(1) of the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, likely will turn on the strength of this scientific evidence, as well as the other evidence presented in its sMRTP application.

Congress included Section 911 to protect the public against a repeat of public health disasters like the "light" and "low-tar" cigarette fraud of past decades, in which false industry assurances deceived consumers, especially youth and young adults, that some tobacco products were less harmful than others. Given what is at stake for public health, FDA must ensure that independent researchers, policymakers, public health groups and other members of the public have a meaningful opportunity to provide input on the scientific evidence advanced by Philip Morris Products S.A. in support of its application, including its Perception and Behavior Studies.

Therefore, the American Lung Association joins the UCSF TCORS in calling on FDA to post the missing Perception and Behavior studies and extend the comment period to at least 30 days from the date the complete IQOS application has been made available to the public.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Harold Wimmer". The signature is written in a cursive style with a large initial 'H'.

Harold P. Wimmer  
President and CEO

