October 11, 2017

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-2017-D-3001, Modified Risk Tobacco Product Applications: Applications for IQOS System with Marlboro Heatsticks, IQOS System with Marlboro Smooth Menthol Heatsticks, and IQOS System with Marlboro Fresh Menthol Heatsticks Submitted by Philip Morris Products S.A.; Availability, 82 Fed. Reg. 27487 (June 15, 2017)

Dear Director Zeller:

We write in support of the October 2, 2017 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 modified risk tobacco product application in the above-referenced docket.

When FDA announced, in June of this year, that the IQOS modified risk application was being made available for public comment, the agency indicated that, due to the large size of the application, it will be posted in batches on a rolling basis, to allow appropriate redactions. FDA indicated that the applications would be available for public comment for 180 days after the posting of the first batch of application documents. According to this timeline, the comment period now extends through December 12, 2017. FDA also indicated that, if fewer than 30 days remain in the comment period when the final batch is posted, FDA will extend the comment period "to allow for at least 30 days of public comment from the day the final batch is posted."

Given the sheer volume and complexity of the documents submitted by Philip Morris International (PMI) in support of its IQOS application, and the pace of FDA's release of those documents to the public, it is now clear that FDA should revise its current comment period. As of the present time, two critical application Modules remain undisclosed; these include the scientific studies and analysis presented by PMI and the relevant references. As matters presently stand, the public may have as few as 30 days to review and comment on the full extent of the IQOS application, including the studies and references offered in support of the application. Whether PMI 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 the scientific evidence presented in its modified risk application. The materials that remain to be produced are likely to be complex, voluminous, and

of critical importance. Allowing the public as little as 30 days to assess, and comment on, this evidence, is wholly inadequate.

Section 911 was enacted 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 that some cigarettes were safer than others caused millions of health-conscious smokers to keep smoking instead of quitting. 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 PMI in support of its application. Therefore, we join the UCSF TCORS in calling on FDA to create a 180-day public comment period, running from the date the complete IQOS application has been made available to the public.

Thank you for your consideration.

Sincerely,

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative