November 21, 2017

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

Re: Docket No. FDA-2017-D-3001

Dear Director Zeller:

This letter renews the October 11, 2017 request made by the undersigned organizations, that FDA extend the deadline for submission of comments in the above-designated docket until six months following the publication of the final installment of the application and requests a similar postponement for the submission of public comments to the Tobacco Products Scientific Advisory Committee (TPSAC). We reiterate our request.

In June 2017, the FDA accepted for filing the application of Philip Morris International for designation of its tobacco product, IQOS, as a modified risk product. Because of the resources the applicant has devoted to the development and promotion of the product—and is capable of devoting in the future-- and the novelty of the product, the application is of unprecedented importance to the public health. Moreover, if granted, the IQOS application would be the first modified risk application granted by FDA. Because of the importance of this application, the ability of the public to participate in FDA's consideration of the application is vital. The Tobacco Control Act specifically provides for public participation in that process.

The public can participate meaningfully in the process only if it has access to data contained in the application. Unfortunately, despite the fact that FDA received the application more than five months ago, the agency has still not released studies that are important parts of the application. We understand that FDA does not plan to release such studies until November 24, and that the public may have to file comments as soon as December 24.[1]

[1] On November 21 FDA announced that it would establish a new deadline for comments in light of the fact that portions of the application still have not been published and that the new deadline will not be sooner than 30 days from the publication of the last installment of the application.

In our October 11 letter, we protested the current timeline, which makes it impossible for public commenters to prepare comments that adequately address the complex issues raised by the application. The materials included in this application are both voluminous (approximately 2 million pages) and exceedingly complex. To expect members of the public to analyze and prepare comments on this massive application within thirty days of the release of the final installment effectively precludes meaningful public participation. The imposition of such a deadline is particularly unreasonable given the fact that the applicant had unlimited time to prepare the application and FDA accepted the application for filing many months ago. FDA should not have started the clock running on the public comment period until the entire application was released. We reiterate our request that the public comment period be extended until six months after the full application is made available.

In addition to making adequate public comment impossible, the FDA's scheduling of the TPSAC meeting for January 24 and 25 makes it impossible for the agency to take public comments into account in formulating relevant questions to be addressed by TPSAC. In contrast, during FDA's consideration of the Swedish Match modified risk application, the timeline for public comment enabled the agency to consider those comments long before TPSAC met to review the application. *See* 79 Fed. Reg. 51183 (August 27, 2014). Given the important role assigned to TPSAC in the application process by the Tobacco Control Act, limiting the impact of the public's views on TPSAC's deliberations further compromises the scientific integrity of the review this application will receive. Both the deadline for public comment to TPSAC and the TPSAC meeting itself should be postponed to give the public adequate time to prepare comments that could help inform the issues for consideration by TPSAC.

The time constriction for public comment is the result of FDA's failure to make the entire application available to the public after it had been accepted and filed. FDA should not accept and file an application unless and until the agency is prepared to make it public. FDA's failure to do so in this case should not be permitted to diminish the role of public comments in the consideration of this highly significant application. FDA should take appropriate action to ensure that members of the public have a meaningful opportunity to analyze the application in its entirety and prepare comments both to FDA and to TPSAC.

Respectfully submitted,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative