May 9, 2014

Mr. Mitchell Zeller
Director, Center for Tobacco Products
9200 Corporate Blvd.
Rockville, MD 20850

Re: Docket No. FDA-2014-N-0189; Opposition to Requests for Extension of the Comment Period

Dear Mr. Zeller:

The Campaign for Tobacco-Free Kids, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association and Legacy submit this letter in strong opposition to the requests by Altria and the Cigar Association of America to lengthen the comment period on the FDA's proposed deeming rule in the above-designated docket.

The deeming rule is designed to protect the public health from deadly products that are currently not subject to any regulation. It is especially important to protect those segments of the public that are most vulnerable to exploitation, such as youth, who are, based on reliable government reports, using the deemed products in significant and rising numbers. Promulgation of this proposed rule took far too long. It is now urgent for FDA to move as promptly as possible to issue a final rule within a year. An extension of time for comments will only delay action on an urgent priority that has already been delayed for too long. It is an indisputable fact that this regulation cannot begin to protect the public health until a final rule is made effective.

Although the deeming rule does present a large number of questions for resolution, stakeholders have had three years since FDA first announced its intention to promulgate such a proposed rule in which to formulate their positions. None of the subjects covered in the proposed rule comes as a surprise. Moreover, industry representatives spent months presenting detailed arguments with regard to these subjects in meetings with the Office of Information and Regulatory Affairs, all of which are publicly documented. The idea that the industry, with all its resources, is somehow unable to formulate its position on these issues within the time period established in the proposed regulation is ludicrous.

For decades the tobacco industry has argued against regulation on the basis that further research is necessary before the government takes action to protect the public. It is an argument the industry makes whenever government proposes to take any measure that might reduce tobacco use. These arguments will be made regardless of whether FDA agrees to an extension of the comment period. Delay is what the industry seeks in order to continue the very behaviors and actions that demand regulation.

Philip Morris argues that the 75-day period is not as long as the time period permitted for comment on several other issues. Neither of these issues, however, involved comments on a proposed rule. Both involved the formulation of policies at earlier stages of the regulatory process and did not delay the issuance of a rule.

FDA should deny the requests for extension of time to file comments in this docket and it should do so promptly.

Respectfully submitted,

American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco Free Kids
Legacy