December 20, 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:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write in response to the notice of modified risk tobacco product applications (MRTPAs) 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. as posted by the Food and Drug Administration (FDA) in the June 15, 2017 *Federal Register*.

The AAFP strongly urges the FDA to extend the deadline for submission of comments until at least six months following the publication of the final installment of the application. The June 2017 partial application of Philip Morris International for designation of its tobacco product, IQOS, as a modified risk product is of unprecedented importance to the public health since, if granted, the IQOS application would be the first modified risk application granted by FDA. It is therefore tremendously important for the public health community to fully comment on all relevant materials and application information. We remind the FDA that the *Tobacco Control Act* specifically calls for public participation in these processes, which can only be achieved when the public has access to all data contained in the application.

The materials included in this application are exceedingly lengthy and complex; thus, a thirty-day comment period is insufficient. It effectively precludes meaningful public participation.

In the absence of clear scientific evidence of the safety (or decreased risk) of these products, it is premature for the FDA to move forward with this application. The AAFP calls on the FDA to not approve new forms of tobacco products, especially labeled as having less risk, without public review of the evidence for same.

Tobacco use (cigarettes, cigars, snuff, chewing tobacco, and other tobacco products) is documented by the U.S. Surgeon General as the leading preventable cause of death and illness in our nation. Annually, more than 480,000 people die from tobacco use and secondhand smoke; greater than the number of deaths caused by HIV/AIDS, alcohol, automobile accidents, murder, suicide, drugs and fires combined. Each year, smoking related illness costs the United States more than $300 billion:

approximately $170 billion in direct medical costs, $156 billion in loss of productivity and $5.6 billion loss of productivity from secondhand smoke. 5.6 million of today's Americans 18 and younger will die prematurely from a smoking related illness if smoking rates do not decline.

No matter how it is delivered, nicotine, a key ingredient in all tobacco products, is an addictive drug. Tobacco use by and around children and adolescents is of particular concern due to increased risk for addiction and passive exposure. Since the 1964 Surgeon General's report, cigarette smoking has been causally linked to diseases of nearly all organs of the body, to diminished health status, and harm to the fetus, and 14 different cancers. Smoking is the leading cause of cancer and death from cancer. Research continues to link smoking to other common diseases, including diabetes mellitus, rheumatoid arthritis, and colorectal cancer. Special dangers exist for specific subpopulations of smokers such as pregnant women who suffer higher rates of spontaneous abortions, stillbirths, premature births and low birth weight babies.

Given that nicotine is an addictive drug, the FDA must have full jurisdiction over all tobacco products and nicotine delivery devices. Further, FDA decisions should be subject to the same standard of review that generally applies under the *Food, Drug and Cosmetic Act*. The tobacco industry should respond to the same regulatory forces that govern other similar industries and should not be able to choose the amount of regulation they accept. Further, the FDA should have authority to regulate the manufacture, sale, labeling, distribution and marketing of tobacco products and nicotine delivery devices including products such as nicotine water.

About Family Medicine
Family physicians are dedicated to treating the whole person. These residency-trained, primary care specialists provide a wide variety of clinical services. They treat babies with ear infections, adolescents with depression, adults with hypertension, and seniors with multiple chronic illnesses. With a focus on prevention, primary care, and overall care coordination, they treat illnesses early and, when necessary, refer their patients to the right specialist and advocate for their care. One out of every five office visits in the United States are made with family physicians. More than 192 million office visits are made to family physicians each year. This is 66 million more than the next largest medical specialty. More Americans depend on family physicians than on any other medical specialty.

We appreciate the opportunity to provide these comments. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org with any questions or concerns.

Sincerely,

John Meigs, Jr., MD, FAAFP
Board Chair