



September 1, 2017

Scott Gottlieb, M.D.  
Commissioner  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. FDA-2017-D-3001-0002, 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

Dear Dr. Gottlieb,

The American Vaping Association (AVA) is pleased to submit our comments regarding the modified risk tobacco product applications (MRTP) for iQOS and its associated varieties of Marlboro Heatsticks presently pending before the FDA. The AVA is a nonprofit organization that advocates for regulatory and legislative policies that recognize the harm reduction benefits of vapor products and other reduced-risk alternatives to combustible cigarettes. As strong believers in the possibility of the United States attaining a ‘smoke-free’ future with technology, innovation, and a recognition of informed human choice, we strongly recommended that the FDA approve these MRTP applications.

As it stands today, adult smokers in approximately twenty-five countries have legal access to iQOS. The story is different in the United States, where the hurdle of filing a modified risk tobacco product application has kept the product off store shelves. This reflects the unfortunate reality of tobacco regulation in the U.S. today; it is easier for an existing cigarette company to bring a new combustible cigarette product to the market than it is for the same company to be innovative with an aim towards greatly reducing exposure to toxicants and contaminants.

In its submission, PMI has argued extensively and convincingly that a smoker who switches to iQOS will be exposed to dramatically lower concentrations of the chemicals responsible for the bulk of death and disease caused by smoking. Moreover, published research suggests that smokers who quit by using iQOS make similar health advancements as those who quit using tobacco products entirely.<sup>1</sup> In essence, PMI has spent billions of dollars to prove what has been a basic tenet of tobacco harm reduction since Dr. Michael Russell first wrote in the *British Medical Journal* in 1976, “Smokers smoke for the nicotine, but they die from the tar.”

---

<sup>1</sup> Frank Lüdicke, MD, et. al.; Effects of Switching to the Menthol Tobacco Heating System 2.2, Smoking Abstinence, or Continued Cigarette Smoking on Clinically Relevant Risk Markers: A Randomized, Controlled, Open-Label, Multicenter Study in Sequential Confinement and Ambulatory Settings (Part 2), *Nicotine & Tobacco Research*, ntx028, <https://doi.org/10.1093/ntr/ntx028>

We are encouraged by the data on cessation and falling cigarette sales coming out of Japan. Of course, any examination of data from Japan must be considered in light of the fact that nicotine-containing vapor products remain largely inaccessible. Nonetheless, the most recent quarterly report from Japan Tobacco illustrates the impact that iQOS is having on cigarette consumption in Japan. In the first six months of 2017, cigarette sales fell by 11%. A fall of this sort was not previously forecast, as the company was forced to reduce their cigarette consumption forecast for the last six months of 2017 by another 3 billion cigarettes.

Of course, heat-not-burn products are going to make some members of the tobacco control and public health communities very uncomfortable. After all, many activists have spent years fighting the products sold by the applicants. The hand wringing of these groups – so far as they just reflect an ideological and moral opposition to PMI possibly being a part of the solution to the smoking epidemic rather than a true critique of the science presented by PMI – should play no role in the FDA’s decision making. As is evident by their reaction to vapor products, tobacco control activists have been complacent for far too long and their discomfort with these products should be seen as a virtue, rather than a negative.

Our only concern with this MRTP application is centered on a condition that the applicant cannot be expected to change. If this application is granted, adult smokers will be accurately informed that iQOS poses less risk to users than smoking. That is great and we support that. However, it will remain a federal felony for manufacturers of vapor products, smokeless tobacco, and smokeless nicotine products to truthfully inform consumers that their products do not contain smoke, let alone that they are less hazardous than smoking. With surveys showing that many American smokers have wildly inaccurate risk perceptions of different nicotine products, it is clear that long-term efforts are needed to reform this system to ensure that all manufacturers of lower-risk products – and not just those with billions of dollars to spend – can make truthful claims about lifesaving products.

Adult smokers deserve access to a wide variety of smoke-free nicotine and tobacco products. While a smoker who switches to iQOS will still be exposed to more chemicals than they would if they switched to a vapor product, smokeless tobacco, or smokeless nicotine product, iQOS products nonetheless offer smokers a way out that will expose them to far less toxic chemicals than they would if they had kept smoking combustible cigarettes.

It’s time to tell the truth to adult smokers. For the reasons highlighted above, we urge you to approve the present MRTP applications.

Sincerely,

A handwritten signature in cursive script that reads "Gregory Conley". The signature is written in black ink and is positioned above the typed name and title.

Gregory Conley  
President – American Vaping Association