FDA Authorizes Marketing of *IQOS* as a Modified Risk Tobacco Product

https://www.businesswire.com/news/home/20200707005847/en/FDA-Authorizes-Marketing-IQOS-Modified-Risk-Tobacco

NEW YORK--(BUSINESS WIRE)--Regulatory News:

The U.S. Food and Drug Administration (FDA) today authorized the marketing of *IQOS*, Philip Morris International's (PMI) electrically heated tobacco system, as a modified risk tobacco product (MRTP). In doing so, the agency found that an *IQOS* exposure modification order is appropriate to promote the public health.

- Today's decision demonstrates that *IQOS* is a fundamentally different tobacco product and a better choice for adults who would otherwise continue smoking

- *IQOS* is the first and only electronic nicotine product to be granted marketing orders through the FDA's MRTP process

- The FDA authorized the marketing of *IQOS* with the following information:

  - The *IQOS* System heats tobacco but does not burn it
  - This significantly reduces the production of harmful and potentially harmful chemicals
  - Scientific studies have shown that switching completely from conventional cigarettes to the *IQOS* system reduces your body's exposure to harmful or potentially harmful chemicals.

- The agency concluded that the available scientific evidence demonstrates that *IQOS* is expected to benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products

- The FDA's decision further builds on the emerging independent international scientific consensus that *IQOS* is a better choice than continuing to smoke, and follows the FDA's April 2019 decision authorizing the commercialization of *IQOS* in the U.S.

- The FDA's decision provides an important example of how governments and public health organizations can regulate smoke-free alternatives to differentiate them from cigarettes in order to protect and promote the public health

This decision follows a review of the extensive scientific evidence package PMI submitted to the FDA in December 2016 to support its MRTP applications.

Commenting on the FDA's announcement, André Calantzopoulos, PMI's Chief Executive Officer, said:

"The FDA's decision is a historic public health milestone. Many of the tens of millions of American men and women who smoke today will quit—but many won't. Today's decision makes it possible to inform these adults that switching completely to *IQOS* is a better choice than continuing to smoke. FDA determined that scientific studies show that switching completely from conventional cigarettes to *IQOS* reduces exposure to harmful or potentially harmful chemicals.

IQOS is a fundamentally different product than combustible cigarettes and must be regulated differently, as the FDA has recognized. Now—more than ever—there is an urgent need for a fundamentally different conversation on a cooperative approach to achieve a smoke-free future. The FDA's decision provides an important example of how governments and public health organizations can regulate smoke-free alternatives to differentiate them from cigarettes in order to promote the public health.

We are excited that this important decision will help guide the choices of adult smokers in the U.S. The best choice for health is to never start smoking or to quit altogether. For those who don't quit, the best thing they can do is switch to a scientifically substantiated smoke-free product. As of March 31, 2020, PMI estimates that approximately 10.6 million adult smokers around the world have already stopped smoking and switched to *IQOS*. We believe that this decision can help to further accelerate the transition of U.S. adults away from cigarettes. We, along with our licensee Altria, are committed to guarding against unintended use and fully support FDA's focus on protecting youth.

Today's decision is a result of our ongoing commitment to put science at the forefront as we continue on our quest to replace cigarettes with smoke-free alternatives as quickly as possible.

We look forward to working with the FDA to provide any additional information they may require in order to market *IQOS* with reduced risk claims.

Harnessing innovations like *IQOS* to dramatically speed-up the decline in cigarette smoking is the opportunity of this century. Comprehensive, science-based regulation can help to rapidly shift adult smokers who would otherwise continue smoking to better options, while simultaneously guarding against unintended consequences."

Note to Editor

The MRTP marketing orders were issued pursuant to a 2009 law that empowers FDA to regulate tobacco products, including through oversight of innovative tobacco products.

PMI submitted MRTP applications for the *IQOS* device and three HeatStick variants: *Marlboro HeatSticks*, *Marlboro Smooth Menthol HeatSticks*, and *Marlboro Fresh Menthol HeatSticks*.

On April 30, 2019, the FDA authorized *IQOS* for sale in the U.S. through issuance of premarket tobacco authorization marketing orders that deemed the marketing of the product appropriate for the protection of public health.

On March 30, 2020, PMI submitted a supplemental premarket tobacco product application for the *IQOS* 3 tobacco heating device with the FDA.

Philip Morris International: Delivering a Smoke-Free Future

Philip Morris International (PMI) is leading a transformation in the tobacco industry to create a smoke-free future and ultimately replace cigarettes with smoke-free products to the benefit of adults who would otherwise continue to smoke, society, the company and its shareholders. PMI is a leading international tobacco company engaged in the manufacture and sale of cigarettes, as well as smoke-free products and associated electronic devices and accessories, and other nicotine-containing products in markets outside the United States. In addition, PMI ships a version of its *IQOS* Platform 1 device and its consumables authorized by the U.S. Food and Drug Administration to Altria Group, Inc. for sale in the U.S. under license. PMI is building a future on a new category of smoke-free products that, while not risk-free, are a much better choice than continuing to smoke. Through multidisciplinary capabilities in product development, state-of-the-art facilities and scientific substantiation, PMI aims to ensure that its smoke-free products meet adult

consumer preferences and rigorous regulatory requirements. PMI's smoke-free *IQOS* product portfolio includes heat-not-burn and nicotine-containing vapor products. As of March 31, 2020, PMI estimates that approximately 10.6 million adult smokers around the world have already stopped smoking and switched to PMI's heat-not-burn product, available for sale in 53 markets in key cities or nationwide under the *IQOS* brand. For more information, please visit www.pmi.com and www.pmiscience.com.

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