



PHILIP MORRIS INTERNATIONAL

PRESS RELEASE

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Philip Morris International Announces U.S. Food and Drug Administration Authorization For Sale of IQOS in the United States

NEW YORK, United States - April 30, 2019 - The U.S. Food and Drug Administration (FDA) today confirmed that IQOS, Philip Morris International's electrically heated tobacco system, is appropriate for the protection of public health and has authorized it for sale in the United States. FDA's [decision](#) follows its comprehensive assessment of PMI's premarket tobacco product applications (PMTAs) filed with the Agency in 2017.

Unlike cigarettes, the IQOS system heats — but does not burn — tobacco. It is the first electrically heated tobacco product to qualify for sale in the U.S. pursuant to the 2009 law that empowers FDA to regulate tobacco products, including through oversight of innovative products.

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

"The FDA's decision to authorize IQOS in the U.S. is an important step forward for the approximately 40 million American men and women who smoke. Some will quit. Most won't, and for them IQOS offers a smoke-free alternative to continued smoking. In just two years, 7.3 million people around the world have abandoned cigarettes and switched completely to IQOS. Today's decision by FDA makes this opportunity available to American adult smokers. All of us at PMI are determined to replace cigarettes with smoke-free alternatives that combine sophisticated technology and intensive scientific validation. FDA's announcement is a historic milestone."

He added, "The order sets out clear commercialization guidelines, including marketing requirements, that maximize the opportunity for adults to switch from cigarettes, while minimizing unintended use. We fully support this objective. FDA has set a high standard and we look forward to working with them to implement the order so that IQOS is reaching the right audience—current adult smokers.

PMI will bring IQOS to the U.S. market through an exclusive license with Altria Group, Inc., whose subsidiary Philip Morris USA has the market expertise and infrastructure to ensure a successful launch. PM USA is ready to deploy its initial lead market plans for IQOS.

PMI submitted a comprehensive body of scientific evidence in support of the PMTAs and of the parallel applications for IQOS as a "Modified Risk Tobacco Product", which FDA continues to review.

Note to Editor

PMP SA submitted PMTA applications for IQOS and three HeatStick variants: *Marlboro HeatSticks*, *Marlboro Smooth Menthol HeatSticks*; and *Marlboro Fresh Menthol HeatSticks*.

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, smoke-free products and associated electronic devices and accessories, and other nicotine-containing products in markets outside the U.S. 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, 2019, PMI estimates that approximately 7.3 million adult smokers around the world have already stopped smoking and switched to PMI's heat-not-burn product, which is currently available for sale in 47 markets in key cities or nationwide under the *IQOS* brand. For more information, please visit www.pmi.com and www.pmiscience.com.