PHILIP MORRIS INTERNATIONAL

The FDA authorizes the sale of Iqos 3 in US

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The U.S. Food and Drug Administration grants premarket tobacco product application orders to an updated version of our electronically heated tobacco system.

The U.S. Food and Drug Administration (FDA) has authorized an updated version of our electronically heated tobacco system for sale in the U.S., after concluding it was appropriate for the protection of the public health.

The FDA's ruling on *IQOS 3* follows an assessment of a premarket tobacco product application (PMTA) that PMI filed with the agency in March 2020. The *IQOS 3* device contains a number of technological advancements, compared to a previously authorized IQOS device, including longer battery life and quicker recharge between uses.
In its decision, the FDA noted that International survey data they had reviewed found no evidence of increased uptake of *IQOS* by youth or young adults, while use patterns available for a previously authorized version of *IQOS* within the U.S. have not raised new concerns regarding product use in youth and young adults.
The *IQOS 3* PMTA authorization is independent of the MRTP authorization for the *IQOS 2.4* device. PMI expects to file an MRTPA seeking an exposure modification marketing order for the *IQOS 3* device.

"Another important step forward"

Responding to the FDA's announcement, PMI's CEO André Calantzopoulos said: "The agency's decision to authorize *IQOS 3* in the

U.S. is another important step forward for the tens of millions of American men and women who currently smoke.

“In just five years, approximately 11.7 million people around the world have stopped smoking and switched to *IQOS*, and we believe bringing a more modern version of *IQOS* to the U.S. will only accelerate switching by adults who smoke.

“The order is subject to the same comprehensive commercialization requirements set in the April 2019 PMTA marketing orders for *IQOS 2.4*, which aim to maximize the opportunity for adults who would otherwise continue to smoke to switch from cigarettes, while minimizing unintended use.

“We, along with our licensee Altria, are committed to guarding against unintended use and fully support FDA’s focus on protecting youth.”

Notably, the FDA authorization does not mean the FDA “approved” *IQOS 3*. FDA does not approve tobacco products and any representation to the contrary would violate U.S. law.

Before receiving MRTP marketing orders in July 2020, *IQOS 2.4* was authorized for sale via the PMTA pathway in April 2019.

Transforming to a smoke-free future

PMI is transforming to focus scientifically substantiated better alternatives to replace cigarettes as soon as possible for adult smokers who would otherwise continue smoking.

To date, we have invested USD 7.2 billion in the research and development of our smoke-free products.

We believe that with the right regulatory encouragement and support from civil society, cigarette sales can end within 10 to 15 years in many countries.

Our ambition is to deliver a smoke-free future for all.