- Skip to main content
- Skip to FDA Search
- Skip to in this section menu
- Skip to footer links


U.S. flag An official website of the United States government Here's how you know

Dot gov

The .gov means it's official.
Federal government websites often end in .gov or .mil. Before sharing sensitive information, make sure you're on a federal government site.


SSL

The site is secure.
The **https://** ensures that you are connecting to the official website and that any information you provide is encrypted and transmitted securely.

U.S. Food and Drug Administration

- Search
- Menu

Search FDA Search FDA Submit search

Featured

- Contact FDA
- FDA Guidance Documents
- Recalls, Market Withdrawals and Safety Alerts
- Press Announcements
- Warning Letters
- Advisory Committees
- En Español

Products

- Food
- Drugs
- Medical Devices
- Radiation-Emitting Products
- Vaccines, Blood, and Biologics
- Animal and Veterinary
- Cosmetics
- Tobacco Products

Topics

- About FDA
- Combination Products

FDA News Release

FDA Authorizes Marketing of IQOS Tobacco Heating System with ‘Reduced Exposure’ Information

Agency Will Closely Monitor Real-World Data to Assess if Marketing Continues to be Appropriate

For Immediate Release:
July 07, 2020

Today, the U.S. Food and Drug Administration authorized the marketing of Philip Morris Products S.A.’s “IQOS Tobacco Heating System” as modified risk tobacco products (MRTPs). This marks the second set of products ever to be authorized as MRTPs and the first tobacco products to receive “exposure modification” orders, which permits the marketing of a product as containing a reduced level of or presenting a reduced exposure to a substance or as being free of a substance when the issuance of the order is expected to benefit the health of the population. Importantly, the authorization for these products requires the company to conduct postmarket

surveillance and studies to determine whether the MRTP orders continues to be appropriate, including assessing the potential for increased use among youth.

"Through the modified risk tobacco product application process, the FDA aims to ensure that information directed at consumers about reduced risk or reduced exposure from using a tobacco product is supported by scientific evidence and understandable," said Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products. "Data submitted by the company shows that marketing these particular products with the authorized information could help addicted adult smokers transition away from combusted cigarettes and reduce their exposure to harmful chemicals, but only if they completely switch. The FDA will closely monitor how IQOS is used by consumers to determine if these products meet this potential and do not cause increased use among youth. It is important to note that these products are not safe, so people, especially young people, who do not currently use tobacco products should not start using them or any other tobacco product."

The IQOS Tobacco Heating System includes the electronic IQOS device that generates a nicotine-containing aerosol by heating tobacco-filled sticks wrapped in paper, specifically Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks and Marlboro Fresh Menthol Heatsticks. The FDA previously authorized the marketing of these products without modified risk information in April 2019 via the premarket tobacco application (PMTA) pathway.

Today's action pertains to the separate MRTP applications for these products and further authorizes the manufacturer to market these specific products with the following information:

"AVAILABLE EVIDENCE TO DATE:

- 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 significantly reduces your body's exposure to harmful or potentially harmful chemicals."

Even with this action, these products are not safe nor "FDA approved." The exposure modification orders also do not permit the company to make any other modified risk claims or any express or implied statements that convey or could mislead consumers into believing that the products are endorsed or approved by the FDA, or that the FDA deems the products to be safe for use by consumers.

There are two types of MRTP orders the FDA may issue: a "risk modification" order or an "exposure modification" order. The company had requested both types of orders for the IQOS Tobacco Heating System. After reviewing the available scientific evidence, public comments and recommendations from the Tobacco Products Scientific Advisory Committee, the FDA determined that the evidence did not support issuing risk modification orders at this time but that it did support issuing exposure modification orders for these products. This determination included a finding that issuance of the exposure modifications orders is expected to benefit the health of the population as a whole.

In particular, the agency determined the company demonstrated that because the IQOS Tobacco Heating System heats tobacco and does not burn it, it significantly reduces the production of harmful and potentially harmful chemicals compared to cigarette smoke. Furthermore, studies showed switching completely from combusted cigarettes to the IQOS Tobacco Heating System significantly reduces the body's exposure to 15 specific harmful and potentially harmful chemicals. The toxicological assessment also found that, compared with cigarette smoke, IQOS aerosols contain considerably lower levels of potential carcinogens and toxic chemicals that can harm the respiratory or reproductive systems. Additionally, the FDA found that the applications supported the required consumer understanding findings.

Today's authorization requires Philip Morris Products S.A. to conduct postmarket surveillance and studies to determine the impact of these orders on consumer perception, behavior and health, and to enable the FDA to review the accuracy of the determinations upon which the orders were based. These postmarket requirements

include a rigorous toxicity study using computer models to help predict potential adverse effects in users. The orders also require the company to monitor youth awareness and use of the products to help ensure that the marketing of the MRTPs does not have unintended consequences for youth use. The company must also keep the FDA apprised of efforts to prevent youth access and exposure.

These requirements are in addition to the postmarket requirements and restrictions previously placed on these products in their April 2019 PMTA authorizations, such as reporting information to the FDA about consumer research studies, sales and advertising information and adverse experiences, among others. In particular, to limit youth access to the products and to limit youth exposure to IQOS advertising and promotion, the PMTA authorization placed stringent restrictions on how the products are marketed – particularly via websites and through social media platforms – by including requirements that advertising be targeted to adults of legal age to purchase tobacco products.

The company must request and receive authorization from the FDA to continue marketing the products with the same modified exposure information after the initial orders expire in 4 years. The FDA also may withdraw the initial and any potential subsequent exposure modification orders if the agency determines that, among other things, the orders are no longer expected to benefit the health of the population as a whole, for example as a result of an uptake in use of the products by youth or former smokers, or a decrease in the number of current smokers who completely switch to the products.

The MRTP pathway outlined in the 2009 Family Smoking Prevention and Tobacco Control Act allows companies to submit applications for the FDA to evaluate whether a tobacco product may be sold or distributed for use to reduce harm or the risk of tobacco-related disease. By law, the FDA must also ensure that the advertising and labeling of modified risk products enables the public to understand the modified risk or modified exposure information and to understand the significance that information has in the context of total health and in relation to all tobacco-related diseases and health conditions.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Related Information

Related Information

- Modified Risk Tobacco Products
- Philip Morris Products S.A. Modified Risk Tobacco Product (MRTP) Applications

###

Inquiries

Media:
Alison Hunt
202-308-5496

Consumer:
888-INFO-FDA

- ## Content current as of:

  07/07/2020

- ## Follow FDA

  - Follow @US_FDA on TwitterExternal Link Disclaimer
  - Follow FDA on FacebookExternal Link Disclaimer
  - Follow @FDAmedia on TwitterExternal Link Disclaimer

More Press Announcements

Footer Links

- FDA Archive
- About FDA
- Accessibility

- Visitor Information
- Website Policies / Privacy
- No FEAR Act

- FOIA
- HHS.gov
- USA.gov

Contact FDA Follow FDA on Facebook Follow FDA on Twitter View FDA videos on YouTube Subscribe to FDA RSS feeds
FDA Homepage
Contact Number 1-888-INFO-FDA (1-888-463-6332)
Back to Top