This document is scheduled to be published in the
Federal Register on 05/10/2024 and available online at
https://federalregister.gov/d/2024-10054, and on https://govinfo.gov

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-3001]

Modified Risk Tobacco Product Application: Renewal Applications for IQOS 2.4 System Holder and Charger, Marlboro Amber HeatSticks, Marlboro Green Menthol HeatSticks, and Marlboro Blue Menthol HeatSticks, Heated Tobacco Products and Heated Tobacco Product Consumables, Submitted by Philip Morris Products S.A.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity to provide public comment on modified risk tobacco product applications (MRTPAs). The applications are for the renewal of existing MRTP orders for IQOS 2.4 System Holder and Charger, Marlboro Amber HeatSticks, Marlboro Green Menthol HeatSticks and Marlboro Blue Menthol HeatSticks, Heated Tobacco Products (HTPs) and HTP Consumables, submitted by Philip Morris Products S.A.

DATES: Submit either electronic or written comments on the application beginning [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. FDA will establish a closing date for the comment period as described in section I.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-3001 for "Modified Risk Tobacco Product Applications: Renewal Applications for IQOS 2.4 System Holder and Charger, Marlboro Amber HeatSticks, Marlboro Green Menthol HeatSticks and Marlboro Blue Menthol HeatSticks, Heated Tobacco Products (HTPs) and HTP Consumables, Submitted by Philip Morris Products S.A." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Adrian Mixon or Dhanya John, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of modified risk tobacco products (MRTPs). MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless an order issued by FDA pursuant to section 911(g) of the FD&C Act is effective with respect to such product.

Section 911(d) of the FD&C Act describes the information that must be included in a MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the FD&C Act to make a MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911 of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (2). The applicant, Philip Morris Products S.A., is seeking a renewal under section 911(g)(2) of an order previously issued under section 911(g)(2) of the FD&C Act.

FDA may issue an order under section 911(g)(2) of the FD&C Act with respect to a tobacco product that does not satisfy the section 911(g)(1) standard. A person seeking an order under section 911(g)(2) of the FD&C Act must show that:

- Such an order would be appropriate to promote the public health;

- Any aspect of the label, labeling, and advertising for the product that would cause the product to be an MRTP is limited to an explicit or implicit representation that the tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;
- Scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards for obtaining an order under section 911(g)(1) of the FD&C Act;
- The scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies;
- The magnitude of overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
- The product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;
- Testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents or has been demonstrated to present less of a risk of disease than one or more other commercially marketed tobacco products; and

- Issuance of the exposure modification order 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.

Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole.

FDA is issuing this notice to inform the public that the MRTPAs for the following products submitted by Philip Morris Products S.A. have been filed and are being made available for public comment:

- MR0000254.PD1: IQOS 2.4 System Holder and Charger
- MR0000254.PD5: Marlboro Amber HeatSticks
- MR0000254.PD6: Marlboro Green Menthol HeatSticks
- MR0000254.PD7: Marlboro Blue Menthol HeatSticks

The applicant is seeking renewal of the authorization to market the IQOS 2.4 System Holder and Charger, Marlboro Amber HeatSticks[(1)], Marlboro Green Menthol HeatSticks[(2)] and Marlboro Blue Menthol HeatSticks,[(3)] products that previously received authorization under section 911(g)(2) of the FD&C Act[(4)] to be marketed as modified risk tobacco products with reduced exposure claims. For purposes of premarket review, FDA has identified these tobacco products as HTPs. HTPs meet the definition of a cigarette, but the tobacco is heated and not combusted (products that do not exceed 350° C). The applicant is including information from the previous MRTPAs by cross-reference.

FDA will post the application documents, including any amendments, to its website for the MRTPAs (see section II) for public comment on a rolling basis as they are redacted in

---

[1] Product name was previously Marlboro Heatsticks.
[2] Product name was previously Marlboro Smooth Menthol Heatsticks.
[3] Product name was previously Marlboro Fresh Menthol Heatsticks.
[4] The notice of availability for the IQOS MRTPAs that received modified risk granted orders appeared in the *Federal Register* of June 15, 2017 (82 FR 27487), and the docket containing notices and public comments, FDA-2017-D-3001, is accessible at: https://www.regulations.gov/docket/FDA-2017-D-3001.

accordance with applicable laws. In this document, FDA is announcing the availability of the first batch of application documents for public comment. FDA intends to establish a closing date for the comment period that is both at least 180 days after the date of this notice and at least 30 days after the final documents from the application are made available for public comment. FDA will announce the closing date at least 30 days in advance. FDA believes that this comment period is appropriate given the volume and complexity of information in the MRTPA that has not already been available for public comment as part of the previously authorized MRTPAs for the IQOS system.

FDA will notify the public about the availability of additional application documents and comment period closing date via the Agency's web page for the MRTPA (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. To receive email alerts, visit FDA's email subscription service management website (https://www.fda.gov/about-fda/contact-fda/get-email-updates), provide an email address, scroll down to the "Tobacco" heading, select "Modified Risk Tobacco Product Application Update", and click "Submit". FDA does not intend to issue additional notices in the *Federal Register* regarding the availability of additional application documents, including amendments, or the comment period for this MRTPA. To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

II. Electronic Access

Persons with access to the internet may obtain the document(s) https://www.fda.gov/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications.

Dated: May 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-10054 Filed: 5/9/2024 8:45 am; Publication Date: 5/10/2024]