4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Modified Risk Tobacco Product Applications: Applications for IQOS System with Marlboro Heatsticks, IQOS System with Marlboro Smooth Menthol Heatsticks, and IQOS System with Marlboro Fresh Menthol Heatsticks submitted by Philip Morris Products S.A.; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the period for public comment on modified risk tobacco product applications (MRTPAs) submitted by Philip Morris Products S.A. for its IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks.

DATES: FDA is extending the comment period on the MRTPAs made available for public comment through the notice of availability that appeared in the *Federal Register* of June 15, 2017 (82 FR 27487).

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: Applications for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks 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. Please note that FDA intends to establish a date on which the comment period will close by publishing a notice in the *Federal Register* (see SUPPLEMENTARY INFORMATION).

- 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or 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.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 1-877-CTP-1373, AskCTP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of June 15, 2017 (82 FR 27487), FDA published a notice of availability of the first batch of documents from modified risk tobacco product applications (MRTPAs) submitted by Philip Morris Products S.A. and gave the public 180 days to comment on the applications. In that notice, FDA announced that it would post the remaining MRTPA documents on a rolling basis as they were redacted in accordance with applicable laws and that it would extend the comment period if fewer than 30 days remained when the last batch of application documents was posted. In this notice, FDA is extending the period for public comment. Once all documents from the MRTPAs, including amendments, are posted, FDA intends to issue a notice in the *Federal Register* announcing when the comment period will close, which will be no earlier than 30 days from the date the last batch of application documents is posted. As stated in the *Federal Register* notice of June 15, 2017, FDA believes that this comment period is appropriate given the volume and complexity of the applications being posted.

FDA is required by section 911(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387k(e)) to make an 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(g) 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.

II. Electronic Access

Persons with access to the internet may access the application documents at:

http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm546281.htm.

Dated: November 16, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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