4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1051]

Modified Risk Tobacco Product Applications: Applications for 10 Products Submitted by Swedish Match North America Inc.; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the period for public comment on modified risk tobacco product applications (MRTPAs) submitted by Swedish Match North America Inc. for 10 tobacco products and announcing the availability for public comment of amendments to the MRTPAs. The notice of availability for the originally-filed applications appeared in the Federal Register of August 27, 2014 (79 FR 51183). In that notice, FDA requested comments on the 10 originally-filed MRTPAs that are posted on http://www.regulations.gov and FDA's Web site. The comment period on these originally-filed applications closed on February 23, 2015. FDA is reopening the comment period to seek comment specifically on amendments made to the originally-filed MRTPAs submitted by Swedish Match North America Inc.

DATES: Submit either electronic or written comments on the amendments by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with Docket Number FDA-2014-N-1051.

FOR FURTHER INFORMATION CONTACT: Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1-877-287-1373, AskCTP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 27, 2014 (79 FR 51183), FDA published a notice of availability of MRTPAs submitted by Swedish Match North America Inc. for 10 tobacco products and gave the public 180 days to comment on the applications.

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 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.

FDA has received and accepted a number of amendments to Swedish Match North America Inc.'s 10 originally-filed MRTPAs and is making these amendments available (except for matters in the amendments that are trade secrets or otherwise confidential commercial

information) for public comment. FDA is reopening the period for public comment so that the public has the opportunity to review and comment on these amendments.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.accessdata.fda.gov/Static/widgets/tobacco/SMNA_MRTPA_FDA-2014-N-1051.html or http://www.regulations.gov.

Dated: July 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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