

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

V. 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>.

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cvm> or <http://www.regulations.gov>.

Dated: July 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18796 Filed 7–30–15; 8:45 am]

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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 August 31, 2015.

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>.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

David Anderson, University of Oregon, Eugene: Based on an assessment conducted by the University of Oregon, Eugene (UOE), the Respondent's admission, and analysis conducted by ORI, ORI and UOE found that Mr. David Anderson, Graduate Student, UOE, engaged in research misconduct in research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grants R01 MH087214, R01 MH077105, and TA MH020002.

ORI found that Respondent engaged in research misconduct by falsifying and/or fabricating data in the following four (4) publications:

- *Journal of Neuroscience* 31(3):1128–38, 2011 (hereafter referred to as "Paper 1").

Journal of Experimental Psychology: Human Perception and Performance