

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]

BILLING CODE 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 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.

[FR Doc. 2015–18782 Filed 7–30–15; 8:45 am]

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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

39(3):824–835, 2012 (hereafter referred to as “Paper 2”).

- *Attention, Perception and Psychophysics* 74(5):891–910, 2012 (hereafter referred to as “Paper 3”).

- *Psychological Science* 24(6):929–38, 2013 (hereafter referred to as “Paper 4”).

ORI found that Respondent knowingly falsified data by removing outlier values or replacing outliers with mean values to produce results that conform to predictions. Specifically, these falsifications appear in:

1. Figures 4 and 8 in Paper 1.
2. Figures 3C, 3D, and 3E in Paper 2.
3. Figures 3B, 7C, 7D, and 8B in Paper 3.
4. Figures 3E and 3F in Paper 4.

Mr. Anderson has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on June 23, 2015:

(1) To have his research supervised; Respondent agreed that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which his participation is proposed and prior to his participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of his research contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that any institution employing him shall submit in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(4) to assist UOE in advising publishers of the need to retract or correct the following papers:

- *Journal of Neuroscience* 31(3):1128–38, 2011.
- *Journal of Experimental Psychology: Human Perception and Performance* 39(3):824–835, 2012.
- *Attention, Perception and Psychophysics* 74(5):891–910, 2012.
- *Psychological Science* 24(6):929–38, 2013.

FOR FURTHER INFORMATION CONTACT: Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Donald Wright,
Acting Director, Office of Research Integrity.
[FR Doc. 2015–18794 Filed 7–30–15; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–0407–60D]

Agency Information Collection Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). A 60-day **Federal Register** Notice has been published for this system. This request is to approve a revision to a currently approved collection with OMB number 0990–0407, and is not a new request for approval.

DATES: Comments on the ICR must be received on or before September 29, 2015.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–0990–0407–60D for reference.

Information Collection Request Title: Think Cultural Health (TCH) Web site Quality Improvement Effort—OMB No. 0990–0407 REVISION—HHS/OS/OMH

Abstract: The Office of Minority Health (OMH), Office of the Secretary (OS), Department of Health and Human Services (HHS) is requesting approval by OMB on a revised data collection. The Think Cultural Health (TCH) Web site is an initiative of the HHS OMH’s Center for Linguistic and Cultural Competence in Health Care (CLCCHC), and is a repository of the latest resources and tools to promote cultural and linguistic competency in health and health care. The TCH Web site is unlike other government Web sites in that its suite of e-learning programs affords health and health care professionals the ability to earn continuing education credits through training in cultural and linguistic competency. The revision to this information collection request includes the online Web site registration form, course/unit evaluations specific to the resource or e-learning program course/unit completed, follow up surveys, focus groups, and key informant interviews.

Need and Proposed Use of the Information: The data will be used to ensure that the offerings on the TCH Web site are relevant, useful, and appropriate to their target audiences. The findings from the data collection will be of interest to HHS OMH in supporting maintenance and revisions of the offerings on the TCH Web site.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (hours)	Total burden (hours)
Registration Form	Health and Health Care Professionals.	9460	1.00	3/60	473
Course/unit Evaluation Form	Health and Health Care Professionals.	9460	1.00	5/60	788