DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0309]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (GFI) #198 entitled ''Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products'' (VICH GL45). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance is an annex to a VICH guidance GFI #73 entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R). This VICH guidance document is intended to provide guidance on the application of reduced designs (*i.e.,* bracketing and matrixing) for stability studies conducted in accordance with the principles outlined in VICH GL3(R).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT: Mai Huynh, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0670, *mai.huynh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Six observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, one representative from the industry of Canada, one representative from the government of South Africa, and one representative from the industry of South Africa. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Guidance on Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products

In the **Federal Register** of July 21, 2009 (74 FR 35875), FDA published a notice of availability for a draft guidance entitled ''Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products'' (VICH GL45) giving interested persons until August 20, 2009, to comment on the draft guidance. FDA did not receive comments on the draft guidance. Comments received by other VICH member regulatory agencies were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated July 20, 2009. The final guidance is a product of the Expert Quality Working Group of the VICH.

This VICH guidance document provides guidance on bracketing and matrixing study designs. Specific principles are defined in this guidance for situations in which bracketing or matrixing can be applied. This VICH guidance document is intended to address recommendations on the application of bracketing and matrixing to stability studies conducted in accordance with principles outlined in the VICH guidance GFI #73 entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision) VICH GL3(R)'' that published in the **Federal Register** of November 23, 2007 (72 FR 65751).

III. Significance of Guidance

This guidance, developed under the VICH process, has been revised to conform with FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather ''guideline.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirements,'' unless FDA is using these words to describe a statutory or regulatory requirement. The guidance represents the current thinking of FDA on Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of applicable statutes and regulations.

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]

BILLING CODE 4164–01–P

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