Tobacco Products Scientific Advisory Committee (TPSAC)

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)
FDA White Oak Conference Center
Building 31, Room 1503
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 6-7, 2019

These summary minutes for the February 6-7, 2019 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on February 28, 2019.

I certify that I attended the February 6-7, 2019 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

_____/s/_____
Caryn Cohen, MS
Designated Federal Officer, TPSAC

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Robin J. Mermelstein, PhD
Chair, TPSAC

Meeting of the Tobacco Products Scientific Advisory Committee

February 6-7, 2019

The Tobacco Products Scientific Advisory Committee (TPSAC) of the Food and Drug Administration, Center for Tobacco Products (CTP) met on February 6-7, 2019 at the FDA White Oak Conference Center, Building 31, Room 1503, 10903 New Hampshire Avenue, Silver Spring, MD 20993. Prior to the meeting, committee members and invited participants were provided copies of the background materials from the FDA and the applicant, and the submissions from the public. The meeting was called to order by Robin J. Mermelstein, PhD (Chair); the conflict of interest statement was read into the record by Caryn Cohen, MS (Designated Federal Officer). There were approximately 75 persons in attendance. There were seventeen speakers for the Open Public Hearing (five for the first session and 12 for the second).

Agenda: *On February 6-7, 2019, the Committee convened for two sessions. The first session convened on February 6, 2019, during which the Committee discussed an amendment to the modified risk tobacco product applications (MRTPAs), submitted by Swedish Match North America for the following snus smokeless tobacco products:MR0000020: General Loose; MR0000021: General Dry Mint Portion Original Mini; MR0000022: General Portion Original Large; MR0000024: General Classic Blend Portion White Large-12ct; MR0000025: General Mint Portion White Large; MR0000027: General Nordic Mint Portion White Large-12ct; MR0000028: General Portion White Large; and MR0000029: General Wintergreen Portion White Large. The second session convened, after the first session concluded, on February 6, 2019 and continued when the Committee reconvened on February 7, 2019. During the second session the Committee discussed the modified risk tobacco product application (MRTPA), submitted by Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company LLC for the following smokeless tobacco product:MR0000108 Copenhagen Snuff Fine Cut.*

Attendance:

TPSAC Members Present (Voting):
Robin J. Mermelstein, PhD (Chair)
Laura J. Bierut, MD
Sonia A. Duffy, PhD, RN, FAAN (*Representative of the General Public)*
Sara P. Herndon, MPH (Employee of a state or local government or of the Federal Government)
Richard O'Connor, PhD
Deborah J. Ossip, PhD
James F. Thrasher, PhD
Kenneth E. Warner, PhD
Michael Weitzman, MD

Industry Representative Members Present (Non-voting):
William Andy Bailey, PhD *(Representative of the interests of tobacco growers)*
Willie McKinney, PhD, DABT *(Representative of the interests of the tobacco manufacturing industry)*
David M. Johnson, PhD *(Representative of the interests of small business tobacco manufacturing industry)*

Ex Officio Participants Present (Non-Voting):
Brian King, PhD, MPH (CDC)
Kay L. Wanke, PhD, MPH (NIH)

Consultants Present (Non-Voting):
Lynn Kozlowski, PhD
Olivia Wackowski, PhD, MPH
Irina Stepanov, PhD

FDA Participants (Non-Voting):
Mitchell Zeller, JD
Matthew R. Holman, PhD
Benjamin J. Apelberg, PhD, MHS

Designated Federal Officer:
Caryn Cohen, MS

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The agenda on February 6-7, 2019 was as follows:

February 6, 2019
<u>Session 1 – Swedish Match Amendment</u>

Call to Order	Robin J. Mermelstein, PhD Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Officer Office of Science, FDA/CTP
Introduction of Committee Members	Robin J. Mermelstein, PhD Chair, TPSAC
Swedish Match USA, Inc. Modified Risk Tobacco Product Amendment	Benjamin Apelberg, PhD Director, Population Health Science Office of Science, FDA/CTP

<u>Applicant Presentation</u>

Swedish Match Overview Presentation	Fredrik Peyron Sr. Vice President for Regulatory Affairs & Group Communications

<u>FDA Presentation</u>:

Swedish Match USA, Inc. Modified Risk Tobacco Product Application Amendment: Consumer Understanding and Intentions	Alexander Persoskie, PhD Social Scientist, Population Health Science Office of Science, FDA/CTP

Clarifying Questions

Open Public Hearing
<u>Speakers</u>:
- Matt Myers
- Gregory Conley
- Alex Clark
- Carrie Wade
- Michael W. Ogden

Committee Questions and Discussion
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Session 2 – Altria Client Services LLC Application on behalf of U.S. Smokeless Tobacco Company LLC

Call to Order	Robin J. Mermelstein, PhD Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Officer Office of Science, FDA/CTP
Introduction of Committee	Robin J. Mermelstein, PhD Chair, TPSAC
U.S. Smokeless Tobacco Company LLC (USSTC) Modified Risk Tobacco Product Application	Benjamin Apelberg, PhD Director, Population Health Science Office of Science, FDA/CTP

Applicant Presentations:

Introduction	Jose Luis Murillo, JD Senior Vice President, Regulatory Affairs Altria Client Services LLC
Scientific Evidence	Mohamadi Sarkar, MPharm, PhD, FCCP Fellow, Regulatory Affairs Altria Client Services LLC
Health Risk	Gary Harvey Vice President and Principal Consultant William E. Wecker Associates, Inc.
Claim Development and Testing	Stephanie Plunkett, PhD Senior Director, Perception and Behavior Research Altria Client Services LLC
Population Impact	Ryan Black, Ph.D. Director, Regulatory Affairs Altria Client Services LLC
Conclusion	Jose Luis Murillo, JD Senior Vice President, Regulatory Affairs Altria Client Services LLC

FDA Presentation:

U.S. Smokeless Tobacco Company LLC (USSTC) Modified Risk Tobacco Product Application: FDA Scientific Presentation	Benjamin Apelberg, PhD Director, Population Health Science Office of Science, FDA/CTP

Clarifying Questions

Adjourn

February 7, 2019
Session 2 (*continued*):

Call to Order	Robin J. Mermelstein, PhD Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Officer Office of Science, FDA/CTP
Introduction of Committee	Robin J. Mermelstein, PhD Chair, TPSAC

Open Public Hearing

Speakers:

- Thomas Briant
- Alex Clark
- Ronald Conyea
- Paul Blair
- Ross Marchand
- Scott D. Ballin
- Guy Bentley
- Michael W. Ogden
- Carrie Wade
- Matt Myers
- Naomi Lopez-Bauman
- Lindsay Mark Lewis

Committee Discussion

Committee Questions and Discussion

Adjourn

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***Questions to the Committee*:**

General Snus MRTPAs (Session 1):

FDA's preliminary assessment of the amendment finds that the applicant has addressed previous concerns by proposing a modified risk claim that is (a) more specific and (b) independent of the warning label; and by conducting a new consumer perception study that does not suffer from the methodological flaws of their original study.

Q1: DISCUSS FDA's preliminary assessment, including whether the revised modified risk claim raises new or additional concerns regarding the potential impact on:

a. consumer understanding; and
b. population health.

Committee Discussion: The Committee largely agreed on the importance of providing accurate information about the relative harms of different kinds of tobacco products. The Committee acknowledged that labeling in general is very challenging, and that constructing wording that relays a perfectly accurate message to
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every unique group and sub-group is likely not possible. Within this context, the applicant's study was reasonable, and their proposed modified risk claim seems to convey a relatively accurate message.

The Committee highlighted the importance of strategic post market surveillance for any product that obtains marketing authorization as a modified risk tobacco product (MRTP).

Copenhagen Snuff Fine Cut MRTPA (Session 2):

Q1: The applicant proposed the following modified risk claim: "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer."

DISCUSS the available scientific evidence and VOTE on the extent to which the proposed modified risk claim is scientifically accurate. (yes/no/abstain)

Committee Discussion and Vote: Overall the Committee agreed that the proposed claim was accurate based on the strength of the scientific evidence. Eight of the nine voting members voted "yes' on this question. One member chose to abstain, noting concern about potential confounding factors such as length of smoking history, genetic risk, or other risk factors that may impact the statement on an individual basis. Still, the simple and specific-to-lung-cancer nature of the statement was noted by the abstaining member.

Q2: In addition to evaluating the proposed modified risk claim for scientific accuracy, FDA also evaluates consumer understanding and perception of the modified risk information in the advertising.
DISCUSS the potential implications of the proposed modified risk information on consumer understanding and perceptions.

Committee Discussion: Overall the Committee expressed the opinion that this was a clear and focused statement that could inform consumers' understanding of comparative risk. There was some concern about whether the wording, "switching completely" adequately conveyed the need to stop smoking altogether. However, overall there seemed to be no evidence that the proposed message was harmful or that people interpreted it as meaning the product was risk-free.

Q3: DISCUSS the potential users of the proposed MRTP.

a. What is the likelihood that cigarette smokers will switch completely to Copenhagen Snuff Fine Cut?
b. Considering the health risks from the use of Copenhagen Snuff Fine Cut and those who may be likely to use the product, what are the groups of potential concern (e.g., users of smokeless tobacco products with lower HPHC levels, youth)?

Committee Discussion: Given how difficult it is to quit smoking completely, and the product's past lack of popularity as compared to cigarettes, it seems unlikely that there would be a substantial change in smokers' behavior resulting from the proposed modified risk claim. However, it is extremely difficult to predict behavior, making post market surveillance essential, with a focus on vulnerable groups such as: youth and young adults; groups (particularly youth) who may initiate tobacco use based on the perception of less risk; former smokers who may return to tobacco use based on the perception of lower risk; and users of smokeless products with fewer harmful and potentially harmful constituents (HPHCs) who may switch to a product with a modified risk claim, based on the perception that it is safer. It will also be important to look for positive change, that is, smokers who stop smoking completely and switch to a product with a modified risk claim.

The meeting adjourned at 11:45 a.m. on February 7, 2019.

Please see the verbatim transcript for details of the discussion.