

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

September 13-14, 2018

These summary minutes for the September 13-14, 2018 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on October 8, 2018.

I certify that I attended the September 13-14, 2018 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

_____/s/_____
Robin J. Mermelstein, PhD
Chair, TPSAC

Meeting of the Tobacco Products Scientific Advisory Committee

September 13-14, 2018

The Tobacco Products Scientific Advisory Committee (TPSAC) of the Food and Drug Administration, Center for Tobacco Products (CTP) met on September 13-14, 2018 at the FDA White Oak Conference Center, Building 31, Room 1503, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002. 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 150 persons in attendance. There were ten speakers for the Open Public Hearing session.

Agenda: *On September 13-14, 2018, the Committee discussed modified risk tobacco product applications (MRTPAs), submitted by R.J. Reynolds Tobacco Company for six products: MR0000068: Camel Snus Frost, MR0000069: Camel Snus Frost Large, MR0000070: Camel Snus Mellow, MR0000071: Camel Snus Mint, MR0000072: Camel Snus Robust, and MR0000073: Camel Snus Winterchil.*

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*)

Gary A. Giovino, PhD

Sara P. Herndon, MPH (Employee of a state or local government or of the Federal Government)

Deborah J. Ossip, PhD

James F. Thrasher, 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):

Alberta Becenti, MPH (IHS)

Brian King, PhD, MPH (CDC)

Kay L. Wanke, PhD, MPH (NIH)

Consultants Present (Non-Voting):

Michael Blaha, MD, MPH

Lynn Kozlowski, PhD

Scott Tomar, DMD, MPH

Olivia Wackowski, PhD, MPH

Speaker:

Irina Stepanov, PhD

FDA Participants (Non-Voting):

Mitchell Zeller, JD
Matthew R. Holman, PhD
Deirdre Kittner, PhD, MPH

Designated Federal Officer:

Caryn Cohen, MS

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*The agenda on September 13-14, 2018 was as follows:*

**September 13, 2018**

|                                                                                                             |                                                                                                                            |
|-------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| Call to Order                                                                                               | Robin J. Mermelstein, PhD<br>Chair, TPSAC                                                                                  |
| Conflict of Interest Statement                                                                              | Caryn Cohen, MS<br>Designated Federal Officer<br>Office of Science, FDA/CTP                                                |
| Introduction of Committee Members                                                                           | Robin J. Mermelstein, PhD<br>Chair, TPSAC                                                                                  |
| Opening Remarks                                                                                             | Matthew R. Holman, PhD<br>Director<br>Office of Science, FDA/CTP                                                           |
| Modified Risk Tobacco Product Applications                                                                  | Deirdre Lawrence Kittner, PhD, MPH<br>Deputy Director, Division of Population Health Science<br>Office of Science, FDA/CTP |
| Toxic and Carcinogenic Constituents in Camel Snus and Other Smokeless Tobacco Products Marketed in the U.S. | Irina Stepanov, PhD<br>Associate Professor<br>University of Minnesota                                                      |

**R.J. Reynolds, Presentations:**

|              |                                                                                                    |
|--------------|----------------------------------------------------------------------------------------------------|
| Introduction | Michael Ogden, PhD<br>Senior Vice President, Scientific & Regulatory Affairs, RAI Services Company |
| Epidemiology | Kristin Marano, MPH, PhD, CPH<br>Director, Scientific & Regulatory Affairs, RAI Services Company   |

Clinical and Preclinical Research

Elaine Round, PhD  
Senior Director, Scientific & Regulatory Affairs,  
RAI Services Company

Risk Perceptions, Comprehension,  
and Likelihood of Use

Saul Shiffman, PhD  
Senior Scientific Advisor, Pinney Associates  
Professor of Psychology, Psychiatry,  
Pharmaceutical Sciences  
and Clinical Translational Science, University of  
Pittsburgh

Population Health Benefit for Camel  
Snus with Modified-Risk Advertising

Geoffrey Curtin, PhD  
Senior Director, Scientific & Regulatory Affairs,  
RAI Services Company

Conclusions

Michael Ogden, PhD  
Senior Vice President, Scientific & Regulatory  
Affairs, RAI Services Company

**FDA Presentations:**

Evidence Related to Substantiation of the  
Modified Risk Information

Mimy Young, PhD  
Division of Product Science  
Office of Science, FDA/CTP

Catherine Corey, MSPH  
Division of Population Health Science  
Office of Science, FDA/CTP

Use and Consumer Perceptions of the  
Proposed MRTPs

Erin Keely O'Brien, PhD  
Division of Population Health Science  
Office of Science, FDA/CTP

Committee Discussion

Adjourn

**September 14, 2018**

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

Open Public Hearing Session Speakers:

- Dennis Hennigan, Campaign for Tobacco-Free Kids
- Nicolas John, R Street Institute
- Gregory Conley, American Vaping Association
- Greg Wilson, Altria Client Services
- Alex Clark, Consumer Advocates for Smoke-free Alternatives Assoc. (CASAA)
- Guy Bentley, Reason Foundation
- David Abrams, New York University College of Global Public Health
- Scott Ballin, Health Policy Consultant
- Jack Mitchell, National Center for Health Research (NCHR)
- Mark Greenwold for Lauren Lempert, University of California, Center for Tobacco Control Research & Education

FDA’s Questions to TPSAC on RJRT’s Camel Snus MRTPAs

Deirdre Lawrence Kittner, PhD, MPH  
Deputy Director, Division of Population Health Science  
Office of Science, FDA/CTP

Committee Discussion of the Questions

Adjourn

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Questions to the Committee:

The applicant submitted modified risk tobacco product applications seeking orders under section 911(g)(1) of the FD&C Act for six Camel Snus products. To authorize a product under section 911(g)(1), the agency must find that the product, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole taking into account both users of tobacco products and those who do not currently use tobacco products.

1. The proposed modified risk claims that the applicant identifies as its “key” claims describe the reduction in risk for specific diseases as a result of completely switching to the six Camel Snus products from cigarettes.

DISCUSS the available scientific evidence and **VOTE** on the extent to which the available scientific evidence substantiates the following modified risk information in the applicant’s advertising: “Smokers who **switch completely** from cigarettes to Camel SNUS can significantly reduce their risk of...”

- a. lung cancer? **8 Yes**
- b. oral cancer? **3 Yes, 2 Abstain, 3 No**
- c. respiratory disease? **8 Yes**
- d. heart disease? **3 Yes, 2 Abstain, 3 No**

2. The applicant’s advertising also contains modified risk statements that describe a reduction in harmful chemicals in Camel Snus vs. cigarettes, or that are not as specific as those presented in Question 1 (e.g., do not reference reduction in specific diseases or the need for complete switching). All of these statements are being evaluated as part of the MRTPAs.

DISCUSS the available scientific evidence and **VOTE** on the extent to which the available scientific evidence substantiates the following modified risk information in the advertising:

- a. “...Camel SNUS contains less of the harmful chemicals than cigarettes”? **2 Yes, 3 Abstain, 3 No**
- b. “Smokers who use Camel SNUS instead of cigarettes can significantly reduce their health risks from smoking.” **1 Yes, 2 Abstain, 5 No**
- c. “Switching to snus means less risk for you.” **4 Yes, 1 Abstain, 3 No**
- d. “NO SMOKE = LESS RISK” **6 Yes, 1 Abstain, 1 No**

3. In addition to evaluating the proposed modified risk for scientific accuracy, FDA is also evaluating consumer understanding and perception of the modified risk information in the advertising. The applicant plans to communicate all of the modified risk information together, i.e., the first page has less specific modified risk information, while the second and third pages have more specific modified risk information and additional information the applicant refers to as “balancing information” (e.g., that Camel Snus and other tobacco products contain nicotine and are addictive; the recommendation that smokers concerned about the health risks of smoking should quit and talk to a healthcare provider).

DISCUSS potential implications of the proposed modified risk information, including the non-specific modified risk language, as described in Question 2, on consumer understanding and perceptions and tobacco use behavior:

- a. Can the non-specific modified risk information be misinterpreted?
- b. Is there sufficient evidence that consumers would understand the non-specific modified risk information?
- c. Is there sufficient evidence about the impact of the non-specific modified risk information on the likelihood of use?
- d. Is there sufficient evidence about the impact of the non-specific modified risk information on poly tobacco use or partial switching?

The TPSAC noted a lack of specificity in some of the proposed claims. For example, “switching” could be interpreted as complete switching or partial switching; “reduce health risks” may refer to specific health risks or any risks associated with smoking; “harmful chemicals” does not identify which chemicals or in what proportions.

4. **DISCUSS** the potential users of the proposed MRTPs.

- a. What is the likelihood that cigarette smokers will switch completely to the six Camel Snus products?
- b. Are there other groups of potential users, particularly unintended users (e.g., youth, former cigarette smokers), of concern?

The TPSAC stressed the importance of considering the impact of the proposed claims on vulnerable populations such as, pregnant women, children and adolescents, and people with certain medical conditions. Additionally, they noted that people with low health literacy may have more difficulty correctly interpreting certain messaging. Moreover, the potential for abuse of these products, once an advertising campaign is launched, is largely unknown.

The committee stressed the need for effective post-market surveillance if/when any claims are authorized.

The meeting adjourned at 12:30 p.m. on September 14, 2018.

Please see the verbatim transcript for details of the discussion.