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

April 9-10, 2015

On April 9-10, 2015, the Committee will discuss modified risk tobacco product applications (MRTPAs) submitted by Swedish Match North America, Inc. for 10 tobacco products:

- MR0000020: General Loose, smokeless tobacco, loose snus, 1.59 oz (45g), cardboard can (SKU 4852);
- MR0000021: General Dry Mint Portion Original Mini, smokeless tobacco, snus portions, 0.21 oz (6g), 20—0.3g portions, plastic can (SKU 4800);
- MR0000022: General Portion Original Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24—1g portions, plastic can (SKU 4880);
- MR0000023: General Classic Blend Portion White Large, smokeless tobacco, snus portions, 0.48 oz (13.5g), 15—0.9g portions, plastic can (SKU 4877);
- MR0000024: General Classic Blend Portion White Large, smokeless tobacco, snus portions, 0.38 oz (10.8g), 12—0.9g portions, plastic can (SKU 4878);
- MR0000025: General Mint Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24—1g portions, plastic can (SKU 4876);
- MR0000026: General Nordic Mint Portion White Large, smokeless tobacco, snus portions, 0.48 oz (13.5g), 15—0.9g portions, plastic can (SKU 4876);
- MR0000027: General Nordic Mint Portion White Large, smokeless tobacco, snus portions, 0.38 oz (10.8g), 12—0.9g portions, plastic can (SKU 4875);
- MR0000028: General Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24—1g portions, plastic can (SKU 4881); and
- MR0000029: General Wintergreen Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24—1g portions, plastic can (SKU 4882).

April 9, 2015

8:30 Call to Order  
Philip P. Huang, MD, MPH  
Acting Chair, TPSAC

8:35 Conflict of Interest Statement  
Caryn Cohen, MS  
Designated Federal Official  
Office of Science, FDA/CTP

8:40 Introduction of Committee Members  
Philip P. Huang, MD, MPH  
Acting Chair, TPSAC

8:45 Opening Remarks  
Mitchell Zeller, JD  
Director, FDA/CTP

9:00 Modified Risk Tobacco Product Applications  
CDR Raquel Peat, PhD, MPH  
Chief, Regulatory Project Management  
Branch IV  
Division of Regulatory Project Management  
Office of Science, FDA/CTP  
Conrad J. Choiniere, PhD  
Director, Division of Population Health Science  
Office of Science, FDA/CTP

9:30 Break
### Swedish Match North America, Inc., Presentations:

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation</th>
<th>Speaker</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>9:45</td>
<td>Introduction and Overview</td>
<td>Jim Solyst</td>
<td>Vice President, Federal Regulatory Affairs, Swedish Match North America</td>
</tr>
<tr>
<td></td>
<td>Scientific Literature Review Conducted by ENVIRO and Characterizing the Swedish Human Health Evidence</td>
<td>Dr. Joe Rodricks</td>
<td>Principal, ENVIRO</td>
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<tr>
<td></td>
<td>Description of the Evidence: Clinical Trials, Premarket Consumer Perception Study, and the Dynamic Population Modeler</td>
<td>Dr. Lars-Erik Rutqvist</td>
<td>Sr. Vice President, Scientific Affairs, Swedish Match</td>
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### Clarifying Questions

#### 12:00

Lunch

#### 1:00

**FDA Presentations:**

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<tr>
<td>1:00</td>
<td>Epidemiological Evidence Related to the SMNA MRTPA Snus Products and Gum Disease or Tooth Loss</td>
<td>Hannah R. Day, PhD</td>
<td>Epidemiologist, Office of Science, FDA/CTP</td>
</tr>
<tr>
<td></td>
<td>Epidemiological Evidence Related to SMNA Snus and Mouth Cancer</td>
<td>Cindy Chang, PhD, MPH</td>
<td>Epidemiologist, Office of Science, FDA/CTP</td>
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<tr>
<td></td>
<td>Overall Health Effects of Swedish Match Snus Products</td>
<td>Lester Jao Lacorte, MD, CCRP</td>
<td>Medical Officer, Office of Science, FDA/CTP</td>
</tr>
<tr>
<td></td>
<td>Applicability of Swedish Epidemiological Data to the United States</td>
<td>Bridget K. Ambrose, PhD, MPH</td>
<td>Epidemiologist, Office of Science, FDA/CTP</td>
</tr>
<tr>
<td></td>
<td>Consumer Understanding and Implications of Modified Risk Information in a Warning Label</td>
<td>Sarah Johnson, PhD</td>
<td>Social Scientist, Office of Science, FDA/CTP</td>
</tr>
<tr>
<td></td>
<td>Postmarket Surveillance and Studies</td>
<td>Benjamin Apelberg, PhD, MHS</td>
<td>Chief, Epidemiology Branch, Office of Science, FDA/CTP</td>
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### Clarifying Questions

#### 3:15

Break
3:30 Open Public Hearing

Geoffrey Curtin, RAI Services Company
Scott Ballin, Health Policy Consultant
Patricia Kovacevic, Lorillard Tobacco Co.
Lars Ramström, Institute for Tobacco Studies
Denny Hennigan, Campaign for Tobacco-Free Kids
Gal Cohen, PAX Labs

4:30 Committee Discussion

5:00 Adjourn

**April 10, 2015**

8:00 Call to Order Philip P. Huang, MD, MPH
Acting Chair, TPSAC

8:05 Conflict of Interest Statement Caryn Cohen, MS
Designated Federal Official
Office of Science, FDA/CTP

8:10 Introduction of Committee Members Philip P. Huang, MD, MPH
Acting Chair, TPSAC

8:15 Introduction of the Acting Commissioner, FDA Mitchell Zeller, JD
Director, FDA/CTP

Remarks Stephen Ostroff, MD
Acting Commissioner, FDA

8:30 Review of First Day and Conrad J. Choiniere, PhD
Questions to the Committee
Director, Division of Population
Health Science
Office of Science, FDA/CTP

Clarifying Questions

Committee Discussion

10:00 Break

10:15 Committee Discussion (continued)

12:00 Lunch

1:00 Committee Discussion (continued)

3:00 Break

3:15 Committee Discussion (continued)

5:00 Adjourn