DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
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From: Matthew R. Holman, Ph.D.
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To: Tobacco Products Scientific Advisory Committee (TPSAC)

Subject: April 6, 2017, TPSAC Meeting

Thank you for agreeing to participate in the upcoming meeting of the TPSAC.

Under section 910(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA may refer premarket tobacco product applications (PMTAs) to TPSAC. Section 911(f)(1) of the FD&C Act also directs FDA to refer modified risk tobacco product applications (MRTPAs) to TPSAC. On April 6, 2017, FDA will present information to TPSAC on the processes used in review of tobacco product applications. Topics will include the statutory standards applicable to the different types of applications, the scientific basis for review decisions, with a focus on PMTA and MRTPA, and the role of TPSAC in the review process.

Summary of Briefing Package Contents:

- Technical Project Lead (TPL) Reviews of the Swedish Match North America, Inc. Applications for:
  - Premarket Tobacco Product Applications (PMTAs)
  - Modified Risk Tobacco Product Applications (MRTPAs)

- Background Materials for the April 2015 TPSAC Meeting on MRTPAs Submitted by Swedish Match North America, Inc.:
  - FDA Briefing Document
  - Section 911 of the FD&C Act
  - Applicant Briefing Document

- FDA Presentations from the April 2015 TPSAC Meeting:
  - Modified Risk Tobacco Applications
  - Epidemiological Evidence Related to the SMNA MRTPA Snus Products and Gum Disease or Tooth Loss
  - Snus and Oral Cancer in Sweden

    - Overall Health Effects of Swedish Match Snus Products
    - Applicability of Swedish Epidemiological Data to the United States
    - Consumer Understanding and Implications of Modified Risk Information in a Warning Label
    - Postmarket Surveillance and Studies

- Draft Guidance Documents:
    - Applications for Premarket Review of New Tobacco Products
    - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)
    - Modified Risk Tobacco Product Applications

    - Proposed Topics for Discussion for April 6, 2017 (attached)

The TPL reviews are the most critical documents that you should read, as they provide an overall understanding of activities related to FDA's actions on these MRTPAs and PMTAs. The other background material is provided so that you have additional information if you would like more information than provided in the TPL reviews. It is also important to understand that we will not be evaluating any of the background material during the April 6th meeting. This material is provided in order for you to understand past actions related to PMTAs and MRTPAs and be prepared for discussion at the meeting. We look forward to seeing you on April 6th.

Proposed Topics for Discussion
Tobacco Products Scientific Advisory Committee Meeting
April 6, 2017

In relation to meeting preparation:

1. How was the information provided to the TPSAC prior to the 2015 meeting on the MRTPAs for the SMNA snus products helpful in preparing for the meeting?
2. How do you anticipate preparing for upcoming application review TPSAC meetings?
3. What information would be most useful to receive prior to an application review TPSAC meeting?
4. What information would likely be least useful prior to an application review TPSAC meeting?
5. How would having only an Executive Summary or only the sections of the application that FDA planned to discuss, compared to having the entire application, impact your ability to prepare for an application review TPSAC meeting and give advice to FDA?

In relation to the meeting itself:

1. How was the information provided during the presentations at the 2015 meeting on the MRTPAs for the SMNA snus products helpful in providing advice to FDA?
2. What information would be useful as part of the meeting presentations during an application review TPSAC meeting?
3. What information would *not* be useful as part of the meeting presentations during an application review TPSAC meeting?
4. How might the TPSAC meeting be structured so that the committee is best positioned to provide advice to FDA?