Note: revisions made by the TPSAC appear in *italics*.

With respect to the relative health risks to individual users of these snus products (i.e., the Swedish Match North America, Inc. snus tobacco products that are the subject of these applications):

1. Discuss the evidence regarding the association between the ten snus products and gum disease or tooth loss. Please address the following issues in your discussion.
   - Biological plausibility that gum disease or tooth loss in snus users would differ from those in users of other smokeless tobacco products;
   - Confidence in the information from studies that only include young adults under the age of 25, given that the prevalence of periodontal disease increases with age;
   - Confidence in the information on tooth loss from the use of snus, where the studies presented in the application evaluated the number of teeth between snus users and non-users in cross-sectional studies;
   - Sufficiency of information from studies where the number of snus users in many of the cross-sectional surveys was fewer than 50.
   
   a. Does the evidence support that these snus products do not pose risks of gum disease to individual users of these products? (vote)
   b. Does the evidence support that these snus products do not pose risks of tooth loss to individual users of these products? (vote)

2. Discuss the evidence regarding the association between these ten snus products and oral cancer.
   a. Does the evidence support that these snus products do not pose risks of oral cancer to individual users of these products? (vote)

3. Discuss the evidence regarding the association between the ten snus products and overall risks to health as compared to cigarettes.
   a. Should the comparison focus on the major smoking-related diseases according to population burden or assess all relevant health outcomes? (vote)
   b. Does the evidence support the statement that health risks to individual users from using these snus products exclusively, are “substantially lower” than the health risks from smoking cigarettes? (vote)
   c. Does the evidence support that the proposed warning statement adequately communicates the potential health risks to individual users of these snus products? (vote)

4. Assuming that the behavior of U.S. population does mimic those in Sweden with respect to the use of snus, what information would the Committee need to know about the snus products that are used in Sweden and the snus products that are the subject of these applications in order to have confidence that the health outcomes observed in Sweden would also be observed in the U.S.? For example, would it be sufficient to know that the exposures to individual users of the Swedish products are comparable to the exposures to individual users of these snus products, or would knowledge about other characteristics of the tobacco product be needed to determine that the health outcomes would likely be comparable?
With respect to the likelihood that existing users of tobacco products who would otherwise stop using those products will instead switch to these snus tobacco products, and the likelihood that persons who do not use tobacco products will start using these snus tobacco products:

5. Discuss the evidence regarding the likely impact of these ten snus products on tobacco use behaviors among tobacco users and non-users.
   a. Does the Committee believe that the epidemiological data from Sweden concerning tobacco use behavior provide relevant information on the:
      i. The likelihood that current tobacco users in the U.S. will switch to the use of these snus products? (vote)
      ii. The likelihood that non-users of tobacco in the U.S. will initiate the use of these snus products? (vote)
   b. The applications did not include several types of studies that could be useful in order to assess impacts on behavior, such as actual use studies, self-selection studies, or other behavioral studies. Does the Committee believe that the applications include sufficient information on the behavioral aspects of the use of these snus products among the U.S. population? (vote)

With respect to enabling consumers to comprehend the modified risk information and understand its relative significance in the context of total health: (time permitting)

6. The applicant proposes to include modified risk information within a warning label. FDA has potential concerns that inclusion of information about relative benefits of product use within a warning label may raise additional questions regarding consumer comprehension of the modified risk information and perceptions of the product.
   a. From the perspective of enabling consumers to understand the modified risk information in the context of total health, does the Committee believe it is appropriate to include modified risk information within the context of the required warning label as opposed to in a statement separate from, and in addition to, the warning label? (vote)

With respect to postmarket surveillance and studies to be conducted by Swedish Match North America, Inc.: (time permitting)

7. If FDA were to issue an order allowing the marketing of these snus products as modified risk tobacco products, what recommendations does the Committee have for postmarket surveillance and studies?
   a. What elements should Swedish Match North America, Inc. include in a postmarket surveillance and studies program in order to monitor product use transitions for these snus products, which may have a low prevalence of use?
   b. What methods does the Committee recommend that Swedish Match North America, Inc. employ for assessing the impact of a specific modified risk tobacco product marketing on perceptions and behavior in a postmarket setting, particularly among youth?
   c. What sources of data does the Committee recommend that Swedish Match North America, Inc. use for providing information on impacts resulting from the marketing of the products as modified risk tobacco products?
   d. What additional information does the Committee recommend that FDA request from the applicant regarding plans to conduct postmarket surveillance and studies?