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? (yes/no/abstain)
   b. oral cancer? (yes/no/abstain)
   c. respiratory disease? (yes/no/abstain)
   d. heart disease? (yes/no/abstain)

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 cigarette smoke"? (yes/no/abstain)
   b. "Smokers who use Camel SNUS instead of cigarettes can significantly reduce their health risks from smoking." (yes/no/abstain)
   c. "Switching to snus means less risk for you." (yes/no/abstain)
   d. "NO SMOKE = LESS RISK" (yes/no/abstain)

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?

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?