Meeting of the Tobacco Products Scientific Advisory Committee
February 6-7, 2019

Questions

General Snus MRTPAs:

FDA's preliminary assessment of the amendment finds that the applicant has addressed previous concerns by proposing a modified risk claim that is (a) more specific and (b) independent of the warning label; and by conducting a new consumer perception study that does not suffer from the methodological flaws of their original study.

Q1: DISCUSS FDA's preliminary assessment, including whether the revised modified risk claim raises new or additional concerns regarding the potential impact on:

a. consumer understanding; and
b. population health.

Copenhagen Snuff Fine Cut MRTPA:

Q1: The applicant proposed the following modified risk claim: "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer."

DISCUSS the available scientific evidence and VOTE on the extent to which the proposed modified risk claim is scientifically accurate. (yes/no/abstain)

Q2: In addition to evaluating the proposed modified risk claim for scientific accuracy, FDA also evaluates consumer understanding and perception of the modified risk information in the advertising.

DISCUSS the potential implications of the proposed modified risk information on consumer understanding and perceptions.

Q3: DISCUSS the potential users of the proposed MRTP.

a. What is the likelihood that cigarette smokers will switch completely to Copenhagen Snuff Fine Cut?
b. Considering the health risks from the use of Copenhagen Snuff Fine Cut and those who may be likely to use the product, what are the groups of potential concern (e.g., users of smokeless tobacco products with lower HPHC levels, youth)?