

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC) Meeting

January 22, 2026

DRAFT QUESTIONS

DISCUSSION 1: Accuracy of Proposed Modified Risk Claim

Background

- The proposed modified risk claim: “Using ZYN instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”
- The majority of HPHCs are below the level of quantification in ZYN, and the biomarker study of people who use nicotine pouches are consistent with the product chemistry data.
- In absence of long-term health risk studies of nicotine pouches, Swedish snus epidemiological studies show that snus use is lower risk compared to combusted cigarette smoking for mouth cancer, heart disease, stroke, lung cancer, emphysema, and chronic bronchitis.

Discuss whether the proposed modified risk claim is substantiated by the scientific evidence.

DISCUSSION 2: Consumer Understanding and Perceptions

Background

- The applicant provided evidence about whether consumers understood:
 - The risk reduction described in the claim (i.e., ZYN confers lower risk than combusted cigarettes).
 - Although conferring lower risk than combusted cigarettes, ZYN still confers health risks.
 - How to use ZYN to confer lower health risks.

Discuss the available evidence about consumers’ understanding of the proposed modified risk claim and their perceptions of ZYN.

DISCUSSION 3: Impact to People Who Use Combusted Cigarettes

Background

- Nicotine pouch use is most common among adults who recently quit other tobacco products.
- 24% of participants in the PMTA Patterns of Use study who used ZYN completely switched from other tobacco products to ZYN by the end of a 10-week study.

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DRAFT QUESTIONS (cont.)

- In the Consumer Perceptions and Likelihood of Use study, viewing the proposed claim did not impact intentions to use ZYN among those who were using tobacco products.

If ZYN is marketed with the proposed claim, discuss the evidence regarding the likelihood that people who currently use combusted cigarettes will completely switch to ZYN, and/or will dual use ZYN and combusted cigarettes long-term.

DISCUSSION 4: Impact to People Who Do Not Use Tobacco Products

Background

- Based on the information currently available, youth use of nicotine pouches is relatively low.
- Viewing the proposed claim did not increase intentions to use ZYN.

If ZYN is marketed with the proposed claim, discuss the evidence regarding the likelihood that persons who do not use tobacco products will start using ZYN.