

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC) Meeting

October 7, 2025

DRAFT QUESTIONS

1. DISCUSSION: IQOS and nonclinical toxicity evidence

Background: The findings from most nonclinical toxicological studies published since the issuance of the modified risk granted orders (MRGOs) and reviewed by FDA did not identify new toxicological concerns about IQOS. However, four newly published nonclinical studies that used rodent models to study IQOS aerosol exposure found that exposure to IQOS aerosols had respiratory, cardiovascular, and reproductive/developmental toxic effects that were comparable to or more severe than CC smoke exposure (Gu et al., 2023; Nitta et al., 2022; Qiu et al., 2023; Yoshida et al., 2020).

Discuss the strength of the noncancer toxicity evidence from those four animal studies in the context of the totality of toxicological evidence, including any limitations of these and other studies that may limit their conclusions.

2. DISCUSSION: Totality of evidence and long-term disease risk

Background: There is evidence of large overall reductions in harmful and potentially harmful constituents (PHHCs) in IQOS aerosols compared to CC smoke; however, newly available nonclinical data from predictive computational toxicology studies and rodent models raise questions about the genotoxic and noncancer toxicological effects of exposure to IQOS aerosols.

Consider the totality of the toxicological evidence that is now available and discuss the implications for long-term disease risks of exposure to IQOS aerosols relative to CC.

3. DISCUSSION: IQOS patterns of use

Background: The applicant was unable to conduct all planned PMSS, including the cohort study designed to evaluate the impact of marketing IQOS with the authorized modified risk claim on tobacco product use behavior. Accordingly, FDA received limited evidence regarding the impact of marketing IQOS with the claim on patterns of tobacco use.

Discuss the likely patterns of IQOS use behavior when marketed as an MRTP in the U.S. Based on the available evidence, consider the likely patterns of use with a specific focus on the likelihood that people who use CC will switch completely to IQOS and the likelihood that they will dual use IQOS and CC.