

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)
Tobacco Products Scientific Advisory Committee (TPSAC)

Questions for the Committee
January 24-25, 2018

1. Discuss evidence related to the health risks of the *IQOS* system and the appropriateness of the proposed modified risk information.
 - a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: “Scientific studies have shown that switching completely from cigarettes to the *IQOS* system can reduce the risks of tobacco-related diseases.”? **(Vote)**
 - b. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: “Switching completely to *IQOS* presents less risk of harm than continuing to smoke cigarettes.”? **(Vote)**

2. Discuss evidence related to human exposure to harmful or potentially harmful chemicals when combusted cigarette smokers completely switch to the *IQOS* system, including the implications of changes in exposure for long-term disease risk and the appropriateness of the proposed modified risk information.
 - a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: “Scientific studies have shown that switching completely from cigarettes to the *IQOS* system significantly reduces your body’s exposure to harmful or potentially harmful chemicals.”? **(Vote)**
 - b. If the answer to question 2a is “yes”, has the applicant demonstrated that the reductions in exposure are reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality? **(Vote)** *[To be answered by Committee members who voted “yes” to 2a.]*

3. Discuss evidence regarding the likelihood that existing combusted cigarette smokers will initiate use of the *IQOS* system, completely switch to *IQOS*, and/or become long-term dual users of *IQOS* and combusted cigarettes.
 - a. What is the likelihood that that U.S. smokers would completely switch to use of the *IQOS* system? **(High/Medium/Low)**
 - b. What is the likelihood that U.S. smokers would become long-term dual users of *IQOS* and combusted cigarettes? **(High/Medium/Low)**

4. Discuss evidence regarding the likelihood that persons who do not use tobacco products will start using the *IQOS* system.
 - a. What is the likelihood that U.S. never smokers, particularly youth, will become established users of the *IQOS* system? **(High/Medium/Low)**
 - b. What is the likelihood that former smokers will re-initiate tobacco use with the *IQOS* system? **(High/Medium/Low)**

5. Discuss evidence regarding consumer comprehension and perceptions of the proposed modified risk labeling and advertising.
 - a. Has the applicant demonstrated that, after viewing the proposed modified risk labeling and advertising, consumers accurately understand the risks of *IQOS* use as conveyed in the modified risk information? **(Vote)**
 - b. What additional information, if any, needs to be communicated, other than what has been proposed by the applicant, for consumers to understand the health risks of the *IQOS* system?