Topics for Discussion

At the meeting, FDA will present to the Advisory Committee some of the requirements related to the marketing of modified risk tobacco products (MRTP). The Committee will also hear presentations from others regarding the assessment of product risks to individuals and to the population as a whole. After the presentations, FDA will ask TPSAC to consider scenarios of hypothetical MRTPs.

During the discussion of the scenarios, FDA seeks input from the Committee on the following topics:

1. How would you recommend that FDA evaluate the relative health risks to individuals of the MRTP?

2. How would you recommend that FDA evaluate the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the MRTP?

3. How would you recommend that FDA evaluate the increased or decreased likelihood that persons who do not use tobacco products will start using the MRTP?

4. How would you recommend that FDA evaluate the risks and benefits to persons from the use of the MRTP as compared to the use of drug or device products for smoking cessation approved by the FDA to treat nicotine dependence?

5. How might FDA collectively evaluate the information related to topics 1-4 in order to determine the potential effects of an MRTP on the health of the population?