MEMORANDUM

DATE: August 13, 2013
FROM: Director, Office of Science, Center for Tobacco Products, FDA
TO: Tobacco Products Scientific Advisory Committee (TPSAC)
SUBJECT: August 16 Meeting of the Tobacco Products Scientific Advisory Committee (TPSAC)

Thank you for your participation in the upcoming meeting of the TPSAC.

This meeting will provide the opportunity for the Center for Tobacco Products (CTP) to elicit comments from the TPSAC and the public regarding how FDA may evaluate the effects of a proposed modified risk tobacco product (MRTP) on the health of individual tobacco users and the population as a whole. The Committee will be asked to consider how FDA might evaluate information regarding:

- the relative health risks to individuals of the MRTP;
- the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the MRTP;
- the increased or decreased likelihood that persons who do not use tobacco products will start using the MRTP; and,
- 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.

At this meeting, FDA will provide an overview of Section 911 of the Food, Drug & Cosmetic (FD&C) Act, which relates to modified risk tobacco products.

Summary of Briefing Package Contents:

- Excerpt from the FD&C Act: Sections 911
- Topics for Discussion

We look forward to seeing you on August 16th.