MEMORANDUM OF CONVERSATIONS

Friday, May 24th, 2013 Friday, June 7, 2013 Thursday, June 27, 2013 *Via Conference Calls*

Participants: Ashley Ross – Center for Tobacco Products (CTP)

Joelle Lester, Staff Attorney, Tobacco Control Legal Consortium (TCLC), Desmond Jensen, Staff Attorney, (TCLC), Petitioning the FDA

Subject: Procedural Questions re Citizen Petition to the FDA Related to Prohibiting Menthol as a Characterizing Flavor in Cigarettes

Friday, May 24th, 2013

- Petitioners asked CTP Office of Policy (OP) staff the criteria for when FDA issues an FR notice to announce the opening of a Citizen Petition (CP) docket. Specifically, petitioners asked if there would be a notice for the menthol CP, and if not, if one could be requested.
- CTP staff immediately directed this procedural question to the Center's Office of Regulations (OR).

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- Upon instruction from OR and OP leadership, CTP staff explained to the petitioners that:
 - o Issuing a notice for a CP docket is at the discretion of the Commissioner
 - CTP staff must follow established procedures for reviewing and responding to the petition, including
 - not being able to discuss the petition with the petitioners, and
 - following appropriate protocol for formal acknowledgement of the petitioners' inquiry and CTP staff response
- CTP staff told the petitioners that CTP was exploring this protocol and would be back in touch should additional action be required.

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• Upon further clarification from OR and OP leadership, CTP staff reported back to the petitioner that their inquiry and related conversations with CTP staff would be formally entered into the docket.

Ashley Ross Policy Analyst, Public Health Liaison Branch, Office of Policy, Center for Tobacco Products