FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 14, 2016

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss the strengths and weaknesses of the completed randomized controlled trial (RCT) with regard to the study design including the novel primary endpoint.

2. **DISCUSSION:** Discuss the potential impact of the variability in data collection, adverse event coding, and case definition on the primary endpoint. Because of this variability, discuss which analysis and results most appropriately describe the effect of the smoking cessation therapies on neuropsychiatric events.

3. **DISCUSSION:** Discuss how you weigh the evidence contributed by the observational studies when evaluating the risk of serious neuropsychiatric adverse events in patients taking smoking cessation products.

4. **DISCUSSION:** Based on the results of the clinical trial and observational studies, discuss the impact of psychiatric history on the occurrence of neuropsychiatric adverse events during smoking cessation therapy.

5. **VOTE:** Based on the data presented on the risk of serious neuropsychiatric adverse events with smoking cessation products, what would you recommend?

   A. Remove the boxed warning statements regarding risk of serious neuropsychiatric adverse event

   B. Modify the language in the boxed warning

   C. Keep the current boxed warning

6. **DISCUSSION:** Explain the rationale for your answer to #5, and discuss any additional labeling actions you think the Agency should take regarding the risk of serious neuropsychiatric adverse events with smoking cessation products.