

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

Nonprescription Drugs Advisory Committee (NDAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 18, 2019

DRAFT QUESTIONS

1. **DISCUSSION:** Discuss the efficacy of nicotine mouth spray (1mg per spray) as an over-the-counter (OTC) smoking cessation aid. Consider the differences between the efficacy data from studies A6431111 and NICTDP3038.
2. **DISCUSSION:** Discuss the results of the label comprehension study and its implications for efficacy in the OTC consumer setting.
3. **VOTE:** Do the data provide substantial evidence of efficacy of nicotine mouth spray (1mg per spray) as a smoking cessation aid in the OTC setting?
 - a. If no, what further data should be obtained?
4. **DISCUSSION:** Discuss the safety of nicotine mouth spray 1mg per spray as a smoking cessation aid in the OTC setting.
5. **DISCUSSION:** Discuss the potential for abuse of nicotine mouth spray (1 mg per spray) by the adult and pediatric populations in the OTC setting. Consider its pharmacokinetic profile and other characteristics that are different from currently marketed OTC nicotine replacement therapy products.
6. **VOTE:** Do the data provide substantial evidence of safety of OTC use of nicotine oral spray (1 mg per spray)?
 - a. If no, what further data should be obtained?
7. **VOTE:** Is the risk/benefit profile of nicotine mouth spray (nicotine 1 mg per spray) supportive of OTC use as a smoking cessation aid?
 - a. If yes, do you have additional comments or recommendations for labeling?
 - b. If no, what further data should be obtained?