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

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the Peripheral and Central Nervous System Drugs Advisory Committee (PCNS)
April 14, 2023

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss the overall benefit/risk assessment of brexpiprazole for the treatment of agitation associated with Alzheimer's dementia. In your discussion, take into consideration the following:
    - The increased risk of death among elderly patients with dementia receiving antipsychotic treatment
    - The risks of medications that are often used off-label for the treatment of agitation in dementia (e.g., antiepileptics, benzodiazepines) without established evidence of efficacy.

2. **DISCUSSION:** Discuss whether there is a population of patients with Alzheimer's dementia for whom the benefit/risk of brexpiprazole appears acceptable. Is there a population for whom the benefit/risk does not appear to be favorable?

3. **VOTE:** Has the Applicant provided sufficient data to allow identification of a population in whom the benefits of treating agitation associated with Alzheimer's dementia with brexpiprazole outweigh its risks?

    - If you do not believe the Applicant has provided sufficient data, what additional data is needed to support the use of brexpiprazole for the treatment of agitation associated with Alzheimer's dementia?