

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

Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
October 19, 2016

QUESTIONS

1. **DISCUSSION:** The Applicant's trials limited enrollment to adults at least 50 years of age, had numerous exclusion criteria, and had no restrictions on fluid intake.

Discuss whether the Applicant studied desmopressin in the appropriate patient population.

2. **DISCUSSION:** Discuss the clinical significance of the observed treatment effects of desmopressin on nocturia compared to placebo.
3. **DISCUSSION:** Discuss whether the safety of desmopressin has been adequately characterized, and whether additional safety data are needed.
4. **DISCUSSION:** Nocturia is a symptom that can be caused by many conditions, some of which may co-exist in the same patient.

Discuss whether the Applicant's proposed broad indication for the treatment of nocturia that does not specify the underlying etiology is clinically appropriate. If it is, discuss the adequacy of the Applicant's data to support this proposed indication, or whether additional data are necessary. If additional data are necessary, discuss what data would be needed to support the broad indication.

5. **VOTE:** Is there sufficient evidence to conclude that at least one of the desmopressin doses is effective?

Provide rationale for your answer. If you voted "Yes", specifically comment on which dose(s) are effective and whether the data support the proposed regimen of starting with 0.75 mcg nightly then titrating to 1.5 mcg nightly, if needed, after 2-4 weeks.

6. **VOTE:** Do the benefits of desmopressin outweigh the risks and support approval?

Provide rationale for your answer. If you voted "Yes," specify the indication that is supported by your benefit/risk assessment. If you voted "No," include recommendations for additional data that might support a favorable benefit/risk assessment.