

**FOOD AND DRUG ADMINISTRATION (FDA)**

Center for Drug Evaluation and Research (CDER)

*Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting*

November 4, 2021

**QUESTION**

---

---

1. **VOTE:** Has the Applicant provided substantial evidence of effectiveness for carbetocin nasal spray (LV-101) in the treatment of hyperphagia associated with Prader Willi syndrome?