

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

Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting
March 30, 2022

DRAFT QUESTIONS

1. **VOTE:** Do the data from the single randomized, controlled trial and the open-label extension study support a conclusion that sodium phenylbutyrate/taurursodiol is effective in the treatment of patients with amyotrophic lateral sclerosis (ALS)?
 - a. If you voted “no”, please discuss what additional information you would consider necessary to support a conclusion that sodium phenylbutyrate/taurursodiol is effective in the treatment of patients with ALS.