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

Oncologic Drugs Advisory Committee (ODAC) Meeting
October 4, 2023

QUESTIONS

NDA 215500

eflornithine tablets (DFMO)

Applicant: US WorldMeds

PROPOSED INDICATION:

- to reduce the risk of relapse in pediatric patients with high-risk neuroblastoma who have completed multiagent, multimodality therapy.

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1. **DISCUSSION**: Discuss the strengths and limitations of the externally controlled trial results to support the use of DFMO in pediatric patients with high-risk neuroblastoma.

2. **DISCUSSION**: Discuss the strengths and limitations of the additional nonclinical and clinical data to support the use of DFMO in pediatric patients with high-risk neuroblastoma.

3. **VOTE:** Has the Applicant provided sufficient evidence to conclude that DFMO improves event-free survival in patients with high-risk neuroblastoma?