

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
Oncologic Drugs Advisory Committee (ODAC) Meeting

October 4, 2023

DRAFT AGENDA

The Committee will discuss new drug application (NDA) 215500, for eflornithine tablets, submitted by USWM, LLC (doing business as US WorldMeds). The proposed indication (use) for this product is to reduce the risk of relapse in pediatric patients with high-risk neuroblastoma who have completed multiagent, multimodality therapy.

9:30 a.m.	Call to Order	Christopher H. Lieu, MD Acting Chairperson, ODAC
9:35 a.m.	Introduction of Committee/ Conflict of Interest Statement	Joyce Frimpong, PharmD Acting Designated Federal Officer, ODAC
9:40 a.m.	FDA Opening Remarks	Diana Bradford, MD Cross Disciplinary Team Leader Division of Oncology 2 (DO2) Office of Oncologic Drugs (OOD) Office of New Drugs (OND), CDER, FDA
10:00 a.m.	APPLICANT PRESENTATIONS	US WorldMeds
	Introduction	Kristen Gullo Vice President of Development and Regulatory Affairs US WorldMeds
	High-risk Neuroblastoma (HRNB) Unmet Need and DFMO Development History	Giselle Sholler, MD Division Chief Pediatric Hematology, Oncology and Bone Marrow Transplant Penn State Health Children's Hospital
	DFMO Efficacy	Thomas Clinch Senior Director Biometrics and Clinical Development US WorldMeds
	Clinical Perspective	Susan L. Cohn, MD Professor and Director of Clinical Sciences Department of Pediatrics University of Chicago Medicine
	Conclusion	Kristen Gullo

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
Oncologic Drugs Advisory Committee (ODAC) Meeting

October 4, 2023

DRAFT AGENDA (cont.)

10:50 a.m. **FDA PRESENTATIONS**

Eflornithine (DFMO) for patients with high-risk neuroblastoma who have completed multiagent, multimodality therapy

Elizabeth S. Duke, MD
Clinical Reviewer
DO2, OOD, OND, CDER, FDA

Arup Sinha, PhD
Statistics Reviewer
Division of Biometrics V
Office of Biostatistics (OB), CDER, FDA

Emily Wearne, PhD
Nonclinical Reviewer
Division of Hematology Oncology Toxicology (DHOT)
OOD, OND, CDER, FDA

11:40 a.m. Clarifying Questions

12:30 p.m. **LUNCH**

1:10 p.m. Charge to the Committee

Nicole Drezner, MD
Deputy Division Director
DO2, OOD, OND, CDER, FDA

1:15 p.m. **OPEN PUBLIC HEARING**

2:15 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **ADJOURNMENT**