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

Oncologic Drugs Advisory Committee (ODAC) Meeting

October 4, 2023

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**

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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**	