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

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Psychopharmacologic Drugs Advisory Committee (PDAC)

November 19, 2024

DRAFT AGENDA

The Committees will discuss the reevaluation of the Clozapine Risk Evaluation and Mitigation Strategy (REMS) and possible changes to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of clozapine.

8:30 a.m.	Call to Order and Introduction of Committee	**James Floyd, MD, MS** Acting Chairperson, DSaRM
8:35 a.m.	Conflict of Interest Statement	**Jessica Seo, PharmD** Acting Designated Federal Officer, DSaRM
8:40 a.m.	FDA Opening Remarks	**Tiffany R. Farchione, MD** Director Division of Psychiatry (DP) Office of Neurosciences (ON) Office of New Drugs (OND) CDER, FDA
8:50 a.m.	Clozapine Background & Regulatory History	**Leah Hart, PharmD** Risk Management Analyst Division of Risk Management (DRM) Office of Medication Error Prevention and Risk Management (OMEPRM) Office of Surveillance and Epidemiology (OSE) CDER, FDA
9:10 a.m.	**INDUSTRY PRESENTATIONS**	**Clozapine Product Manufacturers Group (CPMG)**
	Overview of Clozapine	**Jason A. Gross, PharmD** Vice President, Scientific Affairs HLS Therapeutics
	Clinical Context of Clozapine	**John M. Kane, MD** Professor, Department of Psychiatry and Molecular Medicine The Donald and Barbara Zucker School of Medicine at Hofstra/Northwell Institute of Behavioral Science, Feinstein Institutes for Medical Research

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DRAFT AGENDA (cont.)

	INDUSTRY PRESENTATIONS (CONT.)	
	Clinical Implications	**Robert O. Cotes, MD** Professor, Department of Psychiatry and Behavioral Sciences Emory University School of Medicine
	REMS Operation and Assessments	**James Shamp** Vice President, Data Intelligence and Program Analytics United BioSource (UBC)
	AE Reporting, Stakeholder Feedback, and Opportunities for Improvements	**Jason A. Gross, PharmD**
10:25 a.m.	Clarifying Questions	
10:55 a.m.	**BREAK**	
11:10 a.m.	**FDA PRESENTATIONS**	
	Summary of Studies Conducted for FDA's Re-Evaluation of the Clozapine REMS	**Cynthia LaCivita, PharmD** Director DRM, OMEPRM, OSE, CDER, FDA
	FDA's Updated Assessment of Severe Neutropenia and Gaps in Healthcare	**Carolyn Tieu, PharmD, MPH** Team Leader DRM, OMEPRM, OSE, CDER, FDA
12:05 p.m.	Clarifying Questions	
12:35 p.m.	**LUNCH**	
1:35 p.m.	**OPEN PUBLIC HEARING**	
3:05 p.m.	**BREAK**	
3:20 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	