

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

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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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**