

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

QUESTIONS

1. **DISCUSSION:** How reassured or concerned are you that current and potential clozapine healthcare providers have sufficient knowledge and access to resources about the risk of neutropenia and need for absolute neutrophil count (ANC) monitoring?

2. **DISCUSSION:** How reassured or concerned are you that current and potential clozapine healthcare providers will perform ANC monitoring without the requirements of the Risk Evaluation and Mitigation Strategy (REMS)?

3. **VOTE:** Are the requirements for the prescriber to document ANC results and the pharmacy to verify the ANC results through the REMS necessary to ensure safe use?
 - a. Yes.
 - b. No.

Please provide your rationale for your vote.

4. **VOTE:** Is the requirement to educate healthcare providers through the REMS about the risk of severe neutropenia and the need for ANC monitoring necessary to ensure safe use?
 - a. Yes.
 - b. No.

Please provide your rationale for your vote.