FDA is temporarily exercising additional enforcement discretion with respect to certain Clozapine REMS program requirements to ensure continuity of care for patients taking clozapine. FDA is aware health care professionals and patients continue to experience ongoing difficulties with the Clozapine REMS program, including issues with patient access to clozapine for patients recently discharged from an inpatient setting. To address the concern that inpatient pharmacies are only allowed to dispense a 7-days' supply of clozapine to the patient upon discharge, FDA does not intend to object if:

- Inpatient pharmacies dispense a days' supply of clozapine that aligns with the patient's monitoring frequency (e.g., weekly monitoring = 7 days' supply, twice monthly monitoring = 14 days' supply, monthly monitoring = 30 days' supply) upon discharge from an inpatient facility.

FDA continues to exercise the enforcement discretion announced in November 2021, including FDA does not intend to object if:

- Pharmacists dispense clozapine without a REMS dispense authorization (RDA).
- Wholesalers ship clozapine to pharmacies and health care settings without confirming enrollment in the REMS

Abrupt discontinuation of clozapine can result in significant complications for patient treatment. Health care professionals should use their clinical judgment with regard to prescribing and dispensing clozapine to patients with an absolute neutrophil count (ANC) within the acceptable range.

We understand that difficulties with the Clozapine REMS program have caused frustration and have led to problems with patient access to clozapine. FDA takes these concerns seriously. Continuity of care, patient access to clozapine, and patient safety are our highest priorities. We are working closely with the Clozapine REMS program administrators to address these challenges and to avoid interruptions in patient care.

We encourage pharmacists and prescribers to continue working with the Clozapine REMS to complete certification and prescribers should continue to enroll patients and submit the Patient Status Form.
If you have questions or concerns about the Clozapine REMS Program or its website, please contact FDA at druginfo@fda.hhs.gov, 1-855-543-3784 or 301-796-3400.

Dated: November 2, 2022