



**FDA REQUIRED
UPDATED REMS
SAFETY
INFORMATION**

ACTION NEEDED: Changes to the Clozapine REMS

- Subject:** - Current wholesalers/distributors must re-enroll in the Clozapine REMS
- Program changes effective November 15, 2021.
- **Request assistance with informing pharmacies of changes**

Dear Wholesaler/Distributor:

The Clozapine REMS requirements and REMS Administrator are changing. As a result, you will need to take action and re-enroll in order to continue distributing clozapine.

Starting November 15, 2021, you may only distribute clozapine when:

1. You re-enroll in the modified Clozapine REMS as a distributor through the Clozapine REMS,
2. The requesting pharmacy is certified in the modified Clozapine REMS, and
3. You verify the pharmacy's certification through the Clozapine REMS.

Please complete and return the enclosed Wholesaler-Distributor Registration Form by faxing it to 800-878-5927 by November 15, 2021 to ensure you may continue to distribute in the modified Clozapine REMS. Once your re-enrollment is complete, you will be contacted to coordinate receiving the new daily pharmacy eligibility file.

In addition, the Clozapine REMS Sponsors request your assistance in preparing pharmacies for the modified Clozapine REMS. Between the dates of August 15, 2021 and December 31, 2021, please provide copies of the enclosed Pharmacy Letter and Fact Sheet: What's Changed with the Clozapine REMS Program for Pharmacies to any pharmacy that orders clozapine.

For additional information related to the Clozapine REMS and recent program modifications, please call **1-888-586-0758**.

Sincerely,

Clozapine REMS