February 17, 2022

Via email: mdirst@psych.org

Dear Ms. Dirst,

We want to thank the organizations for sharing their thoughts and concerns about the recent modification to the Clozapine REMS during the December 2 and 16, 2021 FDA listening sessions, and in your letter received on February 14, 2022. We appreciate your commitment to safely providing clozapine to a vulnerable population.

Due to problems with implementation of the modification to the Clozapine REMS program and its potential impact on patient care, the FDA communicated on November 19, 2021 that, with respect to certain Clozapine REMS program requirements, we did not intend to object if:

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

The conditions outlined in the November 19, 2021 communication do not expire on February 17, 2022. Although these measures are intended to be temporary, the FDA continues not to object if pharmacies dispense clozapine without an RDA or if wholesalers ship clozapine to pharmacies and health care settings without confirming enrollment in the REMS. We are assessing implementation metrics from the Clozapine REMS and will use them to inform our future actions with respect to enforcement of these requirements without disrupting patient care. We understand that stakeholders will need advance notification when the November 19, 2022 decision is lifted and acknowledge your request for a 60 days' notice.

FDA continues to prioritize its work to minimize the potential negative impact on patient care of the modification of Clozapine REMS that was implemented on November 15, 2022. We are working closely with the Clozapine Product Manufacturers Group (CPMG) to address issues that are identified in your February 14, 2022 letter; however, this will take additional time and may require public input.

Sincerely,

Patrizia A. Cavazzoni -S

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