AMERICAN PSYCHIATRIC ASSOCIATION

800 Maine Avenue, S.W.
Suite 900
Washington, D.C. 20024

March 3, 2022

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear U.S. Food & Drug Administration:

The following FOIA request is being submitted by the American Psychiatric Association (APA). APA is located at 800 Maine Ave SW, Ste 900, Washington DC 20024 and can be reached at 571-319-3024.

It is our understanding that the FDA has regulated distribution of Clozapine through the Risk Evaluation and Mitigation Strategy (REMS) since 2008. We further understand that on July 29, 2021, FDA approved modifications to the Clozapine REMS to ensure that the benefits of the drug outweigh the risk of severe neutropenia and that these new requirements went into effect on November 15, 2021.

APA respectfully requests the following information with respect to the Clozapine REMS program:

1. Documents and contracts that describe the relationship between the FDA and the Clozapine Product Manufacturers' Group (CPMG) from the beginning of the Clozapine REMS program (2008) through the present.
2. Documents and contracts that describe the relationship between the FDA and/or CPMG and the prior and current Clozapine REMS websites (www.clozapinerems.com and www.newclozapinerems.com) developer/owner from the beginning of the Clozapine REMS program until now.
3. Documents defining the entity that owns the data under each of the contracts relevant to (1) and (2) and the location of the data.
4. Documents stating where data from 2008 REMS to the 2021 REMS is located.
5. Assessments of the REMS programs from 2008, 2015, and 2021.
6. Description of the approval processes for patients, pharmacists, and clinicians seeking re-certification and re-enrollment in the newly modified Clozapine REMS program.
7. Complaints received from patients, pharmacists, and clinicians about the re-certification and re-enrollment processes in the newly modified REMS program implemented by November 15, 2021.
8. Documentation of the steps taken to resolve complaints regarding recertification and re-enrollment processes in the newly modified REMS program.
9. The applications the FDA approved from the CPMG in 2008, 2015, and 2021.

10. Application and contract awards for the Clozapine REMS website vendor.
11. Call logs from the Clozapine REMS Transition Contact Center from August 2, 2021 – present.

APA is willing to pay any fees associated with this FOIA request.

Sincerely,

Colleen Coyle

Colleen Coyle, JD
General Counsel