



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

March 10, 2020

David Behar, M.D.

(b) (6)

Sent via email to: (b) (6)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the following:

1. Decommission the Clozapine REMS program.
2. Remove the requirement that health care providers be certified in order to prescribe clozapine.
3. Remove language regarding mandatory blood testing and the Clozapine REMS program, replacing them with the following:

Low white blood cell counts (neutropenia). Low white blood cell counts are very common when taking clozapine and may cause serious infections that can lead to death. Your healthcare provider should check your white blood cell counts before and during treatment.

- a. If you develop low white blood cell counts during treatment with clozapine, your healthcare provider may stop your treatment or decrease your dose. Tell your healthcare provider right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.

Your submission was received by this office on 03/10/2020. It was assigned docket number FDA-2020-P-1073. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)