APR 07 2016

MEMORANDUM

TO: **Division of Dockets Management**

FROM: **Elaine Lippmann, Office of Regulatory Policy**
Center for Drug Evaluation and Research

RE: **Docket No. FDA-2012-P-0379**

DATE:

Please consider the citizen petition in the above-referenced docket to have been voluntarily withdrawn without prejudice to resubmission. The citizen petition is dated April 9, 2012, and was submitted by David Behar, M.D.

On February 5, 2016, the Food and Drug Administration sent a letter to the petitioner's last submitted address requesting that the petitioner respond to our request if the petitioner wished to keep the petition active. The letter stated that if we do not receive a written response within 30 days, a copy of the letter would be filed in the docket with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

The letter, postmarked February 9, 2016, was returned to the Agency as undelivered and unable to forward. The petitioner did not submit an alternative address to the petition docket, and we do not have a current address for Dr. Behar.

In light of the above, we are considering the petition to be voluntarily withdrawn without prejudice, and we request closure of this docket.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

FEB - 5 2016

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David Behar, M.D.
206 East Broad Street
Bethlehem, PA 18018

Re: Docket No. FDA-2012-P-0379

Dear Dr. Behar:

According to the records of the Food and Drug Administration's Division of Dockets Management, the petition referenced above has not been resolved.

As part of the Agency's efforts to reduce the backlog of unresolved citizen petitions, the Center for Drug Evaluation and Research (CDER) periodically reviews unresolved petitions assigned to it for action. One goal of this review is to identify citizen petitions that petitioners may believe are no longer timely. CDER believes that having to respond to outdated petitions diminishes the Center's capacity to address petitions that raise urgent public health issues, as well as its capacity to perform its many other duties. Therefore, these outdated petitions have a lower priority, and it is unlikely that the Center will have the resources to respond to them soon.

The referenced petition was submitted prior to FDA's recent actions related to the subject matter of your petition. Specifically, we made changes to the requirements for monitoring, prescribing, dispensing, and receiving clozapine as described in the revised clozapine prescribing information, and in the Clozapine REMS Program. Patients with benign ethnic neutropenia (BEN), who previously were not eligible for clozapine treatment, will now be able to receive the medicine. The revised prescribing information facilitates prescribers' ability to make individualized treatment decisions if they determine that the risk of psychiatric illness is greater than the risk of recurrent severe neutropenia, especially in patients for whom clozapine may be the antipsychotic of last resort.

Given the demand on Agency resources of responding to citizen petitions, and in light of these recent developments, we wish to determine whether you remain interested in pursuing citizen petition FDA-2012-P-0379. Accordingly, we would appreciate it if you would review your petition and respond to the docket number listed above if you wish to keep this petition active. Your response should reference the docket number and may be submitted electronically at www.regulations.gov, or sent to the Food and Drug Administration, Dockets Management Branch, Room 1061, 5630 Fishers Lane, Rockville, MD 20852. If we do not receive a written response from you within 30 days from the date of this letter, a copy of this letter will be filed in Docket No. FDA-2012-P-0379 with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

If you have any questions, please contact Elaine Lippmann of my staff at (301) 796-2895. Thank you for your attention to this matter.

Sincerely,

Deborah Livornese
Director, Division of Regulatory Policy IV (Acting)
Office of Regulatory Policy
Center for Drug Evaluation and Research