DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAR 09 2015

Charles Bennett, M.D., Ph.D., M.P.P.
Center for Medication Safety and Efficacy
Southern Network on Adverse Reactions (SONAR)
South Carolina College of Pharmacy/USC Campus
715 Sumter Street, Suite 311-L
Columbia, SC 29208

Re: Docket No. FDA-2014-P-1611

Dear Dr. Bennett:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on September 11, 2014, and submitted on behalf of SONAR. Your petition requests that: (1) additional psychiatric adverse events be added to Levaquin's labeling; (2) FDA require a separate "Psychiatric Effects" heading under the "Warning and Precautions" section of Levaquin's labeling rather than listing psychiatric adverse events under the "Central Nervous System Effects" section of the labeling; and (3) certain psychiatric adverse events be added to the current boxed warning on Levaquin's labeling.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 15, 2014

Charles Bennett, M.D., Ph.D., M.P.P.
Center for Medication Safety and Efficacy
Southern Network on Adverse Reactions (SONAR),
South Carolina College of Pharmacy/USC Campus
715 Sumter Street, Suite 311-L
Columbia SC 29208

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the FDA change the professional labeling for Levaquin under Section 505(o)(4) of FDCA or other appropriate FDCA section(s), in response to new safety information was received by this office on 09/11/2014. It was assigned docket number FDA-2014-P-1611 and it was filed on 10/15/2014. 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,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)