DEPARTMENT OF HEALTH & HUMAN SERVICES

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

DEC 17 2014

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

Re: Docket No. FDA-2014-P-0856

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 June 23, 2014. Your petition requests that the Agency change the professional labeling for Levaquin under Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA) or other appropriate FDCA section(s) in response to new safety information. Specifically, your petition requests that: (1) language be added to Levaquin's labeling regarding "Possible Mitochondrial Toxicity" in section 5 under the Warnings and Precautions heading, (2) a boxed warning be added to Levaquin's labeling regarding "Possible Mitochondrial Toxicity," (3) the above-mentioned labeling changes be made immediately, and (4) "Dear Doctor" letters be distributed regarding these labeling changes and physicians inform patients about the potential impact of "Possible Mitochondrial Toxicity" if they were previously prescribed this drug.

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,

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