U.S. FOOD & DRUG ADMINISTRATION

DEC 17 2019

Dr. Charles Bennett, MD, PhD, MPP
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-2019-P-2998

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 20, 2019. Your petition requests that FDA require changes in the labeling for Levaquin (levofloxacin) to include Fluoroquinolone Associated Disability and Psychiatric Adverse Events to the Boxed Warning and require a risk evaluation and mitigation strategy (REMS) for Levaquin.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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