



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 21, 2019

Charles Bennett
SONAR
715 Sumter Street, Suite 311-L
Columbia, SC 29208

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the following actions: add a Levaquin Black Box warning for Fluoroquinolone-Associated Disability, add a Levaquin Black Box warning to identify psychiatric adverse events, including suicide-related adverse events and require a Risk Evaluation and Mitigation strategy was received by this office on 06/20/2019.

It was assigned docket number FDA-2019-P-2998. 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 Specialist
Division of Dockets Management
FDA/Office of Operations (OO)