Dear Dr. Hamburg and Dr. Ostroff:

**Levaquin Mitochondrial Toxicity Citizen Petition**

Dr. Charles Bennett and The Southern Network on Adverse Reactions (SONAR) submitted a Citizen Petition to the FDA in June, 2014 (**Docket #FDA-2014-P-0856**) asking for warnings to be placed on the Levaquin label regarding possible Mitochondrial Toxicity implicated in neurodegenerative diseases, including ALS, Alzheimer’s, and Parkinson’s. This Citizen Petition is based directly on an April 17, 2013 FDA report.

The FDA response to this petition, sent December 2014, states the FDA would not take action at this time because the Citizen Petition requires “extensive review and analysis by Agency officials.” Since this Citizen Petition is based on the FDA’s own words, from the FDA’s own research, outlined in the FDA’s own report, what the FDA is saying is that Agency officials have to review and analyze what the Agency officials themselves wrote.

**Levaquin Psychiatric Citizen Petition**

Dr. Bennett and The Southern Network on Adverse Reactions (SONAR) submitted a Citizen Petition to the FDA in September, 2014 (**Docket #FDA-2014-P-1611**) asking for additional warnings to be placed on the Levaquin label regarding about possible Psychiatric adverse events.

The FDA response to this petition, sent February 2015, states the FDA would not take action at this time because the Citizen Petition requires “extensive review and analysis by Agency officials.” This is the same response as the one provided by the FDA related to the Levaquin Mitochondrial Toxicity Citizen Petition.

**FDA Responses to Both Citizen Petitions are Unacceptable**

Given (1) the seriousness of the issues in the Levaquin Mitochondrial Toxicity Citizen Petition (neurodegenerative diseases, including ALS, Alzheimer’s and Parkinson’s); (2) that it is based on the FDA’s own report; and (3) that the FDA has made public statements that it is aware of the Levaquin Mitochondrial Citizen Petition, this Citizen Petition deserves a substantive response, not a generic reply.

Given the seriousness of the issues in the Levaquin Psychiatric Citizen Petition, this Citizen Petition deserves a substantive response, not a generic reply.