DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Silver Spring MD 20993

August 16, 2019

Jeremy Turner, Founder, CSO & David L. Hick, CEO
Turner Scientific
1225 Tendick Street
Jacksonville, IL 62650

Sent via email to: dhicks@turnerscientific.com

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting to approve and issue draft guidance document, Ototoxicity: Nonclinical Evaluation During Drug Development was received by this office on 08/14/2019.

It was assigned docket number FDA-2019-P-3886. 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 Dockets Management Staff FDA/Office of Operations (OO)