



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

May 18, 2020

Shahid Ahmed
Chief Scientific Officer
Nexus Pharmaceuticals Inc
400 Knightsbridge Parkway
Lincolnshire, IL 60069

Sent via email to: sahmed@nexuspharma.net

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to declare Levetiracetam Injection 750 mg/IV bag is suitable for the submission as an ANDA or a prior approval supplement was received by our office on 05/18/2020.

It was assigned docket number FDA-2020-P-1393. 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 Officer
Dockets Management Staff
FDA/Office of Operations (OO)