



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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Food and Drug Administration  
Rockville, MD 20857

April 30, 2019

Steven Pikulin  
President  
TechReg Services, Inc.  
17 McIntire Drive  
Hillsborough, NJ 08844-2244

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to determine whether the drug product Norepinephrine Bitartrate Injection, USP with fill volumes of 8 mL per vial and 16 mL per vial are suitable for submission in an ANDA was received by this office on 04/29/2019.

It was assigned docket number FDA-2019-P-2070. 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  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)