



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

December 9, 2019

Mahender Korapti
Chief Operating Officer
Guvam Pharma LLC
33 South Wood Avenue, Suite 600
Iselin, NJ 08830

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA determine that the proposed Phenazopyridine Tablets, 50 mg, 100 mg and 200 mg is suitable for submission in an ANDA was received by this office on 12/08/2019.

It was assigned docket number FDA-2019-P-5791. 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)