DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

December 21, 2020

Michelle R. Ryder
Principal Consultant
Lachman Consulting Services, Inc.
1600 Stewart Ave. Suite 604
Westbury, NY 11590

Sent via email to: ryder@lanchmanconsultants.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to declare that the proposed drug product, Vancomycin Hydrochloride for Oral Solution EQ 125 mg (base)/5 mL is suitable for submission as an ANDA. The prospective RLD, upon which this petition is based, is Vancomycin was received by this office on 12/21/2020.

It was assigned docket number FDA-2020-P-2318. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the suitability 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 Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.12.21 16:51:15 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)