December 16, 2020

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUITABILITY PETITION – WITHDRAWAL REQUEST

RE: FDA-2020-P-2187

Dear Sir or Madam:

Lachman Consultant Services, Inc. hereby requests to withdraw the Suitability Petition submitted on November 11, 2020; assigned Docket number FDA-2020-P-2187 for Vancomycin Hydrochloride Oral Solution. This request is being made without prejudice to future submission.

The Suitability Petition was submitted pursuant to the Federal Food, Drug and Cosmetic Act ("FD&C Act") and in accordance with 21 CFR § 10.25(a) and 10.30 requesting the Commissioner of the Food and Drug Administration to declare that the proposed drug product, Vancomycin Hydrochloride for Oral Solution EQ 125 mg (base)/5mL is suitable for consideration in an Abbreviated New Drug Application (ANDA) based upon Vancomycin Hydrochloride for Oral Solution EQ 250 mg (base)/5mL by ANI Pharmaceuticals Inc., approved under ANDA 061667, as Reference Listed Drug (RLD).

Please advise if additional information is required in order to complete withdrawal request.

Sincerely,

Michelle R. Ryder

Michelle R. Ryder
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Michelle R. Ryder
Principal Consultant
Lachman Consulting Services, Inc.