DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

May 13, 2019

Virendra Srivastava
Alembic Pharmaceuticals Limited
Regd. Off.: Alembic Road
Vadodara – 390 003
INDIA

Sent via email to: virendra.srivastava@alembic.co.in

Dear Petitioner:

Your petition to the Food and Drug Administration requesting the FDA determine from commissioner of Food and Drugs that the withdrawal of the referenced RLD was for reasons other than safety or efficacy and thus permit the filing of an ANDA referencing LEVITRA (Vardenafil Hydrochloride) Tablets, 2.5 mg. was received by this office on 05/09/2019.

It was assigned docket number FDA-2019-P-2290. Please refer 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

Digitally signed by Dynna Bigby
Date: 2019.05.14 09:36:27 -04'00'

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