U.S. FOOD & DRUG ADMINISTRATION

Virendra Srivastava
Head – Corporate Regulatory Affairs
Alembic Pharmaceuticals Limited
Regd. Office: Alembic Road
Vadodara – 390 003
Gujarat, INDIA

Re: Docket No. FDA-2019-P-2290

AUG 12 2019

Dear Mr. Srivastava:

This letter responds to your citizen petition received on May 9, 2019, requesting that the Food and Drug Administration (FDA) (1) determine that the withdrawal of Levitra (vardenafil hydrochloride) tablets, 2.5 milligrams (mg), was for reasons other than safety or efficacy and (2) permit the filing of abbreviated new drug applications referencing Levitra (vardenafil hydrochloride) tablets, 2.5 mg.

Enclosed is a copy of the *Federal Register* notice, published August 12, 2019 (84 FR 155), that announces FDA's determination that Levitra (vardenafil hydrochloride) tablets, 2.5 mg, were not withdrawn from sale for safety or effectiveness reasons. The notice also explains that FDA will maintain Levitra (vardenafil hydrochloride) tablets, 2.5 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book) and will continue to approve abbreviated new drug applications that refer to this drug product as long as they meet all other relevant legal and regulatory requirements.

If you require any further information, please feel free to call me at (301) 796-4673.

Sincerely,

Daniel J. Ritterbeck, J.D.
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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www.fda.gov