Date: May 10, 2019

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

CITIZEN PETITION

Dear Sir/Madam,

The undersigned submits this petition pursuant to 505(j) (7) of the Federal Food, Drug and Cosmetic Act and in accordance with 21 CFR §10.30, § 10.25 and § 314.122 to request the Commissioner of Food and Drugs to make a prompt determination that the discontinuation of the Reference Listed Drug (RLD), LEVITRA (NDA # 021400), 2.5 mg was not for safety and effectiveness reasons. With this determination, the undersign asks that the FDA to declare that it is appropriate to submit an Abbreviated New Drug Application (ANDA) for Vardenafil Hydrochloride Tablets, 2.5 mg that relies on an RLD that is no longer marketed.

A. Action Requested

The RLD upon which this petition is based is LEVITRA (Vardenafil Hydrochloride) Tablets, 2.5 mg application number N021400, applicant BAYER HEALTHCARE PHARMACEUTICALS INC. A copy of the page from the electronic Orange Book, from the FDA website, identifying the RLD i.e., LEVITRA (Vardenafil Hydrochloride) Tablets, 2.5 mg is enclosed in Exhibit-1.

The petitioner seeks a determination 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.

B. Statement of Grounds

Under the Federal FD&C Act, an ANDA must rely on a RLD. See section 505 (j)(2) of Federal FD&C Act. If a listed drug has ceased to be offered for sale by its manufacturers, a person wishing to submit an ANDA for the drug product, must petition FDA for a determination of whether the drug product was withdrawn for reason of safety or effectiveness (21 CFR§ 314.122 & 314.161). If FDA, determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness, then the drug listing is removed from the Orange Book.

Since the Petitioner intends to submit an ANDA, referencing, RLD Product, LEVITRA (Vardenafil Hydrochloride) Tablets, 2.5 mg, therefore, the petitioner requests commissioner of Food and Drugs, to determine about the reason of Discontinuation of RLD Product.

C. Environmental Impact

The actions requested herein are subject to categorical exclusion under 21 CFR 25.31(a).

D. Economic Impact

An economic impact statement will be made upon request should the Commissioner determine such assessment is necessary in evaluating this petition.

E. Certification

The undersigned certifies, that, to the best of knowledge and belief of the undersigned, this petition includes all the information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which is unfavorable to the petitioner.

Please direct any questions or comments regarding this submission to the attention of Virendra Srivastava, Head – Corporate Regulatory Affairs, Phone: +91-265-3007534, Fax: +91-265-2282837, Email: virendra.srivastava@alembic.co.in.

Sincerely,

Virendra Srivastava
Digitally signed by Virendra Srivastava
Date: 2019.05.10 12:40:48 +05'30'

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