August 26, 2022

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

# CITIZEN PETITION

Dear Sir/Madam:

The undersigned, Respira Therapeutics, Inc. (the Petitioner), submits this Petition in accordance with 21 CFR §10.25(a) and §10.30, and pursuant to Sections 505(j) and 505(w) of the Federal Food, Drug and Cosmetic Act and 21 CFR §314.122 and §314.161 to request that the FDA determine whether a listed drug was withdrawn for reasons of safety or effectiveness.

## A. Action Requested

The Petitioner requests that the FDA determine whether LEVITRA® (vardenafil HCl) 20 mg tablets approved under New Drug Application (NDA) 021400 and held by Bayer Healthcare Pharmaceuticals Inc. has been withdrawn for reasons of safety or effectiveness.

## B. Statement of Grounds

LEVITRA (vardenafil HCl) tablets (2.5 mg, 5 mg, 10 mg and 20 mg dose strengths) currently have a marketing status of "Discontinued" in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book". On August 12, 2019, in response to a citizen petition submitted by Alembic Pharmaceuticals Limited, the Federal Register published a notice indicating that the FDA had determined that LEVITRA (vardenafil HCl) 2.5 mg tablets were not withdrawn for reasons of safety or effectiveness. A notation of this determination currently appears in the Orange Book for LEVITRA (vardenafil HCl) tablets; however, it is limited to the 2.5 mg dose strength.

The petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons.

The petitioner hereby requests that the FDA make a similar determination that LEVITRA (vardenafil HCl) 20 mg tablets, approved under NDA 021400, was not withdrawn for reasons of safety or effectiveness.

## C. Environmental Impact

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR §25.31.

**D. Economic Impact**

Pursuant to 21 CFR §10.30(b), upon request by the Commissioner, the Petitioner will submit economic impact information.

**E. Certification**

The undersigned certifies that to the best of their knowledge and belief, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Sincerely,

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