U.S. FOOD & DRUG ADMINISTRATION

Carol Ann Statler, M.D., Ph.D.
President and Chief Medical Officer
Respira Therapeutics, Inc.
628 Middlefield Road
Palo Alto, CA 94301

May 3, 2023

Re: Docket No. FDA-2022-P-2060

Dear Dr. Statler:

This letter responds to your citizen petition received on August 29, 2022, requesting that the Food and Drug Administration (FDA) determine whether Levitra (vardenafil hydrochloride) oral tablets, 20 milligrams (mg), approved under new drug application 021400, held by Bayer Healthcare Pharmaceuticals Inc., have been withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Levitra (vardenafil hydrochloride) oral tablets, 20 mg, were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Levitra (vardenafil hydrochloride) oral tablets, 20 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-4673.

Sincerely,

Daniel J. Ritterbeck -S

Digitally signed by Daniel J. Ritterbeck -S
Date: 2023.05.03 09:25:54 -04'00'

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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