U.S. FOOD & DRUG ADMINISTRATION

Carol Ann Statler, M.D., Ph.D.
Respira Therapeutics, Inc.
628 Middlefield Road
Palo Alto, CA 94301

February 23, 2023

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

Dear Dr. Statler:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 29, 2022, and submitted on behalf of Respira Therapeutics, Inc. Your petition requests that the Agency determine whether Levitra (vardenafil hydrochloride) tablets, 20 milligrams, approved under New Drug Application 021400, held by Bayer Healthcare Pharmaceuticals Inc., have been withdrawn for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2023.02.23 10:19:37 -05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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