August 30, 2022

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

Sent via email to: csatler@respiratherapeutics.com

Dear Petitioner:

Your submission requesting that the Commissioner to 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mg tablets approved under New Drug Application (NDA) 021400 and held by Bayer Healthcare Pharmaceuticals Inc. has been withdrawn for reasons of safety or effectiveness was received and processed under CFR 10.30 by this office on 08/29/2022.

It was assigned docket number FDA-2022-P-2060. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.08.30 10:26:00 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)