May 5, 2020

Mario Danek, CEO
Respira Technologies, Inc.
750 N. San Vicente Blvd.
Suite 800 West
West Hollywood, CA 90069

Re: Docket No. FDA-2019-P-5922

Dear Mr. Danek;

This is an interim response to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised by your citizen petition received on December 16, 2019.

Your petition requests that FDA take certain actions with respect to the electronic nicotine delivery systems (ENDS) to curtail youth initiation and use and to encourage the development and adoption of nicotine products with lower health risks. Specifically, your petition requests that FDA: 1) establish a nicotine standard for ENDS products; 2) establish a product standard for ENDS products that limits exposure to harmful and potentially harmful constituents (HPHCs) and other known toxins; 3) establish standardized warnings and HPHC Fact Panels for ENDS products and heated tobacco products; 4) impose marketing restrictions on ENDS products; 5) establish a voluntary, fast track pathway for the approval of ENDS products; and 6) require manufacturers of approved ENDS products to periodically submit post-market reports to FDA.

Your request raises significant, complex issues requiring extensive review and analysis by Agency officials. 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 we have reached a decision on your request.

Sincerely,

Beverly I. Chernaik -S
Digitally signed by Beverly I. Chernaik -S
Date: 2020.05.05 11:15:42 -04'00'

Beverly Chernaik, J.D.
Director, Office of Regulations
Center for Tobacco Products

U.S. Food & Drug Administration
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