February 12, 2021

Mr. Azim Chowdhury
Keller and Heckman LLP
1001 G Street N.W.
Suite 500 West
Washington, D.C. 20001

Re: Docket No. FDA-2020-P-1797

Dear Mr. Chowdhury:

This letter responds to your citizen petition (FDA-2020-P-1797) submitted on August 24, 2020, and corrected on August 27, 2020, on behalf of certain vapor product manufacturers, retailers, and trade associations.[1] Your petition requests that the Food and Drug Administration (FDA) "seek . . . a 180-day extension of the September 9, 2020 deadline for filing Premarket Tobacco Product Applications ('PMTA'), which was set by the United States District Court for the District of Maryland." FDA has carefully reviewed the arguments in your petition. Without deciding whether your petition is subject to FDA's citizen petition procedures at 21 C.F.R. § 10.30,[2] for the reasons stated below, FDA is dismissing your petition as moot and, in the alternative, denying your petition.

Since FDA received your citizen petition, the September 9, 2020 deadline has passed. Accordingly, as a practical matter, FDA is unable to "seek . . . a 180-day extension of the

[1] These vapor product manufacturers, retailers, and trade associations are: Cream Vapor LLC; Gentleman's Draw; HiggyCigs, LLC; Illumivaption Inc.; Jvapes, LLC; Knoxville Vapor Co./Tri Star Vape Co.; Matrix Minds LLC; Mountain Oak Vapors; Northeast Vapor Supplies, LLC; Prophet Premium Blends LLC; The Vapers Depot; Vapor Station Columbus; Vapor Source, Inc.; Chattanooga Vapor Co.; Global eVapor Consulting; Michigan Vape Shop Owners Organization; Vaping Advocates of Oklahoma; Rocky Mountain Smoke Free Alliance; Kentucky Smoke Free Association; and Smoke-Free Alternatives Trade Association

[2] Requests for the agency to take or refrain from taking enforcement action, and "related correspondence," are not within the scope of FDA's citizen petition procedures. *See* 21 C.F.R. § 10.30(k). An agency denial of a request to take or not take enforcement discretion does not constitute final administrative action. *See* 21 C.F.R. § 10.45.

September 9, 2020 deadline for filing [PMTAs], which was set by the United States District Court for the District of Maryland." FDA is therefore dismissing your petition as moot under 21 C.F.R. § 10.30(e)(2)(iii).

In the alternative, the FDA would independently adopt the same deadline as the U.S. District Court for the District of Maryland. *See* Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised), at 27 ("Even in the absence of this court order, FDA would prioritize enforcement of any ENDS product that lacks a premarket application after September 9, 2020, for the reasons described in this guidance."), *available at* https://www.fda.gov/media/133880/download. The agency continues to prioritize enforcement for ENDS products that lack premarket applications after September 9, 2020, for the reasons stated in that guidance. FDA sought a 120-day extension of the court's original May 12th, 2020, deadline to address concerns related to the unexpected circumstances of the global COVID-19 pandemic, which reflected a balance between FDA's critical public health priority in promptly reviewing tobacco product applications and the difficulties posed by the COVID-19 pandemic. FDA therefore denies your petition on this alternative ground.

FDA will determine whether each application a firm has submitted by the September 9, 2020, deadline meets the applicable statutory and regulatory requirements under sections 905 and 910 of the Federal Food, Drug, and Cosmetic Act to proceed to scientific review. The agency intends to take the firm's individual circumstances into account, including concerns related to COVID-19, as it considers applications that are submitted by the deadline. FDA also intends to take into account relevant considerations in deciding whether to initiate enforcement action against a particular product with respect to applicants who have provided the needed information and made substantial progress toward completion as the one-year period for review comes to an end in September 2021.

Regards,

May D. Nelson -S
Digitally signed by May D. Nelson -S
Date: 2021.02.12 08:36:02 -05'00'

May D. Nelson
Director, Office of Regulations
Center for Tobacco Products
Food and Drug Administration