



April 19, 2023

Marc C. Sanchez
Regulatory Counsel
Local Vape Enterprises, Inc.
1717 Pennsylvania Ave NW, Suite 1025
Washington, DC 20006-3951

Re: Docket No. FDA-2022-P-3070

Dear Mr. Sanchez,

On December 1, 2022, the Food and Drug Administration (FDA) received from Local Vape Enterprises, Inc. (“petitioner”) a petition for administrative stay under 21 C.F.R. § 10.35 pending completion of supervisory review under 21 C.F.R. § 10.75. The petition seeks a stay of a Refuse to Accept (RTA) letter issued on November 1, 2022, for a number of Premarket Tobacco Product Applications (“PMTA”) received by FDA on May 9, 2022, pursuant to section 910(b) of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”).

FDA has reviewed the petition, the request for supervisory review, the RTA letter, and the applicable regulations. For the reasons described below, FDA denies the petition.

BACKGROUND

On May 9, 2022, Local Vape submitted PMTAs for 330 new tobacco products. These products were assigned Submission Tracking Numbers (STNs) PM0005294.PD1-PM0005294.PD330.

On July 20, 2022, Local Vape submitted an FDA Form 4057. This was assigned STN PM0006663.

On July 22, 2022, Local Vape submitted FDA Form 4057a. This was assigned STN PM0006720.

On October 6, 2022, Local Vape submitted another cover letter. This was assigned STN TC0009116.

On November 1, 2022, FDA issued a Refuse to Accept (RTA) letter for all 330 products.

On November 23, 2022, Local Vape filed the request for supervisory review at issue here.

On December 1, 2022, FDA received the petition described above. In a letter to petitioner sent on December 2, 2022, Supervisory Administrative Proceedings Officer Karen Malvin acknowledged receipt of the petitions (“Acknowledgment Letter”).

DISCUSSION

The petitioner seeks a stay of administrative action pursuant to 21 C.F.R. § 10.35.¹ The petitioner seeks a stay “for an indefinite period of time due to the indeterminable timeframe for the Center for Tobacco Products to complete a review under 21 CFR § 10.75.”²

The request for supervisory review pursuant to 21 C.F.R. § 10.75 (“appeal”) of the RTA letter issued to Local Vape Enterprises, Inc., was completed on April 12, 2023.³ Therefore, the request for a stay pending the supervisory review is moot.

CONCLUSION

For the foregoing reasons, the Petition for Administrative Stay of Action submitted under 21 C.F.R. § 10.35 is denied as moot.

Sincerely,

Brian A. King, Ph.D., M.P.H.
Center Director
Center for Tobacco Products

¹ *Petition for Stay of Action*, dated November 18, 2022, page 1.

² *Id.*

³ *Response to Request for Supervisory Review – PM0005294.PD1-PM0005294.PD330* (AP0000204), dated April 12, 2023.