



April 19, 2023

Marc C. Sanchez  
Regulatory Counsel  
Full Curl Sciences Corp.  
1717 Pennsylvania Ave NW, Suite 1025  
Washington, DC 20006-3951

**Re: Docket No. FDA-2022-P-3334**

Dear Mr. Sanchez,

On December 22, 2022, the Food and Drug Administration (FDA) received from Full Curl Sciences Corp. (“FCSC” or “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 December 11, 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, FCSC submitted PMTAs for fifteen products. They were assigned STN PM0005295.PD1-PM0005295.15.

On July 20, 2022, FCSC submitted two different versions of FDA Form 4057. These were assigned STN PM0006651 and PM0006662.

On July 22, 2022, FCSC submitted FDA Form 4057a. This was assigned STN PM0006710.

On September 20, 2022, FCSC submitted a cover letter, FDA Form 4057, and four documents providing method verification for the quantitation of nicotine, various acetates and ketones, propionic acid, and glycidol. These were assigned STN PM0006956.

On October 6, 2022, FCSC submitted a cover letter, which was assigned STN TC0009115.

On October 11, 2022, FCSC submitted a cover letter, FDA Form 4057, three certificate of analyses, and twelve method verification documents. These were assigned STN PM0007017.

On November 1, 2022, FCSC submitted a cover letter, FDA Form 4057, and nine certificate of analyses. These were assigned STN PM0007061.

On November 3, 2022, FCSC submitted a cover letter, FDA Form 4057, and FDA Form 4057b. These were assigned STN PM0007064.

On November 8, 2022, FCSC submitted two cover letters, FDA Form 4057, and FDA Form 4057b. These were assigned STN PM0007079.

On November 30, 2022, FCSC submitted a cover letter, FDA Form 4057, FDA Form 4057a and FDA Form 4057b, which were assigned STN PM0007136.

On December 11, 2022, FDA issued Refuse to Accept (RTA) letters for the fifteen products.

On December 20, 2022, you filed the request for supervisory review at issue here.

On December 22, 2022, FDA received the petition described above. In a letter to petitioner sent on December 23, 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.<sup>1</sup> 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.”<sup>2</sup>

The request for supervisory review pursuant to 21 C.F.R. § 10.75 (“appeal”) of the RTA letter issued to FCSC was completed on April 12, 2023.<sup>3</sup> 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

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<sup>1</sup> *Petition for Stay of Action*, dated December 20, 2022, page 1.

<sup>2</sup> *Id.*

<sup>3</sup> *Response to Request for Supervisory Review – PM0005295.PD1-PM0005295.PD15* (AP0000216), dated April 12, 2023.