# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RE: Serial No. 88/037,218

Mark: AZUCA and design

AZUCA-

Applicant: SRE Wellness Inc
Office Action of: July 08, 2019

Howard Smiga
Trademark Examining Attorney
Law Office 102
United States Patent and Trademark Office

#### APPLICANT'S RESPONSE TO OFFICE ACTION

The Examining Attorney's attention to the present application is noted with appreciation.

The following is the Applicant's response to the Office Action issued and sent via email on July 8, 2019, by Examining Attorney Howard Smiga.

### I. Amendment of the Filing Date to December 20, 2018

The Examining Attorney questioned whether the use of the proposed mark in connection with the proposed goods is lawful under the federal Controlled Substances Act, 21 U.S.C. §§801-971 as of the effective filing date of July 13, 2018. Applicant agrees that if the goods for which a specimen will eventually be submitted will contain Cannabidiol ("CBD"), then the requirements as set forth by the Examining Attorney will need to be satisfied.

As the Examining Attorney correctly noted, on December 20, 2018, the U.S. President signed into effect the Agricultural Improvement Act of 2018 ("2018 United States Farm Bill") which removed hemp from the definition of marijuana and specifically excluded "tetrahydrocannabinols [("THC")] in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946)" from Schedule I, 21 U.S.C. §812(c)(17).

The Applicant respectfully requests an amendment of the filing date of the current application to be December 20, 2018, and the Applicant specifically authorizes such change to the filing date with the filing basis of intent-to-use under section 1(b) 37 C.F.R. §2.34.

# II. Request for Suspension FDCA Related Goods Refusal

The Examining Attorney also refused registration of the applied-for mark alleging that the Applicant does not have bona fide intent to lawfully use the applied-for mark in commerce due to the requirements of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act").

Although the 2018 United States Farm Bill removed hemp from the definition of marijuana, the U.S. Food and Drug Administration ("FDA") approval for hemp products containing THC and CBD is still required. Congress explicitly preserved the FDA's current authority to regulate products containing cannabis or cannabis-derived compounds under the FDCA, and this Act still applies, for instance to foods or dietary supplements of a drug or substance undergoing clinical investigations. FDA still is in charge of such approval.

For the last year or so, i.e. since the enactment of the 2018 United States Farm Bill, the FDA has approved only one (1) cannabis-derived drug (Epidiolex) and three (3) cannabis-related drug products (Marinol, Syndros, Cesamet). See the attached print out from the FDA's website https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd outlining the FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD). Besides that one (1) cannabis-derived drug and three (3) cannabis-related drug products, the FDA has not approved any other medical products containing cannabis or cannabis-derived compounds such as CBD. Also, the FDA has not approved any other non-medical products, such as food, dietary supplements, or the like.

This so-called "turf war" between the USPTO and the FDA leaves many applicants for federal trademark protection, including the present Applicant, caught in the middle, i.e. in legal limbo. On one hand, one governmental agency—the USPTO—is requiring the FDA approval under the FDCA, and on the other hand, the other governmental agency—the FDA—is not providing such approval.

Thus, the Applicant respectfully requests suspension of this application, pending FDA approval due to FDA's ongoing efforts of pursuing an efficient regulatory framework for approving products containing cannabis or cannabis-derived compounds.

U.S. TM SN 88/037,218 AZUCA and design Applicant: SRE Wellness Inc.

# **CONCLUSION**

