January 21, 2026

Iram Baig, MS
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: **IND 110513, Serial No. 0041**, MJP2 Protocol Amendment

Dear Ms. Baig,

Enclosed in this submission is an amendment to Study MJP2, a Phase 2 study of inhaled cannabis for PTSD entitled, "*Phase 2 Multicenter Randomized Placebo-controlled, Double-blind, Parallel Study to Assess the Safety and Efficacy of Inhaled Cannabis in Veterans for Treatment of Posttraumatic Stress Disorder (PTSD)*".

During 2025, study start-up for Study MJP2 proceeded under the FDA-cleared smoking-only protocol, Amendment 3, Version 1 (A3V1). During this same period, the Sponsor submitted a hold response (with additional materials and protocol versions) proposing reintroduction of the vaporization route and engaged in ongoing discussions with the Agency regarding the vaporization device. Those submissions and protocol versions (A3V2) proposing vaporization remained under clinical hold. Accordingly, A3V1 continued to be the sole operative, FDA-cleared protocol for study start-up.

To complete final administrative and operational refinements in advance of study initiation, the Sponsor developed the enclosed MJP2 Amendment 4, Version 1 (A4V1) as an amendment to the cleared smoking-only protocol A3V1. A4V1 removes duplicative procedures, updates screening and secondary outcome measures to reduce participant burden, and incorporates administrative updates for clarity and consistency. MJP2 Protocol A4V1 is provided in this submission for Agency review.

The Sponsor remains committed to addressing the Agency's remaining clinical hold comments related to the vaporization device and intends to submit a future amendment and hold response to propose reintroduction of this administration method. Until such time, all study-related conduct will continue to be conducted solely under FDA-cleared smoking-only protocol version(s), in accordance with Agency direction.

If you have any questions or requests regarding this submission, please contact the designated regulatory lead.

Sincerely,
Rick Doblin
Founder and President