



08 March 2021

Sarah Seung, PharmD
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: IND #110513, Serial No. 0017, Original Protocol Submission for MJP2

Dear Division of Psychiatry Products,

The sponsor is writing to submit the MAPS-sponsored protocol MJP2, 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)*," under IND#110513. As presented in the Sponsor's Development Safety Update Report dated 02 November 2020 (Serial No. 0015) under Section 5.0 Inventory of Clinical Trials Ongoing, Completed and Planned During the Reporting Period, the MJP2 protocol will examine the safety and efficacy of inhaled high THC cannabis versus a Low THC/Low CBD placebo in a Veteran population with chronic PTSD. These data will build on a previous randomized phase 2 study supported by MAPS, which showed good tolerability and significant improvements in PTSD symptoms after three weeks of treatment across all groups, though significant differences between treatment groups and placebo were not detected, likely due to the exploratory study design, large placebo effect, and small sample size. This protocol will provide data on an extended five-week treatment period in a larger sample, using a parallel study design and methods to mitigate placebo response.

Please find the following documents enclosed in submission Serial No. 0017:

- FDA Form 1571, dated 08 March 2021
- FDA Form 3674, dated 08 March 2021
- MJP2 Original Protocol Version 2, dated 26 February 2021
- MJP2 ICF Template, dated 28 February 2021
- FDA Form 1572 Sisley, dated 26 February 2021
- Clinical Investigator CV Sisley
- MJP2 Description of CRFs, dated 12 February 2021
- Relevant measures for MJP2

If there are any questions regarding this submission, please do not hesitate to contact Sponsor Designee, Amy Emerson, [REDACTED]

Sincerely,

Amy Emerson Electronically signed by: Amy Emerson
Reason: I am the approver of this document
Date: Mar 9, 2021 09:43 PST

Amy Emerson
Chief Executive Officer
MAPS Public Benefit Corporation