July 6, 2022

Jerad Wayne Najvar, Legal Counsel
Planet Vapor LLC
117 Park View Circle
Piney Flats, TN 37686

Sent via email to: jerad@najvarlaw.com

Dear Petitioner:

Your petition to the Commissioner of the Food and Drug Administration (FDA) requests the following:

Petitioner requests that the Commissioner of the Food and Drug Administration reconsider the determination, vacate the refuse to file letter, and permit Petitioner to supplement its PMTAs with the manufacturing information that was lacking.

Your petition was received and processed under CFR 10.33 by this office on 07/05/2022. It was assigned docket number FDA-2022-P-1452. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.07.06 11:20:29 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)