July 5, 2022

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1-23 & Room 1061
Rockville, MD 20852

PETITION FOR RECONSIDERATION

RE: Refuse to File letter dated June 3, 2022 (regarding multiple STNs)

The undersigned submits this petition for reconsideration of the decision to the Commissioner of Food and Drugs for the Refuse to File letter dated June 3, 2022 directed to Planet Vapor LLC ("Petitioner").

"Petitioner" submits a Petition for Reconsideration pursuant to 21 C.F.R. § 10.33. Petitioner requests that the U.S. Food and Drug Administration ("FDA" or "the Agency") review and reverse its determination that:

> All your PMTAs do not include a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, your products as required under section 910(b)(1)(C) of the FD&C Act.

Refuse to File letter dated June 3, 2022 at 1 ("RTF").[1]

A. Decision Involved

The decision involved is FDA's refusal to file Petitioner's PMTAs as stated in the June 3, 2022 RTF notice (regarding multiple STNs).

B. Action Requested

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.

C. Statement of Grounds

The only document identified as missing in Petitioners' PMTAs are documents discussing its manufacturing processes, as stated above in the excerpt from the June 3 RTF. The omission of this information from the PMTAs as filed with FDA was an inadvertent clerical error, and the RTF was the first notice Petitioner received that these documents were not actually filed with its

[1] The RTF is not attached to this petition because it has been "previously submitted" into the record (by FDA) "in the same proceeding." *See* 21 C.F.R. § 10.20(c). Since this document is already part of the record, and since large portions of it would have to be redacted before posting to the public as part of this petition, Petitioner has not attached it here, but can do so if requested by FDA for any reason.

submission. Petitioner hired a consultant to assist with preparation of its PMTAs, and Petitioners' staff prepared the manufacturing information in consultation with the consultant. The manufacturing information was completed, and was saved into a folder with working documents that are converted to PDF before they are then copied to a flash drive for filing with FDA. However, upon review of the matter after receipt of the RTF, it is apparent that the manufacturing document—which contains the information found to be lacking as stated in the RTF—was not actually converted to PDF and drug into the final PMTA folder on the flash drive that was submitted to FDA. In other words, while Petitioner prepared the information prior to the deadline and intended to include it in its submission, it was not included, solely due to a clerical error.

In light of these circumstances, Petitioner requests that the RTF be rescinded and that Petitioner be permitted to correct the deficiency by submitting the manufacturing information. This would allow Petitioner to remain in its place in the FDA's process, rather than starting over based on the submission date of a newly filed PMTA. It would also preserve FDA resources by facilitating the continued consideration of the already-filed PMTAs instead of requiring creation of an entirely new docket/STNs.

D. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the petition.

/s/ Jerad Najvar
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