U.S. Food & Drug Administration
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October 18, 2022

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

Re: Docket No. FDA-2022-P-1452

Dear Mr. Najvar:

On July 5, 2022, FDA received from Planet Vapor, L.L.C. ("petitioner") a petition for administrative reconsideration of action under 21 C.F.R. § 10.33, which seeks reconsideration of a Refuse to File letter issued on June 3, 2022 ("RTF") for a number of Premarket Tobacco Product Applications ("PMTA") received by FDA on September 16, 2021, pursuant to section 910(b) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act").

FDA has reviewed the petition, the RTF, and the applicable regulations. For the reasons described below, FDA denies the petition.

I. BACKGROUND

On September 16, 2021, FDA received PMTAs submitted by the petitioner under Section 910(b) of the FD&C Act for its new tobacco products. *See e.g.,* PM0005059.

On June 3, 2022, FDA issued the RTF for the petitioner's PMTAs for new ENDS products. *See* RTF at 1. The RTF explained that the petitioner's PMTAs lacked "[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." *Id.* The RTF further explained that the petitioner's unauthorized products cannot be introduced or delivered for introduction into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA. *Id* at 2.

On July 5, 2022, FDA received the petition described above. In a letter to petitioner sent on July 6, 2022, Acting Director, Dockets Management Staff, Karen Malvin acknowledged receipt of the petition ("Acknowledgment Letter").

II. DISCUSSION

The petitioner requests, pursuant to 21 C.F.R. § 10.33, that the Commissioner reconsider FDA's RTF and allow petitioner to submit the missing information that was not submitted due to a "clerical error." *See* Petition for Reconsideration ("Petition") at 1. As discussed below, FDA

denies this petition because the petitioner has not demonstrated that the Commissioner must or should grant its petition for reconsideration. *See* 21 C.F.R. § 10.33(d).

A. Failure to Meet Criteria for Reconsideration

The petitioner has not demonstrated that the Commissioner must or should grant its petition for reconsideration. Section 10.33(d) provides that the Commissioner "shall" grant a petition for reconsideration if the Commissioner determines all of the following apply:

(1) the petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered;
(2) the petitioner's position is not frivolous and is being pursued in good faith;
(3) the petitioner has demonstrated sound public policy grounds supporting reconsideration; and
(4) reconsideration is not outweighed by public health or other public interests.

FDA need not address whether the petitioner's request is frivolous and is being pursued in good faith (21 C.F.R. § 10.33(d)(2)) because the remaining three criteria are not satisfied, as explained below.

In addition, § 10.33(d) further provides that the Commissioner "may" grant a petition when the Commissioner determines it is in the public interest and in the interest of justice. *Id.* These criteria are not met here.

i) <u>FDA's consideration of the administrative record (21 C.F.R. § 10.33(d)(1))</u>

First, the petitioner has not demonstrated that relevant information or views contained in the administrative record were not previously or adequately considered. The petitioner acknowledges that the required manufacturing information was not included in its submission to the FDA due to a "clerical error." *See* Petition at 1-2.

ii) <u>Public policy grounds supporting reconsideration (21 C.F.R. § 10.33(d)(3))</u>

The petitioner has not demonstrated sound public policy grounds supporting reconsideration. The petitioner acknowledges that the required information was prepared but not submitted to the FDA due to a "clerical error." *Id.* The petitioner argues vacating the RTF and allowing petitioner to submit the missing information would "preserve FDA resources" by not "requiring creation of an entirely new docket/STNs." *Id.* at 2. Petitioner's request to vacate the RTF would undermine FDA's ability to focus its resources on submissions that are ready for scientific review. Also, the RTF of these PMTAs does not prevent the petitioner from submitting a new PMTA which includes the missing information. *Id.* Therefore, the petitioner has not demonstrated how sound public policy grounds support reconsidering the RTF.

iii) Public health or other public interests (21 C.F.R.§ 10.33(d)(4))

Public health and other public interests weigh against the requested reconsideration. The petitioner's request for reconsideration, if granted, would be counter to other public interests. Among those interests, other applicants who received RTF letters for their applications for missing information would not receive the same benefit as the petitioner, unless FDA expended significant resources reconsidering other RTFs.

iv) Discretionary authority to reconsider

Finally, FDA declines to exercise its discretionary authority to reconsider the RTF because doing so would not be in the public interest and in the interest of justice. The petitioner has not shown that the agency's consideration of its application was unjust in any respect. For the reasons already explained, the petitioner has not shown that the agency failed to adequately consider its application. Petitioner acknowledges that the information identified as missing in the RTF was never submitted to FDA. Given the absence of any substantive or procedural error in the agency's decision, reconsideration of the RTF is not in the public interest.

III. CONCLUSION

For the foregoing reasons, the Petition for Reconsideration submitted under 21 C.F.R. § 10.33 is denied.

Sincerely,

Lauren Roth -S
Digitally signed by Lauren Roth -S
Date: 2022.10.18 18:07:23 -04'00'

Lauren K. Roth
Associate Commissioner for Policy
Office of the Commissioner
U.S. Food and Drug Administration