June 17, 2022

Amanda Wheeler, President
American Vapor Manufacturers
1201 Iron Springs Road, Suite 3
Prescott, AZ 86305

Sent via email to: amanda@theavm.org

Dear Petitioner:

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

(1) FDA should exercise enforcement discretion and allow manufacturers of synthetic nicotine e-liquids used in open system ENDS devices who submitted timely PMTAs that meet FDA's criteria for application acceptance (21 C.F.R. § 1105.10) and filing (FDCA § 910(b)) to keep those products on the market for their adult (21+) customers following the end of the "transition period" on July 13, 2022. Specifically, we request that the CTP Office of Compliance and Enforcement ("OCE") permit the continued marketing and sale of such synthetic nicotine e-liquids to adults for the duration of the Agency's full scientific review (i.e., until FDA reaches a final marketing authorization determination) of their respective applications.

(2) The FDA CTP Office of Science ("OS") allow manufacturers of these products to continue to submit additional data and amend their applications, as the time provided (60 days between March 15, 2022, and May 14, 2022) was simply insufficient to prepare all of the product-specific data FDA requires PMTAs contain including, in some cases, long-term (6 months+) clinical or longitudinal evidence.

Your petition was received and processed under CFR 10.30 by this office on 06/16/2022. It was assigned docket number FDA-2022-P-1211. 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: 2022.06.17 11:43:24 -04'00'

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