

September 10, 2020

Re: Confirmation of Access Vapor, LLC's PMTA Submission

To Whom It May Concern:

My name is Marc C. Sanchez, a food and drug attorney in private practice ("Counsel"). At the request of my client Access Vapor, LLC (d/b/a Cali Pods) (the "Company"), I am qualified to make the following written opinion. I am an attorney in good standing with 10-years experience in FDA regulatory law, including tobacco product regulation.

Counsel hereby acknowledges and represents that Company successfully filed a pre-market tobacco application (PMTA) on September 9, 2020 for the Cali Plus Disposable.**

Once a PMTA is received by FDA, an acceptance review is performed. An acceptance review is an administrative review that ensures the product falls under Center for Tobacco Products jurisdiction and confirms that the statutory and regulatory requirements of an application are met based upon Section 910 of the FD&C Act and the criteria set forth in § 1105.10. FDA has indicated the acceptance review may take up to 60-days.

Until the FDA states otherwise, Company may remain on the market.

Kind Regards,



Marc C. Sanchez, Esq.
(msanchez@fdaatty.com)
Regulatory Counsel
Access Vapor, LLC

**See, FDA Statement, Coronavirus (COVID-19) Update: Court Grants FDA's Request for Extension of Premarket Review Submission Deadline for Certain Tobacco Products Because of Impacts from COVID-19 ("Consistent with the original court order, for companies that submit timely applications, the agency may continue to exercise enforcement discretion, meaning their products would generally continue to be marketed without being subject to FDA enforcement actions, for up to one year from the deadline (up to Sept. 9, 2021), unless a negative action is taken by the FDA on an application during that time.") (April 23, 2020; available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline>)).

