









August 28, 2020

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health & Human Services
200 Independence, Ave., S.W.
Washington, D.C. 20201
Alex.Azar@hhs.gov

The Honorable Stephen M. Hahn, Commissioner U.S. Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993 Stephen.Hahn@fds.hhs.gov

Filed at:

Division of Dockets Management U.S. Food and Drug Administration 5630 Fishers Lane, Rm. 1061 Docket No. FDA-2020-P-1797

RE: <u>Comments in Opposition to August 24, 2020 Citizen Petition for Extension of Premarket</u> Tobacco Product Application Filing Deadline, FDA-2020-P-1797

Dear Secretary Azar and Commissioner Hahn:

The undersigned public health organizations submit these comments in strong opposition to the Citizen Petition (Petition), submitted August 24, 2020 by various e-cigarette manufacturers, retailers and trade associations seeking a 180-day extension of the court-ordered deadline of September 9, 2020 for submission of Premarket Tobacco Product Applications (PMTAs) for products on the market as of the effective date of the Deeming Rule subjecting e-cigarettes to FDA regulatory authority. Our organizations were plaintiffs in *American Academy of Pediatrics, et al. v. FDA*, Case no. PWG-18-883 (D. Md.) (AAP v. FDA), the litigation resulting in the court-ordered deadline.

The Petition's 11th hour request for relief from the September 9 deadline relies on the assertion of "extenuating circumstances" resulting from the COVID-19 pandemic, even though the e-cigarette industry has already received the benefit of a previous 120-day extension granted, at FDA's request, by the U.S. District Court for the District of Maryland, from May 12 to

September 9, also due to circumstances surrounding the COVID-19 pandemic.¹ The petitioner companies' request to keep their products, and those of similarly situated businesses, on the market for an additional *six months* without the FDA review required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA) is a transparent attempt to use a global pandemic to evade a statutory mandate that Petitioners have successfully evaded for four years since the issuance of the Deeming Rule in 2016. It is long past time for FDA to finally end what the Maryland federal court called a "holiday" from the industry's legal obligations. 379 F.Supp.3d at 493. For the reasons given below, the Petition should be denied and the September 9 deadline should be fully enforced.

1. Granting the Petition Would Violate the Federal Court's Remedial Order

Petitioners relegate to a footnote (Petition at 3, n.4) their treatment of a key threshold issue: Would the extension requested be consistent with the Maryland district court Remedial Order? The court's order allows an exemption from the September 9 deadline only "for good cause on a case-by-case basis." *AAP v. FDA*, 399 F.Supp.3d at 487. However, Petitioners' description of the conditions manufacturers must satisfy to receive the six-month extension does not include a showing that, absent the extension, they would not be able to submit their applications in a timely manner. Rather, Petitioners would require only that a manufacturer "has already made progress in completing PMTAs prior to the September 9, 2020 deadline, but has been materially delayed *in one or more tasks* due to COVID-19." Petition at 3 (emphasis added). That a manufacturer would be delayed in executing a single PMTA-related task due to COVID-19, without the necessity to show that the pandemic will prevent a timely filing, could never be sufficient to establish "good cause."

In this connection, it is noteworthy that, of the twenty Declarants supporting the Petition, only three (Jennifer Higginbotham, Charlotte Own and Illumivaption, Inc.) could state, under penalty of perjury, that their companies cannot meet the September 9 deadline due to COVID-19. The Declarations are filled with claims that the pandemic has "greatly impacted" the ability of firms to prepare PMTAs (Declaration of Marc Slis, App. at 10), or that companies have "encountered great obstacles," (Declaration of Jourdan Wheeler, App. at 13), or third-party testing has been "severely hampered," (Declaration of James Jarvis, App. at 18), or that they "may not be able to file a complete PMTA" by the deadline. (Declaration of Nicholas Orlando, App. at 28) (emphasis added). Significantly, the President of the Rocky Mountain Smoke Free Alliance concedes that her members "have varied in their ability to complete Premarket Tobacco Application requirements," suggesting that some of the "125 small businesses in the vapor industry" in Colorado may well be able to file by the deadline. (Declaration of Amanda Wheeler, App. at 22). In practice, therefore, this is a request for an across-the-board extension of the application deadline for a category of e-cigarette manufacturers defined by criteria established by the manufacturers themselves, but having little to do with "good cause."

_

¹ The public health groups did not oppose the initial 120-day extension, but indicated that they would likely oppose further extensions. *See* Letter of Jeffrey B. Dubner to Hon. Paul Grimm, *AAP v. FDA*, No. PWG-18-883 (D. Md. Apr. 2, 2020), ECF No. 177.

2. Given the Industry's Years of Delay in Preparing the Required PMTAs, the Current COVID-19 Crisis Cannot Excuse the Failure to Meet the September 9 Deadline

To the extent that e-cigarette companies now find it difficult to meet the September 9 deadline, it is due, not to COVID-19, but to the failure of the industry to take seriously its legal obligations under the Tobacco Control Act over the course of four years.

It is beyond dispute that every e-cigarette manufacturer, including each of the Declarant companies, has known, since May, 2016, when the Deeming Rule was published in final form, that the products it had on the market as of the effective date of the Rule (August 8, 2016) would be required to submit a PMTA.² Moreover, FDA issued a detailed Draft Guidance concerning PMTAs for e-cigarettes when it published the Deeming Rule,³ which it later finalized in substantially similar form.⁴ That Draft Guidance set out, in detail, suggestions for information to be included in PMTAs, including identification of constituents or chemicals in the product, the results of various product testing, use patterns for the product, toxicology information and other data. Moreover, as of May, 2016, e-cigarette companies knew that PMTAs must be filed by the end of the two-year "compliance period" set out in the Deeming Rule, or August 8, 2018.

Thus, by the time FDA published its August, 2017 Guidance extending the e-cigarette application deadline until 2022, e-cigarette companies had the opportunity to and should have made substantial progress in preparing their applications. Even after FDA published its August, 2017 Guidance, FDA repeatedly advised the industry that it should not wait to prepare and file its applications. After it became clear that there had been a dramatic increase in youth usage of e-cigarettes, in September, 2018, then-FDA Commissioner Gottlieb indicated the agency's intent to "revisit" the 2022 deadline. In that same statement, the Commissioner made it clear that "there's no excuse for manufacturers not to file applications with the FDA because the agency hasn't told them what they are expected to do. If any manufacturer wants to get direct, precise

²

² Indeed, FDA first stated its intention to deem all tobacco products, including e-cigarettes, subject to its jurisdiction, in March, 2011. FDA, Letter to Stakeholders from Lawrence R. Deyton, Director, Center for Tobacco Products and Janet Woodcock, M.D., "Regulation of E-Cigarettes and Other Tobacco Products," April 25, 2011. https://www.aaphp.org/Determination. According to the Declarations filed in support of the Petition, this preceded the entry of all the Declarant companies into the e-cigarette market. Thus, every one of these companies knew, before they entered the market, that they eventually would have to obtain marketing orders from FDA for each of their products.

³ FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Draft Guidance for Industry (May 2016), at https://www.fda.gov/media/97652/download. ⁴ FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems,

Guidance for Industry (June 2019) (PMTA for ENDS Guidance), at https://www.fda.gov/media/127853/download.

⁵ FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use (Sept. 11, 2018), https://www.fda.gov/news-events/pressannouncements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemicyouth-e-cigarette-use.

guidance on a specific product application, just call us." Thus, at most there was a one-year period (August 2017-September, 2018) when e-cigarette manufacturers had any reason to assume that they had until 2022 to file their PMTAs. Moreover, during all relevant times, FDA urged companies to prepare and file their applications earlier.

As the Maryland federal court observed, "...manufacturers long have been on notice that they will have to file premarket approval applications, substantial equivalence reports, and exemption requests, and if they have chosen to delay their preparations to do so, then any hardship occasioned by their now having to comply is of their own making." AAP v. FDA, 379 F.Supp.3d at 498. Indeed, the industry's failure to engage with the regulatory process was a central reason for the Maryland federal court to issue its Remedial Order in July, 2019 establishing the May 12, 2020 application deadline. According to the court, "the record before me shows a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so, and it establishes a shockingly low rate of filings." AAP v. FDA, 399 F.Supp. at 485. The court continued: "Thus, the record offers little assurance that, in the absence of a deadline for filing, the industry will do anything other than raise every roadblock it can and take every available dilatory measure to keep its products on the market without approval." Id. As new data emerged in the Fall of 2019 showing a continued dramatic increase in youth usage of e-cigarettes, Acting Commissioner Sharpless again urged companies to file their applications: "And as I've said before, responsible manufacturers certainly don't need to wait to act. We encourage industry to use available FDA resources as a guide for their submissions to the agency." CTP Director Zeller, in his Declaration supporting FDA's request to extend the filing deadline to September 9, noted that "manufacturers have had years to prepare submissions, and indeed several have already submitted applications on which the Agency is conducting scientific review.⁸

Yet, the Declarations filed in support of the Petition, if true, demonstrate that, during the years following the Deeming Rule, many e-cigarette companies simply did not do the work necessary to prepare PMTAs, despite being repeatedly urged to do so by the FDA. Thus, Declarant Troy J. LeBlanc, President of the Kentucky Vaping Retailers, Inc., states that the members of his association "were making efforts to move forward with completing a PMTA for their products at the time the Covid-19 pandemic began," including "assembling information concerning the members' practices, compiling information regarding the constituents of product ingredients and product recipes" and "attempting to obtain product testing by domestic labs at the time the pandemic began" LeBlanc Declaration, App. at 68. Mr. LeBlanc offers no explanation for why the Kentucky retailers did not and could not have done this basic preparatory work years before the COVID-19 pandemic, as FDA had urged them to do. As former Commissioner Gottlieb commented in June of 2019: "I think it's a fair statement that the vaping and e-cig industry doesn't have a single association, company, or other entity that's

-

⁶ *Id*.

⁷ FDA, News Release, FDA issues proposed rule for premarket tobacco product applications as part of commitment to continuing strong oversight of e-cigarettes and other tobacco products (Sept. 20, 2019) https://www.fda.gov/news-events/press-announcements/fdaissues-proposed-rule-premarket-tobacco-product-applications-part-commitment-continuingstrong.

⁸ Second Declaration of Mitchell Zeller, AAP v. FDA, ECF 175-1, filed March 3, 2020, at 7-8.

engaged consistently and constructively with the regulatory process. The entire apparatus seems focused on fighting FDA. That hurts progress long term."

Indeed, the standards proposed by the Petition – most notably, that manufacturers need only have "made progress in completing PMTAs" – would open a loophole so large that it would benefit even manufacturers with no prospect of completing a viable PMTA. A manufacturer could assert that it has "made progress" as minimal as opening an application it never intends to complete. FDA should not grant relief that would allow manufacturers that realistically would not remain on the market if the PMTA requirement were enforced to benefit from the unrelated COVID-19 pandemic.

There is simply no reason for FDA to reward such dilatory tactics through repeated extensions of the PMTA deadline on the industry's behalf. Adhering to the September 9 deadline rewards the responsible companies that long ago took the steps to comply with their regulatory duties, not companies that have made little effort to satisfy what the law requires.

3. <u>Allowing an Additional Six-Month Delay for Open System Products Would Be Harmful to the Public Health</u>

Petitioners make much of the fact that they are requesting a six-month additional extension of the September 9 deadline only on behalf of "certain small vapor manufacturers" that sell only "open system" products that can be filled and refilled with e-liquids, and the e-liquids themselves, but not cartridge or pod-based products. Such open system products, according to the Petition, are typically sold in vape shops, many of which function as manufacturers. Petition at 12. Petitioners cite FDA's January, 2020 Guidance, which prioritized enforcement against flavored cartridge-based products (except menthol flavor), not open-system products, because FDA determined that "cartridge-based products. . . [are the] primary driver in youth experimentation with, and continued use of" e-cigarette products. ¹⁰

Just as the January, 2020 Guidance left large gaps in FDA's enforcement policy that afford young people significant attractive alternatives to cartridge-based products, the Petition calls for an extension of the September 9 deadline for a broad range of products that have contributed to the youth e-cigarette epidemic. For example, e-liquids themselves are sold in more than 15,000 discrete flavors, many of which are sweet fruit and candy-flavored products that are obviously appealing to kids. ¹¹ As Appendix A to these comments shows, many of the Petitioner companies, and members of the Petitioner trade associations, are actively involved in the promotion of flavored e-liquids through social media. Open system products can be filled and refilled with these kid-friendly flavors. Indeed, some open system products, like Smok and

⁹ Scott Gottlieb (@ScottGottliebMD), Twitter (Jun. 11, 2019, 12:50 p.m), https://twitter.com/ScottGottliebMD/status/1138488623152738304.

FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (amended April 2020).
 Greta Zhu, et al., Evolution of Electronic Cigarette Brand from 2013-2014 to 2016-2017: Analysis of Brand Websites, 20 J. Med Internet Res. e80 (2018), https://www.jmir.org/2018/3/e80/.

Suorin, are among the most popular e-cigarette devices among kids. ¹² It should be noted that Petitioners' description of the manufacturers who would be eligible for the requested deadline extension does not exclude those who sell flavored products. *See* Petition, at 2-3.

Moreover, there is little doubt that vape shops are a significant source of e-cigarettes for kids. According to the 2018 National Youth Tobacco Survey (NYTS), 16.5% of middle and high school e-cigarette users under 18 report obtaining e-cigarettes from a vape shop in the past month, compared to 9.8% from a gas station or convenience store. A study in *JAMA Pediatrics* found that in California, e-cigarette sales to minors violations are significantly higher in tobacco and vape shops than in any other type of retailer, with 44.7% selling to underage buyers. Another study examining FDA compliance data between 2017 and 2019 found that Illinois vape shops had a retailer violation rate of 26.4%. The reality of youth usage of open system products, sold predominantly in vape shops, belies any public health justification for allowing such products an additional six-month "holiday" from the enforcement of premarket review. As with other new tobacco products, open system e-cigarettes must be required to demonstrate that they meet the statutory standard of being "appropriate for the protection of the public health."

Petitioners also assert that "adult smokers . . . rely on open systems to move away from more dangerous combustible cigarettes" Petition at 3. But in the Deeming Rule itself, FDA found that "systematic reviews of available evidence indicate that there is currently insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device." More recently, the Surgeon General's report on smoking cessation summarized the existing evidence, concluding that "there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation. In any event, Petitioner's speculation hardly justifies a postponement of premarket review for open system products. Indeed, such FDA review provides an appropriate forum for e-cigarette manufacturers to demonstrate that their products are used predominantly by smokers who otherwise would continue to smoke and that they facilitate complete switching from combustible cigarettes. The requested extension would allow these products to remain on the market for six more months without manufacturers having to prove

_

¹² Karen A. Cullen, et al., *eCigarette Use Among Youth in the United States*, 2019, 322 J. Am. Med. Ass'n 2095-2103 (published online Nov. 5, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6865299/.

¹³ Sherry T. Liu, et al., *Youth Access to Tobacco Products in the United States*, 2016-2018,5 Tobacco Regulatory Sci.,491-501 (2019), https://pubmed.ncbi.nlm.nih.gov/30407588/.

¹⁴ April Roeseler, et al., *Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops*, 173 J. Am. Med. Ass'n Pediatrics 795-797 (published online June 24, 2019), doi:10.1001/jamapediatrics.2019.1571.

¹⁵ Steve Sussman, et al., *Vape-only versus vape-and-smoke shops: sales to minors in four states*, Tobacco Control (published online Mar. 26, 2020),

https://tobaccocontrol.bmj.com/content/early/2020/03/26/tobaccocontrol-2019-055567.

¹⁶ Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (Final Rule), 81 Fed. Reg. 28,974, 29.037 (May 20, 2016).

¹⁷ HHS, Smoking Cessation, A Report of the Surgeon General (2020).

that smokers actually switch to open system products when they otherwise would have continued smoking.

Finally, the COVID-19 pandemic, far from justifying further suspension of premarket review for e-cigarettes, is an additional reason to enforce it. As Dr. Nora Volkow, Director of the National Institute on Drug Abuse, has commented, "[m]uch is still unknown, but it can be expected that persons who smoke, vape, or use certain drugs will be at increased risk of infection and its more severe consequences." At a time when our lungs are under attack by a deadly virus, it has never been more important to subject e-cigarettes to rigorous public health review.

4. Conclusion

The Tobacco Control Act mandates that, before new tobacco products can be marketed, they must undergo FDA review and receive an appropriate marketing order. In direct contravention of the statute, for four years after their products became subject to this mandate, Petitioners and other e-cigarette manufacturers have been able to market their products with no FDA review and no marketing order. It is no accident that, during those four years, use of highly-addictive e-cigarettes by young people has reached what FDA has repeatedly called "epidemic" proportions. To prevent another generation from becoming addicted to tobacco products, FDA must enforce, with no further extensions, the court-ordered September 9 deadline. The Citizen Petition should be denied.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

-

¹⁸ Nora Volkow, *Collision of the COVID-19 and Addiction Epidemics*, 173 Annals of Internal Med. 61-62 (Apr. 2, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7138334/.

Appendix A

Examples of Marketing by Petitioners and Members of Petitioner Trade Associations

Knoxville Vapor, LLC



August 22, 2020

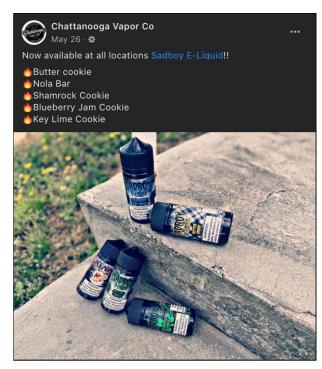
https://www.instagram.com/p/CEMda0oAmmH/



August 17, 2020

https://www.instagram.com/p/CD_2HEJg9rL/

Chattanooga Vapor Co.



May 26, 2020 https://www.facebook.com/Chattanooga VaporCo/photos/a.787402154604919/32 82336331778143/

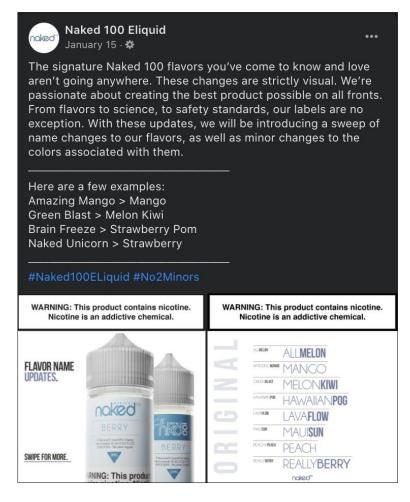


June 4, 2020 https://www.facebook.com/Chattanoo gaVaporCo/photos/a.78740215460491 9/3306575276020915/

August 22, 2020 https://www.facebook.com/Chatta noogaVaporCo/photos/a.8312659 96885201/3518067854871655/



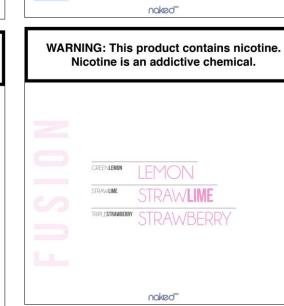
Rocky Mountain Smoke-Free Alliance Member: Naked 100

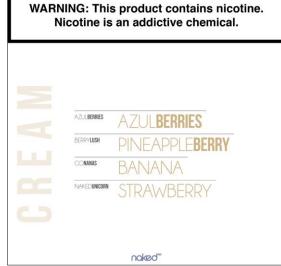


January 15, 2020

https://www.facebook.com/Naked-100-Eliquid-1562075130782612/photos/pcb.2565182553805193/25 65182343805214/





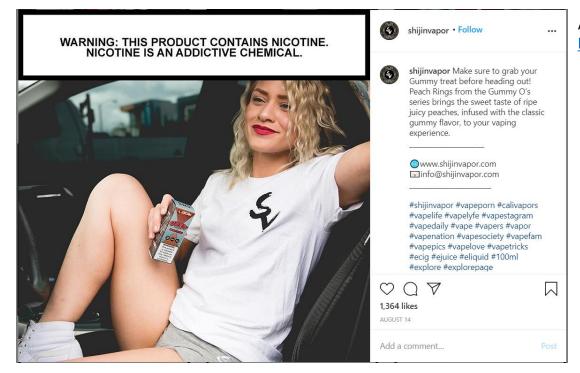




Rocky Mountain Smoke-Free Alliance Member: Shijin Vapor



https://www.instagram.com/shijinvapor/ (last accessed August 26, 2020)



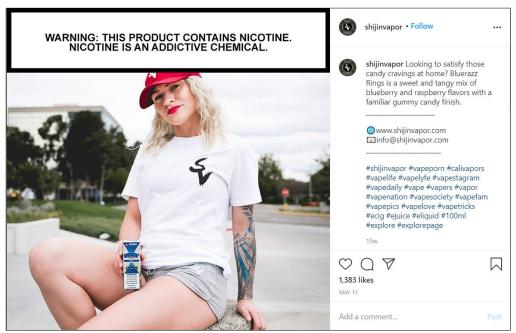
August 14, 2020 https://www.instagram.com/p/CD4eUi4nhd9/

Rocky Mountain Smoke-Free Alliance Member: Shijin Vapor



June 19, 2020

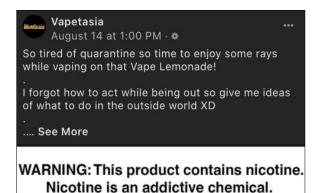
https://www.instagram.com/p/CBoOKAhH0sr/



May 13, 2020

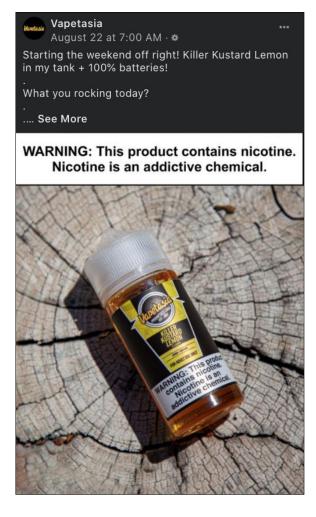
https://www.instagram.com/p/CAJAMnigdTs/

Rocky Mountain Smoke-Free Alliance Member: Vapetasia





August 14, 2020 https://www.facebook.com/vapetasia/photos/a.501313453327643/30309578870 29841/



August 22, 2020 https://www.facebook.com/vapetasia/phot os/a.501313453327643/30534553481134 28/



August 25, 2020 https://www.facebook.com/vapetasia/ph otos/a.501313453327643/306219424057 2872/

Smoke-Free Alternatives Trade Association Member: Giant Vapes



August 5, 2020

https://www.instagram.com/p/CDhSQ-aHnVV/



July 16, 2020

https://www.instagram.com/p/CCtzakmlJdD/

Mountain Oak Vapors (Oviedo Location)



August 14, 2020

https://www.instagram.com/p/CD3whxOA5Gk/

Mountain Oak Vapors (Oviedo Location)



August 24, 2020 https://www.instagram.com/p/CESgC_hA9f_/



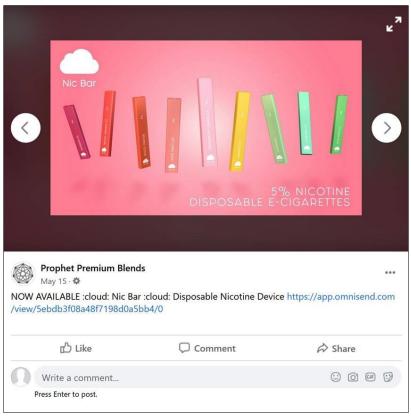
August 24, 2020 https://www.instagram.com/p/CESgC hA9f /

Prophet Premium Blends



January 10, 2020

https://www.facebook.com/Prophetpremium/photos/a.11 78648548832071/2939530489410526/



May 15, 2020

https://www.facebook.com/Prophetpremium/photos/a.11 78648548832071/3244555432241362/

The Vapers Depot (Bradenton Location)



February 12, 2020 https://www.facebook.com/TVD941/photos/a.2003971956 498036/2653796084848950/



February 6, 2020

https://www.facebook.com/TVD941/photos/a.2003971956 498036/2648707002024525/

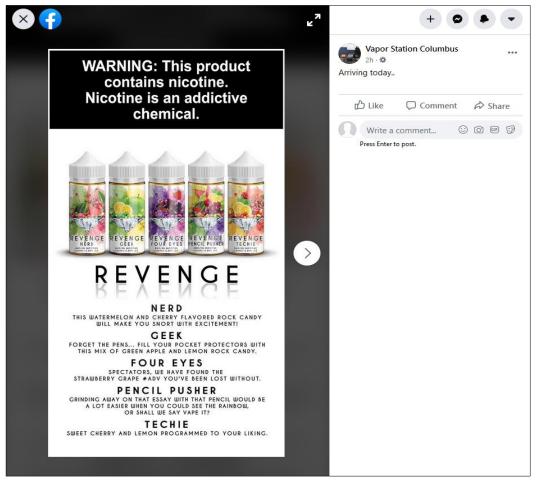
The Vapers Depot (Bradenton Location)



January 31, 2020

https://www.facebook.com/TVD941/photos/a.2 003971956498036/2643826055845953/

Vapor Station Columbus



August 25, 2020 https://www.facebook.com/yaporst

https://www.facebook.com/vaporstationcol umbus/photos/a.139484252918246/143746 1459787179/



August 15, 2020

https://www.facebook.com/vaporstationcolumbus/photos/a .139484252918246/1428867547313237/

Vapor Source, Inc.



February 25, 2020

https://www.facebook.com/vaporsource/photos/a.430692860329037/2919771628087802/.



January 20, 2020

https://www.instagram.com/p/B7jJAEGDkGM/

Michigan Vape Shop Owners Organization Member: Moose Jooce Vape Shops



August 20, 2020

https://www.facebook.com/moosejoocenorth/posts/3153652371370148

Michigan Vape Shop Owners Organization Member: Moose Jooce Vape Shops



August 20, 2020

https://www.facebook.com/moosejoocenorth/posts/3153653628036689/

Michigan Vape Shop Owners Organization Member: Moose Jooce Vape Shops

ml. for \$20!



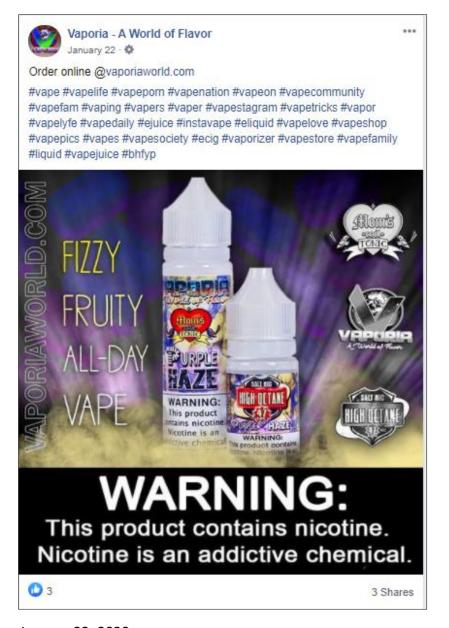
August 20, 2020 https://www.facebook.com/moosejo ocenorth/posts/3153653188036733

ocenorth/posts/3145141798887872/ Moose Jooce Vapeshop North ... August 17 - 3 Coming this week to Moose Jooce North MARNING Available in 3&6 nicotine and 50 mg. salts Kim Shilling Northern Michigan Cloud Makers August 17 Fast Eddie's (makers of PURGE) has been a huge advocate for us...we'll have their Taffy Splash line in later this week! Blue raspberry, banana & strawberry flavors, 100

August 17, 2020

https://www.facebook.com/mooseio

Michigan Vape Shop Owners Organization Member: Vaporia



January 22, 2020 https://www.facebook.com/VaporiaWorld/photos/a.78501 4784922466/2708139179276674/



January 17, 2020

https://www.facebook.com/VaporiaWorld/photos/a.5998093 36776346/2699590126798246

Michigan Vape Shop Owners Organization Member: Vape Escape Vape Shop



August 17, 2020

https://www.facebook.com/vapeescapemonroemi/photos/pcb.3156267807820365/3156256447821501



August 17, 2020

https://www.facebook.com/vapeescapemonroemi/photos/pcb.3156267807820365/3156256471154832

Michigan Vape Shop Owners Organization Member: Podz Cloudz and Coffee



August 19, 2020 https://www.facebook.com/PodzCloudzandCoffee/photos/a.15 17831291874020/2727328080924329



August 9, 2019 https://www.instagram.com/p/B09gwdKIRQT/