



April 30, 2019

Dockets Management Staff (HFA-305)  
 Food and Drug Administration  
 5630 Fishers Lane, Rm. 1061  
 Rockville, MD 20852

RE: Comments in Docket No. FDA-2019-D-0661, “Modifications to Compliance Policy for Certain Deemed Tobacco Products”

The undersigned organizations submit these comments in the above-referenced Docket on the Draft Guidance for Industry on the Food and Drug Administration’s (FDA) proposed Modifications to its Compliance Policy for Certain Deemed Products, issued in March 2019 (Draft Guidance).

The Draft Guidance can be a step forward if it reduces youth access to the flavored products that have contributed so significantly to the problem of youth tobacco use. However, unless strengthened, the Draft Guidance falls short of the forceful action needed to address a public health crisis of this magnitude.

As explained in detail below, on balance we believe the Draft Guidance to constitute an insufficient response to the current crisis of youth e-cigarette use, as well as to the continuing adverse public health consequences of youth cigar smoking, for the following reasons:

- The Draft Guidance will allow flavored e-cigarettes, with great appeal to young people, to remain on the market for years to come without FDA public health review.
- The restrictions on youth access to flavored e-cigarettes at retail stores and on-line proposed in the Draft Guidance are likely to be inadequate to address the youth e-cigarette epidemic.
- The special treatment given to menthol and mint-flavored e-cigarettes in the Draft Guidance has no public health justification and leaves widely available products that the latest survey data shows are commonly used by youth.
- As FDA recognizes, action is needed to curtail advertising and marketing that makes these products attractive to young people, but the proposed prioritization of enforcement against the advertising and promotion of e-cigarettes targeting youth appears insufficient to address the kinds of targeted advertising and promotion most responsible for fueling the current youth e-cigarette epidemic.
- The Draft Guidance lays the appropriate groundwork for action against flavored cigars, but expedited action should be taken to take them off the market and to move toward a rule prohibiting characterizing flavors in cigars.

#### I. THE DRAFT GUIDANCE IS AN INADEQUATE RESPONSE TO THE CURRENT EPIDEMIC OF YOUTH USE OF E-CIGARETTE PRODUCTS

The Draft Guidance correctly acknowledges the breadth of the current epidemic of e-cigarette use among American teens and attempts to take a number of positive steps to address the crisis. However, the Draft Guidance continues the suspension of statutorily-required premarket public health review, announced in August 2017, that is contrary to FDA's statutory obligations and has limited FDA's effectiveness in addressing the crisis. Furthermore, it is FDA's use of its authority and not the tobacco industry's "willingness to protect teens"<sup>1</sup> that will curb the youth e-cigarette epidemic. The Guidance touts FDA's solicitation of solutions from the manufacturers of the top five e-cigarette manufacturers, yet these manufacturers are the cause of the problem. FDA must assert its own authority and not rely on voluntary action from manufacturers to achieve FDA's public health mission.

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<sup>1</sup> Azar, Alex M. and Gottlieb, Scott, "The future of e-cigarettes depends on the industry's willingness to protect teens," *The Washington Post*, March 21, 2018.

A. The Draft Guidance recognizes the recent acceleration of e-cigarette use among youth to epidemic proportions

As the Draft Guidance recognizes, e-cigarette usage among youth recently has risen to epidemic proportions. NYTS data shows a 78 percent increase in current e-cigarette use among high school students between 2017 and 2018 and a 48 percent increase during that year for middle school students. (8)<sup>2</sup> Data from the Monitoring the Future study found similarly sharp increases among 8<sup>th</sup>, 10<sup>th</sup> and 12<sup>th</sup> graders from 2017 to 2018. (8) As Commissioner Gottlieb noted in his statement accompanying issuance of the Draft Guidance, more than 3.6 million middle and high school students are now current (past 30 day) e-cigarette users, an increase of 1.5 million in the last year alone.<sup>3</sup> The Commissioner also noted that, “research shows that kids using e-cigarettes are more likely to take up combustible cigarettes,” thus threatening the steady progress we have made in reducing the prevalence of youth cigarette smoking.<sup>4</sup>

The data also show that the e-cigarette youth epidemic has become, as Commissioner Gottlieb put it last year, “an epidemic of addiction.”<sup>5</sup> FDA cites NYTS data showing that the proportion of current high school e-cigarette users reporting use on 20 days or more of the prior 30-day period had grown from 20 percent in 2017 to 27.7 percent in 2018. (8) This is no doubt due to the sharp increase in the use of JUUL, which the Surgeon General has found to have a “high level of nicotine,” with a typical JUUL pod containing as much nicotine as a pack of 20 regular cigarettes.<sup>6</sup> Commissioner Gottlieb talked about the “painful stories from parents of teenagers, pediatricians and young people themselves” that “make clear that, for many young e-cigarette users, addiction has already taken hold.”<sup>7</sup> Research shows that the popularity of JUUL has spurred a proliferation of JUUL-like devices. One study found 39 JUUL-like devices on the market as of September 2018, with nicotine levels similar or higher to that of JUUL.<sup>8</sup>

FDA states that the Draft Guidance seeks to balance the public health threat of youth addiction “against the potential benefit to providing adult smokers noncombustible options to allow them to completely switch from the use of combustible products.” (12) But the 2018 report of the National Academies of Sciences, Engineering and Medicine (NASEM) concluded, “[o]verall, there is limited

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<sup>2</sup> Numbers in parentheses throughout these comments refer to the pagination of the Draft Guidance.

<sup>3</sup> Statement from FDA Commissioner Scott Gottlieb, M.R., on advancing new policies aimed at preventing youth access to, and appeal of, flavored tobacco products, including e-cigarettes and cigars (March 13, 2019), at 2. (Gottlieb Statement)

<sup>4</sup> Id.

<sup>5</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use (Sept. 12, 2018).

<sup>6</sup> Surgeon General’s Advisory on E-Cigarette Use Among Youth (December 18, 2018).

<sup>7</sup> Remarks by Scott Gottlieb, M.D., Public Hearing on Eliminating Youth Use of Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies (January 18, 2019).

<sup>8</sup> Jackler, RM and Ramamurthi, D, “Nicotine arms race: JUUL and the high-nicotine product market,” *Tobacco Control*, published online February 15, 2019. doi:10.1136/tobaccocontrol-2018-054796

evidence that e-cigarettes may be an effective aid to promote smoking cessation,”<sup>9</sup> and no sound evidence has been cited to reach any other conclusion today. Given the overwhelming, and alarming, evidence of youth usage and addiction, along with the uncertain evidence of e-cigarette effectiveness for smoking cessation, FDA must strike the balance in a way that ensures effective action to curb the current youth epidemic. The statute gives the FDA the authority to prevent an epidemic of use by youth, while still permitting the development and sale of medical products that promote smoking cessation.

Given the seriousness of the current epidemic, stronger actions need to be taken than those set forth in the Draft Guidance, as explained in more detail below.

- B. The Draft Guidance proposes to allow flavored e-cigarettes used by young people to remain on the market for years to come without FDA public health review.

The Draft Guidance presents compelling evidence that flavored e-cigarettes are particularly attractive to youth and a major factor in fueling the current epidemic. FDA cites 2016-2017 PATH study data showing that over 96 percent of 12-17 year olds who had initiated e-cigarette use since the last survey wave started with a flavored product. (9) PATH also shows that 97 percent of current e-cigarette users in that age group reported that they had used a flavored product in the past month and that 70.3 percent said they used the products “because they come in flavors I like.” (9) The NYTS shows that past 30-day use of any flavored e-cigarette increased in 2017-2018 from 60.9 percent to 67.8 percent. (9) As the Draft Guidance notes, “[t]his evidence is consistent with earlier research indicating that flavors increase youth appeal of tobacco products.” (9) It is hardly surprising that JUUL, the product that has established a dominant position in the youth market during the past two years, comes in a variety of flavors appealing to young people.

Because of the clear link between the popularity of flavored e-cigarette products and the epidemic of youth usage of the products, strong action by FDA is needed. FDA recognizes its authority to take off the market the flavored e-cigarettes that are attracting young people, until they undergo the premarket review mandated by statute. It should exercise that authority.

The Draft Guidance expressly recognizes that, as of the effective date of the deeming rule (August 8, 2016), all e-cigarettes not on the market as of the “grandfather date” of February 15, 2007 are new tobacco products requiring premarket authorization. (12) Since no e-cigarettes on the market as of August 8, 2016 have received such premarket orders, they are currently being marketed without statutory authorization. Yet, by virtue of the Compliance Policy announced in August 2017, FDA has effectively suspended the premarket review process,

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<sup>9</sup> NASEM, *Public Health Consequences of E-Cigarettes*, Washington, DC: The National Academies Press, 2018).

allowing manufacturers until August 8, 2022 to file applications for premarket review and then allowing those products to remain on the market for an indefinite period of time while the agency reviews the applications. Thus, the Compliance Policy in effect since August 2017 allows flavored e-cigarettes with intense appeal to youth to remain on the market indefinitely without FDA public health review.

Although the Draft Guidance proposes to require premarket applications for e-cigarettes by August 8, 2021 (a year sooner than the August 2017 Policy), it continues to allow flavored products to remain on the market for an indefinite period during FDA review of the application, until a decision is made. Thus, under the Draft Guidance, manufacturers of flavored products used by millions of young people are not even required to submit applications for premarket review for over two more years – a full five years since the deeming rule took effect – and their products will remain on the market for an indefinite period after that. Given that usage of e-cigarettes by high school students rose 78 percent in a single year, allowing e-cigarette manufacturers over two more years to even file applications for premarket review, and allowing FDA an indefinite period to review them and make its determinations, all while flavored products remain on the market, will have adverse public health consequences. Immediate action to remove from the market flavored e-cigarettes that have not been subject to public health review is even more pressing given that Commissioner Gottlieb acknowledged in February that the epidemic of youth usage is likely to worsen, stating, “Based on a growing body of evidence, I fear the youth trends will continue in 2019...The signs we’re seeing are not encouraging. They point to continued growth in youth use of these products.”<sup>10</sup>

There is no public health justification for continuing to suspend premarket review of e-cigarettes for years to come. On the one hand, the Commissioner states that the August 2017 Guidance extended premarket review compliance deadlines for e-cigarettes to allow FDA time to issue additional guidance and rules on the requirements for premarket submissions to allow manufacturers to file “higher quality applications.”<sup>11</sup> Almost two years later no additional guidance or rules for premarket tobacco applications have yet been issued. At the same time, however, the Commissioner implores manufacturers to “not wait to submit premarket tobacco product applications for ENDS products, flavored or otherwise.”<sup>12</sup> The Commissioner also points to the value of the Guidances previously issued by FDA on premarket applications and encourages manufacturers to meet with FDA personnel “about their preparation of premarket submissions.”<sup>13</sup> These statements appear to recognize that manufacturers have sufficient guidance now to submit applications that FDA is currently prepared to review. There is no rationale for the continued

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<sup>10</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on new data demonstrating rising youth use of tobacco products and the agency’s ongoing actions to confront the epidemic of youth e-cigarette use (February 11, 2019).

<sup>11</sup> Gottlieb Statement, at 5.

<sup>12</sup> Gottlieb Statement, at 5.

<sup>13</sup> Id. at 6.

suspension of premarket review for products that are addicting our young people on a daily basis.

C. Restrictions on youth access to flavored e-cigarettes at retail stores and on-line are inadequate to address the youth e-cigarette epidemic

Instead of rescinding the August 2017 Compliance Policy for flavored e-cigarettes in its entirety, the Draft Guidance indicates that FDA will enforce the premarket review requirements as to flavored products (other than tobacco-flavored, mint-flavored and menthol-flavored), if “sold in locations that minors are able to enter at any time (e.g., the entire establishment or an area within the establishment)” (13). The Guidance provides too little information on how a store would qualify. We believe no store should qualify unless it is illegal for the store to permit a person under the designated age to enter and the store must be subject to penalties if and when it does not comply. A store owner voluntarily putting up a sign designating the store as age-restricted with no enforceable mechanism or penalty is an invitation to abuse. Similarly, although Commissioner Gottlieb indicated in November 2018 that FDA would not revisit its Compliance Policy for products sold exclusively in age-restricted locations or in sections of an establishment that prevents entry of minors,<sup>14</sup> the Draft Guidance lacks clarity as to what qualifies as a covered age-restricted section within a facility sufficient to allow a product to avoid the premarket review requirements.

Moreover, assuming that it will be possible for a product to avoid enforcement of the premarket review requirements through creation of age-restricted areas within stores, the Draft Guidance offers little real guidance as to what in-store restrictions on youth access will be deemed sufficient. Thus, even if made final, the youth access restrictions in the Draft Guidance are likely to lead to little change in retailer behavior. This non-compliance is especially likely in light of the widespread illegal retail sale of e-cigarettes to minors indicated by the 1,300 warning letters already sent to retailers and the data cited in the Draft Guidance of significant numbers of minors obtaining e-cigarettes from vape shops, gas stations, convenience stores and other retail outlets. (11)

The fundamental problem, though, is that the epidemic of youth usage of e-cigarettes has been so fast-developing, and is now so pervasive, that even if the Draft Guidance is made final, its youth access restrictions are unlikely to be sufficient to bring the epidemic under control. Given the intense demand among

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<sup>14</sup> In his November 15, 2018 Statement, Commissioner Gottlieb said this: “The FDA is not revisiting the compliance policy with respect to ENDS product sold exclusively in age-restricted locations – for instance, a stand-alone tobacco retailer (such as a vape shop) that adequately prevents persons under the age of 18 from entering the store at any time; or, a section of an establishment that adequately prevents entry of persons under the age of 18, and the flavored ENDS products are not visible or accessible to persons under the age of 18 at any time.” The Draft Guidance issued in March, 2019 is far less clear about whether an age-restricted area within a store that is, itself, not age-restricted, would be sufficient to avoid enforcement of the premarket review requirements.

adolescents for these flavored products, particularly JUUL and its imitators, if the products remain on the market too many young people will find ways to obtain them. FDA's proposed enforcement policy to effectuate retail youth access restrictions may be beneficial as far as it goes, but is no substitute for the action that is clearly required: the agency should rescind the August, 2017 Guidance and adhere to the statutory mandate for premarket review of flavored e-cigarettes placed on the market after the grandfather date of February 15, 2007. It also must move quickly to issue proposed and final rules prohibiting all characterizing flavors, except tobacco, in all tobacco products.<sup>15</sup>

Recognizing that, “[m]inors can easily access websites that offer e-cigarettes for sale or distribution,” and that many online sellers do not use adequate age verification (11), the Draft Guidance also proposes to “prioritize enforcement” against products sold online with no limit on the quantity a customer may purchase within a given period of time and products sold online without “independent, third-party age and identity verification services that compare customer information against third-party data sources, such as public records.” (13) Because the Draft Guidance does not indicate how many products may be sold to a customer and in what time frame, even if the Draft Guidance is made final, it will remain possible for bulk on-line sales of large numbers of flavored products to continue. Although enhanced age and identity verification for on-line sales is a step forward, even if the Draft Guidance is made final, these restrictions are unlikely to be sufficiently effective in preventing on-line access by youth. Thus, internet sales of e-cigarettes should be prohibited. Moreover, restrictions on on-line sales are no substitute for the exercise of FDA's statutory responsibility to regulate the product itself under mandatory premarket review.

D. The exemption of mint and menthol-flavored e-cigarettes from the revised Compliance Policy has no public health justification

In addition, FDA proposes to make no changes to the Compliance Policy for menthol and mint-flavored e-cigarettes, for which premarket review applications still need not be filed before August, 2022. Moreover, the proposed youth access restrictions would not apply to these flavors, which would remain as available to youth as they are now. Given the prevalence of these flavors among young e-cigarette users, there is no public health justification for the special treatment the Draft Guidance proposes to give them.

The Draft Guidance relies on various studies supporting the conclusion that “[w]hile minors use mint and menthol ENDS products, it appears that they prefer

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<sup>15</sup> FDA is authorized to allow, and we would not oppose the use of, specific flavors in specific e-cigarette or other non-combustible products for the purposes of facilitating smoking cessation and/or complete switching if the agency determines there is sufficient independently verified research supporting efficacy and demonstrating that the products can be marketed to prevent youth access and initiation and that they do not increase the toxicity of the product.

them substantially less than adults prefer such flavors.” But the issue is not whether minors like mint or menthol more or less than adults, even if the studies answer that question adequately. The issue is whether these flavors are sufficiently attractive to youth that they are contributing to the current youth e-cigarette epidemic. In his statement, Commissioner Gottlieb offered the assurance that “[w]e won’t ignore data regarding the popularity of mint and menthol-flavored ENDS among kids, should the concern rise.” In fact, the Draft Guidance has already ignored such data; it makes no mention whatsoever of the FDA’s own publicly-released data (in collaboration with CDC) from the 2017-2018 NYTS showing that the use of menthol and mint-flavored e-cigarettes increased from 42.3 percent in 2017 to 51.2 percent in 2018.<sup>16</sup> This data is more recent and the study more comprehensive than the flavor preference data relied on in the Draft Guidance.

FDA cites studies showing that in several surveys youth state that they like fruit and candy flavors more than menthol and mint but, as we noted, the NYTS shows that more than half of all youth who use e-cigarettes say they use mint or menthol. If the goal is to remove the e-cigarettes that are most attractive to youth, any proposal that ignores mint and menthol falls short. In addition, a recent survey by Truth Initiative showed that for current JUUL users from 12-17 years old, 16 percent used the mint flavor the last time they used a JUUL, behind only fruit (26 percent) and mango (25 percent). For those between 18 and 21 years old, mint was the most popular flavor, with nearly a third (32 percent) using mint the last time they vaped.<sup>17</sup> Given the highly-addictive qualities of JUUL, it seems readily apparent that young users of JUUL fruit and mango flavors would simply shift to mint if the other flavors were no longer available.

Moreover, the evidence from cigarettes establishes that menthol has unique appeal for youth and has become more popular since other flavored cigarettes were banned. Youth smokers are more likely to use menthol cigarettes than any other age group. Over half (54 percent) of youth smokers ages 12-17 use menthol cigarettes, compared to less than one-third of smokers ages 35 and older.<sup>18</sup> A study analyzing the impact of the 2009 ban on characterizing flavors in cigarettes on youth tobacco use found that use of menthol cigarettes among high schoolers significantly increased after the ban.<sup>19</sup>

There is thus compelling evidence that making fruit and candy flavors more difficult to obtain, but leaving mint and menthol e-cigarettes as accessible to young people as they are now, will simply shift youth e-cigarette users from one flavor to another, rather than meaningfully reducing the rate of youth usage.

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<sup>16</sup> MMWR, November 16, 2018.

<sup>17</sup> Truth Initiative, “Juul fails to remove all of youth’s favorite flavors from stores,”

<sup>18</sup> Villanti, A., et al., “Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004-2014,” *Tobacco Control*, published online October 20, 2016.

<sup>19</sup> Coutemanche, CJ, et al., “Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use,” *American Journal of Preventive Medicine*, published online January 9, 2017.



FDA seeks to justify the special treatment of menthol and mint flavored products by asserting that, “it is possible that mint and menthol-flavored ENDS products may be important to some adults who seek to use specific ENDS products to cease combustible tobacco product use.” (19) FDA, however, offers no studies quantifying the number of adults who are using these particular flavors to switch completely from cigarette smoking or quit tobacco use entirely, how many are succeeding and how many would not have switched completely or quit tobacco use entirely if these flavors were unavailable. The absence of any sound scientific studies to support this hypothesis, in the face of the overwhelming data about youth use, is striking. Without such data, the possibility that adults prefer these flavors more than young people, even if true, in no way establishes a public health benefit from their continued easy availability – especially while menthol cigarettes remain on the market. By contrast, the data strongly establish that mint and menthol flavored products are contributing to the appeal of these products to adolescents.

- E. Enforcement against advertising and promotion of e-cigarettes targeting youth is essential, but such advertising and promotion is defined too narrowly by the Draft Guidance

In the Draft Guidance, FDA also proposes to enforce the premarket review requirements against “ENDS products that are targeted to minors or likely to promote use of ENDS by minors.” (14) The Draft Guidance finds that “many ENDS products are being marketed to minors through a wide variety of media,” including television, radio and social media. (14-15) The Draft Guidance cites examples like the use of “youth appealing cartoons as well as the use of minors or people who appear to be minors in multimedia advertisements.” (15) FDA also cites the warning letters previously issued for products that resemble kid-friendly foods and drinks or other products often consumed by kids, like juice boxes, candy or kid-friendly cereal. (15)

We acknowledge FDA for the actions it has taken against these blatant examples of dangerous marketing of e-cigarettes to children. However, FDA is aware that e-cigarette companies have been using far more sophisticated and effective ways of marketing their products to a broader audience of young people, including teens. JUUL’s spectacular success in attracting the youth market was not an accident. Rather, as a recent Stanford University study shows, JUUL was launched with social media and other advertising using images that overtly targeted young people and, indeed, mimicked the imagery long used by cigarette companies to appeal to youth.<sup>20</sup> JUUL’s marketing has also focused on the social media platforms most used by teens, including Instagram, YouTube and Twitter.<sup>21</sup> As the

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<sup>20</sup> Jackler, Robert K. et al., “JUUL Advertising Over its First Three Years on the Market” (January 24, 2019).

<sup>21</sup> See J. Huang, et al., “Vaping versus JUULing: how the extraordinary growth and marketing of JUUL transformed the US retail e-cigarette market,” *Tobacco Control* 2018: 1-6, doi:10.1136/tobaccocontrol-2018-054382; Chu, D-H, et al., “JUUL: Spreading Online and Offline,” *Journal of Adolescent Health*, 2018, 63(5), 582-586.

appendix to these comments shows, other companies have copied JUUL's sophisticated techniques of marketing to teens, particularly through social media.

Thus, in addressing the marketing of e-cigarettes to youth that has fueled the current epidemic, FDA should not confine itself to actions directed at the use of cartoons, or kid-friendly products, as reprehensible and dangerous as that marketing has been. Rather, FDA should impose on e-cigarettes all the marketing restrictions that currently apply to cigarettes and must actively monitor e-cigarette marketing to expose, and take action against, marketing calculated to attract large numbers of young people. FDA should also consider ways to ensure that social media channels with high levels of youth users are not used as advertising platforms for any tobacco products, including e-cigarettes and cigars. Further, we encourage FDA to work closely with the Federal Trade Commission (FTC) to limit the reach of paid third-party endorsers (also known as influencers).<sup>22</sup> Unless there are comprehensive limitations on marketing, youth will continue to be exposed to tobacco marketing.

## II. GIVEN FDA'S CONCLUSIONS ABOUT THE PUBLIC HEALTH IMPACT OF FLAVORED CIGARS, EXPEDITED ACTION SHOULD BE TAKEN TO TAKE THEM OFF THE MARKET

Four months ago, Commissioner Gottlieb announced that, "flavored cigars should no longer be subject to the extended compliance date for premarket authorization – regardless of the location in which the products are sold."<sup>23</sup> He correctly based this conclusion on research showing that compared to adults (25 or older) who smoke cigars, a higher proportion of youth who smoke cigars use flavored cigars. Thus, he wrote, "eliminating flavors from cigars would likely help prevent cigar initiation by young people."<sup>24</sup> His recognition of the need to rescind the August 2017 compliance policy for flavored cigars was a step forward. However, the Draft Guidance leaves untouched many flavored cigars that were on the market as of February 15, 2007. It is imperative that the FDA quickly follow up with a product standard prohibiting all flavored cigars.

Thus, while the Draft Guidance finds that modifying FDA's previous compliance policy toward flavored cigars would "limit minors' access to a tobacco product that presents substantial risks and provides no public health benefit," (16) it falls far short of what is needed to ensure youth do not continue to use these products. Following the close of the comment period on the Draft Guidance, FDA

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<sup>22</sup> See Petition to Federal Trade Commission for Investigative and Enforcement Action to Stop Deceptive Advertising Online, filed by Campaign for Tobacco-Free Kids, et al. (August 24, 2018), transmitted to FDA by letter of Campaign for Tobacco-Free Kids to CTP Director Mitch Zeller, August 24, 2018.

<sup>23</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes (November 15, 2018), at 8.

<sup>24</sup> Id.

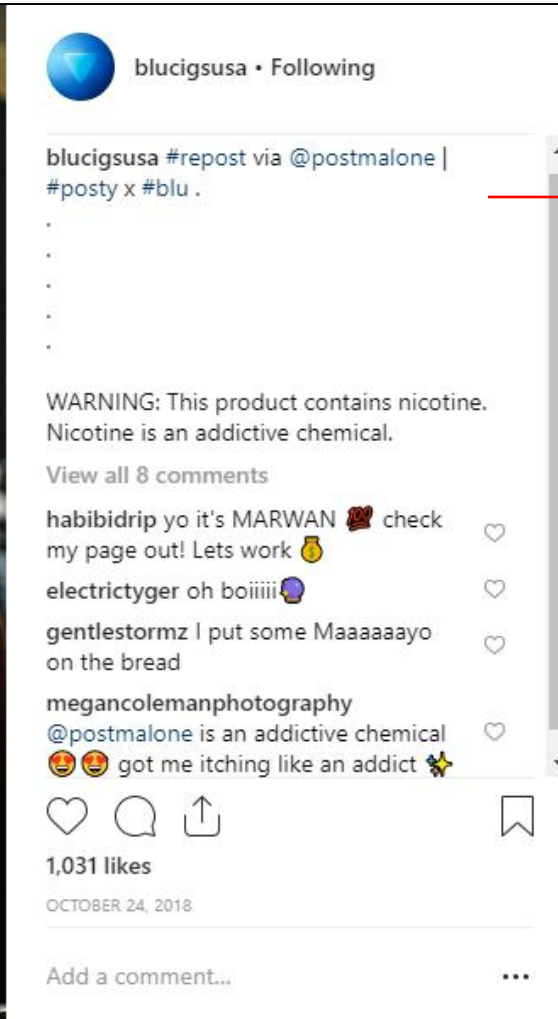
should move with expedition to take flavored cigars off the market. Moreover, given that FDA has indicated its intention to issue a proposed rule prohibiting flavors in cigars, a rule that is necessary to stop the continued sale of flavored cigars that are grandfathered and thus not subject to premarket review, the agency should move quickly to publish a proposed rule. Every day that passes more and more young people are initiating use of these highly-addictive products that endanger their health, now and into the future.

Respectfully submitted,

Action on Smoking & Health  
Allergy & Asthma Network  
American Academy of Family Physicians  
American Academy of Oral and Maxillofacial Pathology  
American Academy of Pediatrics  
American Association for Dental Research  
American Association for Respiratory Care  
American Cancer Society Cancer Action Network  
American College of Physicians  
American College of Preventive Medicine  
American Heart Association  
American Lung Association  
American Medical Association  
American Psychological Association  
American Public Health Association  
American Society of Addiction Medicine  
American Thoracic Society  
Americans for Nonsmokers' Rights  
Association of Schools and Programs of Public Health  
Big Cities Health Coalition  
Campaign for Tobacco-Free Kids  
Community Anti-Drug Coalitions of America  
Counter Tools  
Eta Sigma Gamma – National Health Education Honorary  
Mesothelioma Applied Research Foundation  
National Association of County & City Health Officials  
National Association of Pediatric Nurse Practitioners  
National Association of Social Workers  
National Hispanic Medical Association  
National Network of Public Health Institutes  
Public Health Law Center  
Public Health Solutions  
Society for Cardiovascular Angiography and Interventions  
Students Against Destructive Decisions  
The Society of State Leaders of Health and Physical Education  
Truth Initiative

**Appendix to Public Health Group  
Comments in Docket No. FDA-2019-  
D-0661, “Modifications to  
Compliance Policy for Certain  
Deemed Tobacco Products”**

# Blu: Celebrities/Brand Ambassadors, Social Media



Post Malone is a musician with 15.5 million Instagram followers

# Blu: Celebrities/Brand Ambassadors, Social Media



Niykee Heaton is a singer with 548,000 Twitter followers and 2.9 million Instagram followers

[June 6, 2018](#)

<https://twitter.com/blucigs/status/1004462603953897473>



# Blu: Social Media, Sponsored Parties



blucigsusa • Following  
Minnesota Super Bowl 2018

blucigsusa The @maximmag x blu Super Bowl party is underway! Make sure to follow our IG Story throughout the night for an exclusive look behind the scenes. #mybluis #blu #MaximParty

blucigsusa #blu #mybluis #ecig

darktwistedgenu Super bowl going to be boring due to pop music.



181 likes

FEBRUARY 3

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[February 2, 2018](#)

<https://www.instagram.com/p/Bewnb3zBuBZ/?taken-by=blucigsusa>

# Blu: Popular Youth Magazines; Mocking Health Warnings



Rolling Stone: July 13-27, 2017; December 14-28, 2017

Image courtesy of trinketsandtrash.org



# Blu: Sponsored Party Bus in Atlanta



7/18/18; <https://www.instagram.com/p/BIX0Rw7D4j0/?taken-by=blulanta>

# Blu: Atlanta Art Installation Popular with Kids



christenbabb • Follow  
Antico-Pizza Napoletana

christenbabb Two-thirds of my baby birds. 🐦  
#blulanta #bennett #buzzy #myboys  
mkd1thelen Yummy!!!! Antico!!!!  
jaimiemelaine My fave!



46 likes

JULY 21

Add a comment...



7/21/18; <https://www.instagram.com/p/Blg11GBn2-P/?tagged=blulanta>

# Blu: Social Media, Celebrities/Brand Ambassadors



B. Simone is an actress and singer with 2.7 million Instagram followers

8/12/18; <https://www.instagram.com/p/BmXdDyznb2B/?taken-by=thebsimone2> (also reposted by blu: [https://www.instagram.com/p/BmZmLMIBg\\_o/?taken-by=blucigsusa](https://www.instagram.com/p/BmZmLMIBg_o/?taken-by=blucigsusa))



# Blu: Sponsored Bar Nights



7/27/18; <https://www.instagram.com/p/BluWGxglf5P/?tagged=blulanta>



# Kandy Pens: Social Media

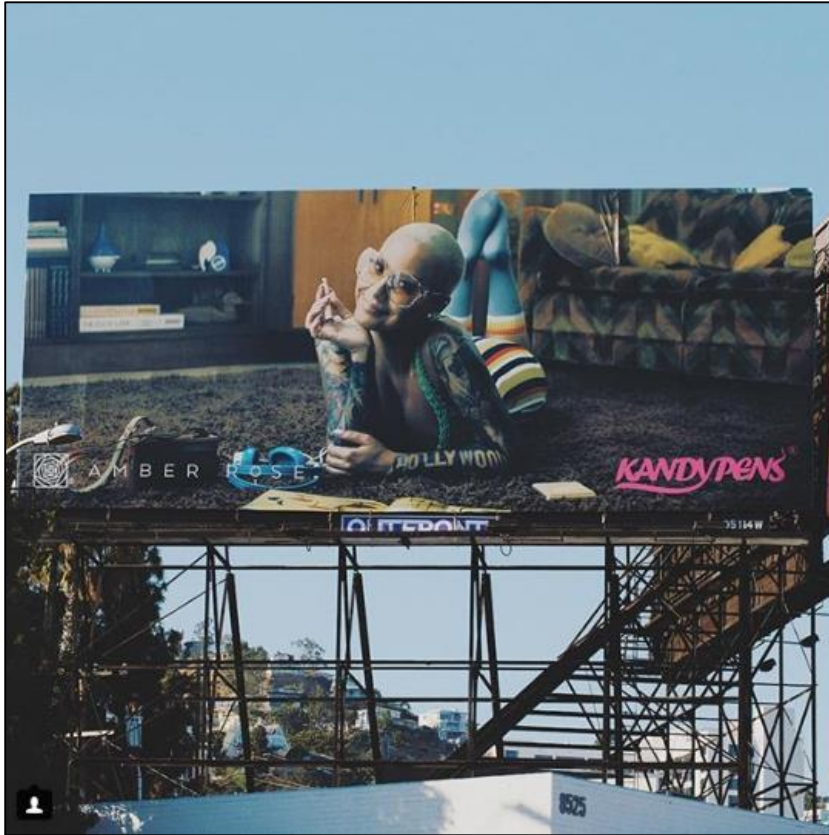


February 13, 2018

<https://www.instagram.com/p/BfJf-hUgj5Z/?hl=en&taken-by=kandypens>



# Kandy Pens: Celebrities/brand ambassadors, billboards, social media



kandypens • Following  
kandypens AMBER ROSE x KANDYPENS  
❤️ #beready

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brujies 🍌🍌🍌

mrpeteywheat Not taking feet off of necks anytime soon.

hightidetoursla 🍌🍌🍌🍌❤️❤️❤️❤️

hurricane\_joe\_ Wave gang

\_ghostfacekellah\_ She doesn't burn though.

kandypens @\_ghostfacekellah\_ 😊

killermunchiesedibles @kandypens 🍌🍌🍌

yungvapedad amber rose is yucky

kandypens @yungvapedad So Profound

queenkimberlyn Just ordered a Slim

hah

❤️

1,0

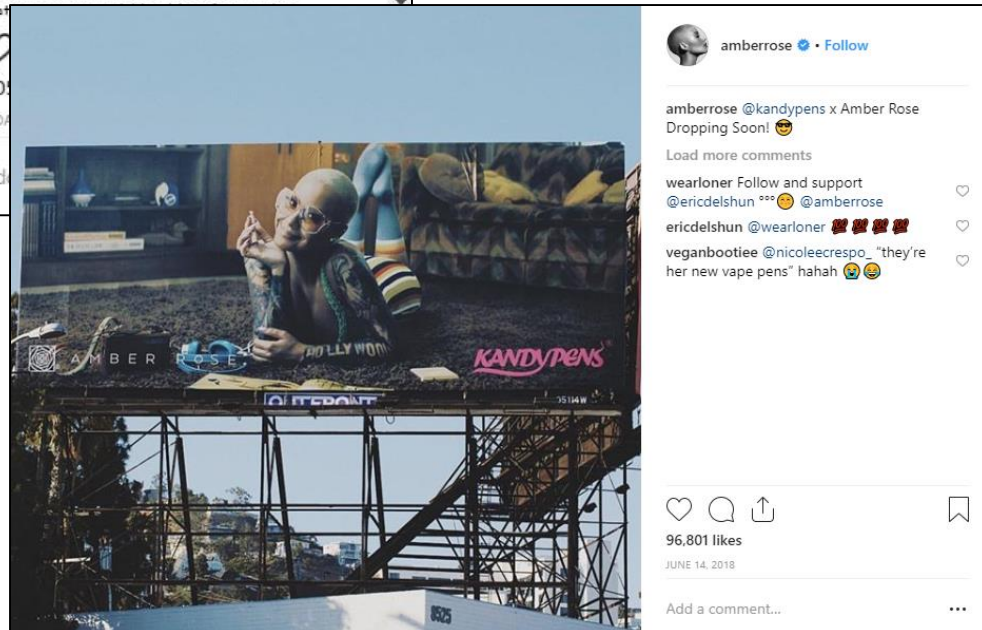
1 D

Ad

June 14, 2018,

[https://www.instagram.com/p/Bj\\_dtUyAr1t/?taken-by=kandypens](https://www.instagram.com/p/Bj_dtUyAr1t/?taken-by=kandypens)

Also posted on Amber Rose's personal Instagram. Amber Rose is a model and actress with 18.7 million Instagram followers



June 14, 2018, <https://www.instagram.com/p/BkBW17PIQ3s/>

# Kandy Pens: Featured Music Artists and Product Placement in Music Videos

**KANDYPENS®** products accessories faq artists news MY ACCOUNT \$0.00

833-326-3904

## ARTISTS

AMBER ROSE

ASAP ROCKY

BOOCZ BOOCETZ

DJ ESCO

DJ KHALED

FATBOY SSE

HARRY FRAUD

LEILANI WOLFRAM

MAALYRAH

PNB ROCK

REGGIE MILLS

YOUNG M.A.

ZAC MANSON

## AS SEEN IN OVER 2 BILLION VIEWS

Famous Dex - Nervous ft. Jay Critch & Rich The Kid

Asian Doll - First Off

B La B Feat. Lil Baby "Sunday Morning"

Young M.A "Car Confessions"

Dave East "I Don't Understand It"

Fat Joe, Chris Brown, Dre - Attention

Young M.A "Wahlinn" feat. KorLeone

Skye & Chris Brown - Fairytale

Dave East - No Stylist ft. BlocBoy JB

DJ Khaled - No Brainer ft. Justin Bieber, Chance the Rapper, Quavo

Dave East & Rick Ross - Fresh Prince of Belaire

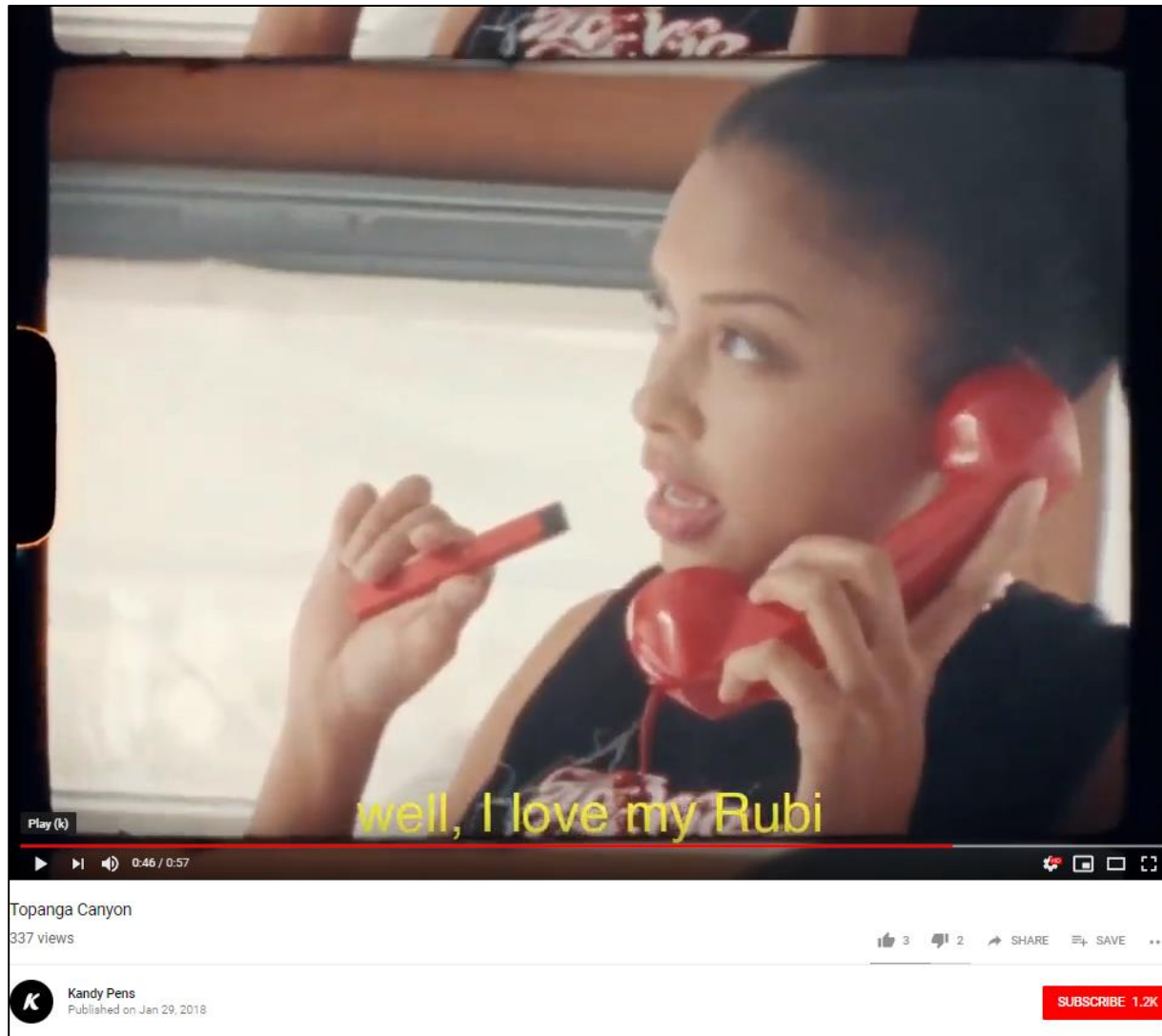
Cuban Doll Feat. Sukihana - Drug Dealer

KANDYPENS

<https://www.kandypens.com/#skycloud>



## Kandy Pens: YouTube Video Promotion



January 29, 2018, <https://www.youtube.com/watch?v=0tpz66dtCC0>

# Myle: Social Media, Product Giveaways



Accessed 4.3.18: <https://www.instagram.com/mylevapor/>; Instagram images are from January 2018; first Instagram post was

# Mojo: Social Media, Brand Ambassadors



Brand ambassador with 72,000 Instagram followers

January 22, 2019 <https://www.instagram.com/p/Bs8hJhKg2OG/>

# Mojo: Social Media, New Flavors

**WARNING: This product contains nicotine.  
Nicotine is an addictive chemical.**

**MOJO**  
DISPOSABLE E-CIG

**NEW  
FLAVOR**  
COMING SOON



vape\_mojito • Following

vape\_mojito Guess the 2nd new flavor!  
Here's a riddle: I have skin but I'm not a  
person. I can be peeled but I'm not a  
potato. I'm a fruit but I'm not an orange. I  
grow on trees but I'm not a banana. I'm  
usually red or green but I'm not a grape.

Type your answers below! 📌

#vapeporn #vapelite #vapelyfe #vapefam  
#vapecommunity #ejuice #vapestagram  
#eliquid #vapeon #vapenation #vaping  
#vapor #instavape #vapedaily #ecig  
#calivapers #vapepics #vapors #vaper  
#vapelove #vapehooligans #cloudchaser  
#girlshovape #dripclub #vapefriends  
#subohm #mojovape #cleanteam  
#disposablevape #ecig

View all 40 comments



170 likes

MARCH 11

Add a comment...

March 11, 2019, <https://www.instagram.com/p/Bu4M3JcAsH3/>

**WARNING: This product contains nicotine.  
Nicotine is an addictive chemical.**

**MOJO**  
DISPOSABLE E-CIG

**NEW  
FLAVOR**  
COMING SOON



vape\_mojito • Following

vape\_mojito New Flavor Alert! 📌 What do  
you think it will be? Let us know your  
guesses in the comments below! We're  
berry excited for you to try it. 🍷 .

#vapeporn #vapelite #vapelyfe #vapefam  
#vapecommunity #ejuice #vapestagram  
#eliquid #vapeon #vapenation #vaping  
#vapor #instavape #vapedaily #ecig  
#calivapers #vapepics #vapors #vaper  
#vapelove #vapehooligans #cloudchaser  
#girlshovape #dripclub #vapefriends  
#subohm #vapeshop #vapesociety  
#notblowingsmoke #vapetricks

marvelthegr8 🍷

miiikav Raspberry?

vapunmagazine What a great shot!

Amazing 🍷



120 likes

1 DAY AGO

Add a comment...

March 20, 2019, <https://www.instagram.com/p/BvPbWMXFrZi/>



# Vaporfi: Social Media, Sports Sponsorship



The image shows an Instagram post from the account 'vaporfi'. The main visual is a promotional graphic for 'TEAM VAPORFI' featuring a shirtless male fighter, Leandro Higo, flexing his muscles. The text on the graphic reads 'TEAM VAPORFI FIGHTS FOR YOUR VAPE RIGHTS', 'BELLATOR 195 7 PM ET, PARAMOUNT NETWORK', and 'LEANDRO HIGO'. The fighter is wearing black and yellow Venum shorts. The background of the graphic is a fiery explosion.

**TEAM VAPORFI**  
FIGHTS FOR YOUR VAPE RIGHTS

**BELLATOR 195**  
7 PM ET, PARAMOUNT NETWORK

**LEANDRO HIGO**

**vaporfi** • Follow

vaporfi It's about to go down! Tune into the #ParamountNetwork at 7 PM ET to catch #Bellator195 as #TeamVaporFi gets ready to fight for your vape rights! Watch as @LeandroHigoMMA, @babyjuggernaut42 and @thearmadillo1 do what they do best. Good luck tonight, gentlemen!

View all 6 comments

vaping\_chubby Boooooooo s3nd me my prize more than a year now if you are really honest and if u really want to send my prize do it NOW prove to us that you are genuine and sincere failed to do so means you are not

vaping\_chubby And dont liked any of my post i dont appreciate especially coming from u. How your sales? Heard its on its lowest

121 likes

MARCH 2, 2018

Add a comment...

March 2, 2018 <https://www.instagram.com/p/Bf1x610Apmz/>

# Mojo: Social Media



“Vape model”  
with 120,000  
Instagram  
followers

December 9, 2018; <https://www.instagram.com/p/BrKQZIThXoA/>

## Device “Skins” to Customize Suorin Device



<https://mightyskins.com/products/sudrop-par-food?variant=13837021118523>