

# **Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization**

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## **Guidance for Industry**

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <https://www.regulations.gov>. Alternatively, submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-2019-D-0661.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. ET.

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Tobacco Products**

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# **Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization**

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## **Guidance for Industry<sup>1</sup>**

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

### **I. INTRODUCTION**

This guidance document describes how we intend to prioritize our enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization.<sup>2</sup>

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<sup>1</sup> This guidance was prepared by the Office of Compliance and Enforcement, Office of Health Communication and Education, Office of Regulations, and Office of Science in the Center for Tobacco Products at FDA.

<sup>2</sup> As with FDA's prior compliance policies on deemed new tobacco products that do not have premarket authorization, this guidance document does not apply to any deemed product that was not on the market on August 8, 2016.

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For ENDS products marketed without FDA authorization, FDA intends to prioritize enforcement against:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.<sup>3</sup>

Further, FDA intends to prioritize enforcement of any ENDS product that is offered for sale after May 12, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).

This guidance does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization. FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data, and it will continue to do so with respect to these products. FDA will take appropriate action regarding tobacco products that are marketed without premarket authorization, including as warranted based on changed circumstances, new information, or to better address minors' use of those products.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## **II. BACKGROUND**

### **A. Statutory and Regulatory History**

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product<sup>4</sup> to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387 through 387u) (section 901(b) of the FD&C Act).

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<sup>3</sup> For purposes of this Final Guidance, FDA's use of the term "minor" refers to individuals under the age of 21. This is consistent with the Further Consolidated Appropriations Act, 2020 (H.R. 1865), signed into law on December 20, 2019, which included a provision amending section 906(d) of the Federal Food, Drug, and Cosmetic Act to increase the federal minimum age to purchase tobacco products from 18 to 21, and adding a provision that it is unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age. In addition, FDA is working to update our regulations within 180 days, consistent with the timeline set forth in the law.

<sup>4</sup> 21 U.S.C 321(rr) (section 201(rr) of the FD&C Act).

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In accordance with that authority, on May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of a tobacco product, except accessories of deemed tobacco products, to be subject to FDA's tobacco product authority. This included electronic nicotine delivery systems (ENDS), cigars, waterpipe (hookah) tobacco, pipe tobacco, nicotine gels, and dissolvables that were not already subject to the FD&C Act (81 FR 28974 at 28976 (May 10, 2016)).

The requirements in Chapter IX of the FD&C Act now apply to deemed products. Particularly relevant to this guidance is section 910, which imposes certain premarket-review requirements for "new tobacco products"—*i.e.*, those that were not commercially marketed in the United States as of February 15, 2007. Accordingly, after the rule's effective date, deemed new tobacco products were required to obtain premarket authorization under Section 910. Deemed new tobacco products that remain on the market without marketing authorization are marketed unlawfully in contravention of the Tobacco Control Act. Through the premarket review process, FDA conducts a science-based evaluation to determine whether a new tobacco product meets the applicable statutory standard for marketing authorization—for example, whether the product is appropriate for the protection of public health with respect to the risks and benefits to the population as a whole, including users and nonusers, and taking into account, among other things, the likelihood that those who do not use tobacco products will start using them.

The preamble to the May 10, 2016, final deeming rule explained that FDA intended to defer enforcement for failure to have premarket authorization during two compliance periods related to premarket review: one for submission and FDA receipt of applications and one for obtaining premarket authorization. The first compliance period depended on the type of application. The compliance date was 12 months from the effective date of the rule for substantial equivalence exemption requests (EX REQs), 18 months for substantial equivalence reports (SE Reports), and 24 months for premarket tobacco applications (PMTAs). In addition, the preamble explained that under the second compliance period:

Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period.<sup>5</sup>

The preamble further explained that this compliance policy did not apply to any new tobacco product that was not on the market on August 8, 2016. Significantly, this policy did not confer lawful marketing status on new tobacco products being marketed without the necessary premarket authorization.

In May 2017, FDA published a guidance document, *Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule*, under which the Agency, as

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<sup>5</sup> 81 FR at 29011.

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a matter of enforcement discretion, stated its intention to defer enforcement for an additional three months for all future compliance dates for requirements under the final deeming rule.

In July 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation that would serve as a multi-year roadmap in an effort to significantly reduce tobacco-related disease and death. Prior to this announcement, nationally representative data suggested that youth use of e-cigarettes had declined beginning in 2016.<sup>6</sup> The comprehensive plan was announced in part to afford the Agency time to explore clear and meaningful measures to make combustible tobacco products less toxic, less appealing, and less addictive. One aspect of the plan involved striking a balance between regulation and encouraging development of innovative tobacco products that may be less harmful than cigarettes. The Agency announced that it planned to issue an updated compliance policy further deferring some enforcement timelines described in the final deeming rule.

In accordance with this comprehensive plan, in August 2017, FDA announced an extension of the period during which it did not intend to initiate enforcement action for premarket review requirements under the final deeming rule (“August 2017 Compliance Policy”) for deemed tobacco products that were on the market on August 8, 2016. This revised policy stated that, for these products, FDA did not intend to initiate enforcement regarding submitting EX REQs, SE Reports, and PMTAs for newly regulated combusted tobacco products (such as most cigars) until August 8, 2021, and FDA did not intend to initiate enforcement regarding EX REQs, SE Reports, and PMTAs for newly regulated noncombusted tobacco products (such as most ENDS products) until August 8, 2022. In addition, FDA revised the compliance policy relating to the period after FDA receipt of EX REQs, SE Reports, and PMTAs for deemed tobacco products that were on the market on August 8, 2016. FDA stated that, under this policy, it intended to continue deferring enforcement until the Agency rendered a decision on an application (*i.e.*, issuance of: a Marketing Order; a No Marketing Order; a Refuse to File; or a Refuse to Accept) or the application was withdrawn.

In March 2018, the August 2017 Compliance Policy was challenged in the U.S. District Court for the District of Maryland, and on May 15, 2019, the court issued an order that vacated the guidance.<sup>7</sup> On July 12, 2019, the court issued a further order directing FDA to require that premarket authorization applications for all new—*i.e.*, not “grandfathered”<sup>8</sup>—deemed tobacco products be submitted to the Agency within 10 months, by May 12, 2020, and providing for a one-year period during which products with timely filed applications might remain on the market

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<sup>6</sup> Jamal, A., A. Gentzke, S.S. Hu, et al., “Tobacco Use Among Middle and High School Students — United States, 2011–2016,” *Morbidity and Mortality Weekly Report*, 66:597–603, 2017, available at: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm>.

<sup>7</sup> *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, 379 F. Supp. 3d 461, 496 (D. Md. 2019).

<sup>8</sup> A “grandfathered” product is one that was on the market as of February 15, 2007. Guidance, Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007, dated September 2014, available at: <https://www.fda.gov/media/123544/download>.

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pending FDA review.<sup>9</sup> As required by the court's order, deemed new tobacco products on the market as of August 8, 2016, for which premarket authorization applications are not filed by May 12, 2020, are subject to FDA enforcement actions, in the Agency's discretion.<sup>10</sup> The court subsequently clarified that its order did not restrict FDA's authority to enforce the premarket review provisions against deemed products, or categories of deemed products, prior to May 12, 2020, or during the one-year review period.<sup>11</sup>

### **B. FDA Response to Evidence of Increasing Youth Use of ENDS Products**

In late 2017, FDA started to see a marked increase in complaints about ENDS products. FDA initiated an investigation of these complaints, the majority of which pertained to minors' access to and use of these products. This new information indicated an alarming increase in the use of ENDS products by middle and high school students. In April 2018, FDA conducted a nationwide undercover enforcement effort that resulted in FDA issuing 56 warning letters to online retailers and 6 civil money penalty (CMP) complaints to retail establishments related to the illegal sales of certain ENDS products to minors. In addition, FDA sent an official request for information to manufacturers of certain ENDS products commonly used by minors requiring them to submit documents to facilitate the Agency's understanding of the reported high rates of youth use and the particular youth appeal of these products. FDA also took measures to address the sale of ENDS products to minors online by contacting eBay to raise concerns over several listings on its website. This resulted in listings for these ENDS products being removed from eBay.

In May 2018, FDA issued 17 warning letters to manufacturers, distributors, and retailers for selling e-liquids with labeling and/or advertising that resemble kid-friendly food products, such as juice boxes, candy, or cookies. The warning letters stated that failure to correct violations may result in FDA initiating further action such as seizure or injunctive relief. Of these warning letters, 13 were issued as part of a joint action with the Federal Trade Commission (FTC).

On September 12, 2018, FDA announced a series of enforcement and other regulatory actions related to the labeling and advertising of ENDS products, including that it had conducted nationwide, undercover investigations of brick-and-mortar and online stores over the summer of 2018 and issued more than 1,300 warning letters and CMP complaints to retailers who illegally sold ENDS products to minors. FDA also issued 12 warning letters to online retailers that were selling misleadingly labeled and/or advertised e-liquids resembling kid-friendly food products such as candy and cookies.

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<sup>9</sup> *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18-cv-883 (PWG), 2019 WL 3067492, at \*7 (D. Md. July 12, 2019) (Dkt. No. 127). The court has granted intervention to vapor industry trade associations for purposes of appealing the court's decision and remedies order. *See American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18-cv-883 (PWG), Dkt. No. 154 (Oct. 2, 2019). An appeal is pending. *See American Academy of Pediatrics v. Cigar Ass'n of America*, Nos. 19-2130, -2132, -2198, -2242 (4th Cir.).

<sup>10</sup> *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18-cv-883 (PWG), 2019 WL 3067492, at \*7 (D. Md. July 12, 2019) (Dkt. No. 127).

<sup>11</sup> *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, Case No. 8:18-cv-883 (PWG), (D. Md. Aug. 12, 2019), Dkt. No. 132.

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In addition, on September 12, 2018, FDA issued letters to five ENDS product manufacturers, requesting each company to submit a plan describing how it would address minors' access to and use of its products.

In response to the September 12<sup>th</sup> letters to industry, manufacturers described safeguards that they could implement to help to restrict minors' access to ENDS products sold at brick and mortar retailers and online. Examples of potential safeguards included:

- Establishing or enhancing programs, such as mystery shopper programs, to monitor retailer compliance with age-verification and sales restrictions;
- Establishing and enforcing contractual penalties for contracted retailers that sell tobacco products to youth;
- Using age-verification technology to better restrict access to the manufacturer's website, such as through independent, third-party age- and identity-verification services that compare customer information against third-party data sources; and
- Limiting the quantity of ENDS products that a customer may purchase within a given period of time.

In conjunction with issuing the September 2018 letters, FDA announced in September 2018 that the Agency was considering whether, in light of current information, it would be appropriate to revisit the August 2017 Compliance Policy, which could result in withdrawing or revising the policy with respect to certain flavored products that may be contributing to the rise in youth use and having firms “remove some or all of [these] products . . . until they receive premarket authorization and otherwise meet all of their obligations under the law.”<sup>12</sup> Following the September 12<sup>th</sup> letters and announcement, FDA repeatedly publicly discussed<sup>13</sup> the fact that these compliance timelines were under reconsideration and solicited the view of stakeholders—including manufacturers, retail associations, and public interest organizations.<sup>14</sup>

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<sup>12</sup> FDA takes new steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access (Sept. 11, 2018), available at: <https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more>.

<sup>13</sup> See, e.g., 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, available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>; Scudder, L., “Vaping and E-Cigarettes in Kids: An Unprecedented Epidemic,” Medscape, January 28, 2019, available at: <https://www.medscape.com/viewarticle/908077?faf=1>.

<sup>14</sup> See, e.g., FDA Public Calendar – Meeting With FDA Officials, available at: <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/public-calendar-meetings-fda-officials> (noting meetings held on October 11, 16, 18, 29 and 30 of 2018; November 13, 2018; and December 19, 2018); February 6, 2019 Letters sent to JUUL Labs, Inc. and Altria Group Inc., requesting meetings to discuss concerns related youth addiction to tobacco products, available at: <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/ctp-letters-industry>.



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Since the effective date of the Deeming Rule in August 2016, FDA has issued more than 10,000 warning letters and more than 1,400 CMP complaints to retailers for the sale of ENDS products to minors. Specifically, from April 2018 through August 2019, FDA issued over 6,000 warning letters and more than 1,000 CMP complaints to retailers for the sale of ENDS products to minors. Since May 2018, FDA has also issued over 40 warning letters to manufacturers, distributors, and retailers for selling e-liquids with false or misleading labeling and/or advertising that resemble kid-friendly products. In June 2019, the Agency issued joint FDA/FTC warning letters to four e-liquid manufacturers for violations related to online posts by social media influencers on the companies' behalf. In September 2019, FDA issued a warning letter to an ENDS manufacturer for marketing unauthorized modified risk tobacco products, including in outreach to youth.<sup>15</sup> FDA will continue to use all available tools to prevent youth use of all tobacco products, including ENDS products.

In 2018, FDA continued to receive information underscoring the problem of youth use of ENDS products. Current e-cigarette use had increased considerably among U.S. middle and high school students during 2017–2018, reversing a decline in e-cigarette use that had been observed in recent years and increasing overall tobacco product use in 2018. Specifically, among high school students, current e-cigarette use had increased by 78 percent in the past year (from 11.7 percent in 2017 to 20.8 percent in 2018,  $p < 0.001$ ), while among middle school students, current e-cigarette use had increased by 48 percent (from 3.3 percent in 2017 to 4.9 percent in 2018,  $p = 0.001$ ).<sup>16</sup> Frequent use among high school students (defined as use on  $\geq 20$  of the past 30 days) also had increased, from 20.0 percent in 2017 to 27.7 percent in 2018 ( $p = 0.008$ ).<sup>17</sup> Data from this study, as well as the concerns described above, prompted FDA to issue a draft guidance, “Modifications to Compliance Policy for Certain Deemed Tobacco Products” (“March 2019 Draft Guidance”), regarding the continued marketing of deemed tobacco products that have not obtained premarket authorization, and to call on industry to do more to keep their products out of the hands of minors.

In 2019, two of the largest surveys of tobacco use among youth found that e-cigarette use has hit the highest levels ever recorded. As detailed in Section IV below, data from both the National Youth Tobacco Survey (NYTS) and the Monitoring the Future (MTF) Study have documented a continued increase in youth use of ENDS products and further underscored the magnitude of the problem. These data, information conveyed to FDA in comments to the March 2019 Draft Guidance, and concern about health and safety issues connected to these products—*e.g.*, the harmful effects of nicotine on adolescent brain development, as well as battery explosions with ENDS products—continue to inform FDA's serious public health concerns regarding the sale of these products without premarket authorization. Repeated exposure to nicotine during

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<sup>15</sup> For more information, please see <https://www.fda.gov/news-events/press-announcements/fda-warns-juul-labs-marketing-unauthorized-modified-risk-tobacco-products-including-outreach-youth>.

<sup>16</sup> Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., “Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018,” *Morbidity and Mortality Weekly Report*, 67(45);1276-1277, 2018.

<sup>17</sup> *Id.*

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adolescence induces long-lasting changes in brain regions involved in addiction, attention, learning, and memory.

Furthermore, as of December 17, 2019, there have been approximately 2,506 reported cases of hospitalizations for lung injuries associated with use of vaping products (“hospitalized EVALI patients”), including 54 confirmed deaths.<sup>18</sup> Working closely with other federal and state agencies, FDA has not been able to determine the cause of this outbreak. It appears that most of the patients impacted by these illnesses reported using THC-containing products, with evidence suggesting that additive agents, specifically Vitamin E, may play a causative role. In many of the cases, individuals reported using multiple products, including some with nicotine. Many different substances and product sources are still under investigation.

Although this guidance does not address products that are not tobacco products, the outbreak of lung injuries associated with use of vaping products illustrates public health and safety concerns that may arise for products for which information related to product safety and health impact are lacking and affirms the importance of the premarket review process, as contemplated by the Tobacco Control Act, to scientifically evaluate products based on a public health standard.

Accordingly, FDA is issuing this Final Guidance to communicate its enforcement priorities with respect to ENDS products. FDA’s decision to exercise its enforcement authorities with respect to particular products will be determined on a case-by-case basis, informed by the enforcement priorities described in this Final Guidance and any other relevant factors.<sup>19</sup>

### **III. DEFINITIONS**

For purposes of this guidance, FDA intends to use the following definitions:

*Cartridge-based ENDS products* are a type of ENDS product that consists of, includes, or involves a cartridge or pod that holds liquid that is to be aerosolized through product use. For purposes of this definition, a cartridge or pod is any small, enclosed unit (sealed or unsealed) designed to fit within or operate as part of an electronic nicotine delivery system.<sup>20</sup>

*Electronic nicotine delivery systems (or ENDS)* include devices, components, and/or parts that deliver aerosolized e-liquid when inhaled. For example, FDA considers vapes or vape pens, personal vaporizers, e-cigarettes, cigalikes, e-pens, e-hookahs, e-cigars, and e-pipes to be ENDS.

*E-liquids* are a type of ENDS product and generally refer to liquid nicotine and nicotine-containing e-liquids (*i.e.*, liquid nicotine combined with colorings, flavorings, and/or other

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<sup>18</sup> See Centers for Disease Control and Prevention, “Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping,” available at [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information).

<sup>19</sup> See *Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (providing that the FD&C Act’s enforcement provisions commit broad discretion to the Secretary to decide how and when they should be exercised).

<sup>20</sup> An example of products that would not be captured by this definition include completely self-contained, disposable products.

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ingredients). Liquids that do not contain nicotine or other material made or derived from tobacco, but that are intended or reasonably expected to be used with or for the human consumption of a tobacco product, may be components or parts and, therefore, subject to FDA's tobacco control authorities.

*Label* means a display of written, printed, or graphic matter upon the immediate container of any article. Section 201(k) of the FD&C Act.

*Labeling* means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. Section 201(m) of the FD&C Act.

*New tobacco product* means (1) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. Section 910(a) of the FD&C Act.

*Tobacco product* means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that under the FD&C Act is a drug (section 201(g)(1) (21 U.S.C 321(g)(1))), a device (section 201(h)), or a combination product (section 503(g) (21 U.S.C 353(g))). Section 201(rr) of the FD&C Act.

## **IV. ENFORCEMENT PRIORITIES REGARDING CERTAIN ENDS PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION**

### **A. Overview**

The Tobacco Control Act provides that new tobacco products (*i.e.*, non-grandfathered products) may not legally be marketed without premarket authorization. Accordingly, all deemed new tobacco products on the market without authorization are illegally marketed products.

Beginning 30 days after issuance of this Final Guidance, FDA intends to prioritize enforcement of the premarket review requirements for certain ENDS products, including against retailers selling such products. Specifically, FDA intends to prioritize enforcement against:

- (1) Flavored, cartridge-based ENDS products (except for tobacco- or menthol-flavored products);
- (2) All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- (3) Any ENDS products targeted to, or whose marketing is likely to promote use by, minors.

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In addition, FDA intends to prioritize enforcement of any ENDS product that is offered for sale in the United States after May 12, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).<sup>21</sup>

FDA will make enforcement decisions on a case-by-case basis, recognizing that it is unable, as a practical matter, to take enforcement action against every illegally marketed tobacco product, and that it needs to make the best use of Agency resources. This guidance does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization, or to sell any tobacco product to minors. The Agency also retains discretion to pursue enforcement action at any time against any deemed new tobacco product marketed without premarket authorization, regardless of whether it falls within one of these categories of enforcement priorities.

### **B. Data Show Substantial Increase in Youth Use of ENDS Products, Particularly Certain Flavored, Cartridge-Based ENDS Products**

At the time FDA issued the August 2017 Compliance Policy to announce changes in its approach to enforcement regarding premarket authorization (as described in the preamble to the final deeming rule), data from the 2016 NYTS showed a decrease in prevalence of current e-cigarette use (*i.e.*, past 30-day use) among high school students, from 16 percent in 2015 to 11.3 percent in 2016.<sup>22</sup> Results from the 2017 NYTS later confirmed that in regards to youth use there was no statistically significant rise at the time, with data suggesting that high school student use had leveled off between 2016 (11.3 percent)<sup>23</sup> and 2017 (11.7 percent).<sup>24</sup>

However, multiple survey results over the past several years demonstrate that there is significant initiation by youth. The recent surge in youth use of ENDS products has caused us to reevaluate our July 2017 assessment and to modify our enforcement priorities for ENDS products. Recent data show an alarming increase in youth use of ENDS products in the past two years. They also show youth are more likely to use certain flavored, cartridge-based ENDS products.

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<sup>21</sup> We note that FDA would be enforcing the priorities discussed in Section IV of this guidance regardless of the court's decision in the *AAP* case. As discussed in this Final Guidance, FDA is implementing this policy to address the alarming increase in youth use of ENDS products as well as other recent health and safety issues regarding such products.

<sup>22</sup> Jamal, A., A. Gentzke, S.S. Hu, et al., "Tobacco Use Among Middle and High School Students — United States, 2011–2016," *Morbidity and Mortality Weekly Report*, 66:597–603, 2017, available at: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm>.

<sup>23</sup> *Id.*

<sup>24</sup> Wang, T.W., A. Gentzke, S. Sharapova, et al., "Tobacco Product Use Among Middle and High School Students – United States, 2011–2017," *Morbidity and Mortality Weekly Report*, 67:629–633, 2018, available at: <http://dx.doi.org/10.15585/mmwr.mm6722a3>.

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Overall, data showed that ENDS product use more than doubled among middle school and high school students from 2017 to 2019.<sup>25</sup> Data from MTF showed that from 2017 to 2018, current (past 30-day) e-cigarette use significantly increased from 6.6 percent to 10.4 percent among 8<sup>th</sup> graders (a 58 percent increase), 13.1 percent to 21.7 percent among 10<sup>th</sup> graders (a 66 percent increase), and 16.6 percent to 26.7 percent among 12<sup>th</sup> graders (a 61 percent increase).<sup>26</sup> This trend continued in the 2019 MTF data. The number of students who had used ENDS products during the previous 12 months and those who had ever used ENDS products significantly increased in 8<sup>th</sup>, 10<sup>th</sup>, and 12<sup>th</sup> grade from 2018 to 2019.<sup>27</sup> Data from the NYTS for the same time period show that, between 2017 and 2018, current e-cigarette use among high school students increased from 11.7 percent to 20.8 percent (a 78 percent increase,  $p < 0.001$ ).<sup>28</sup> Current e-cigarette use among middle school students also increased from 3.3 percent to 4.9 percent over the same time period (a 48 percent increase,  $p = 0.001$ ), which we calculated as an increase of an estimated 180,000 middle school students reporting past 30-day e-cigarette use in one year.<sup>29</sup> The data from 2019 NYTS have also documented that this is the second year in a row where current (past 30-day) e-cigarette use reached new highs among youth.<sup>30</sup> The prevalence of current e-cigarette use among high school students was 27.5 percent and middle school students was 10.5 percent.<sup>31</sup> Among high school students, 4.11 million reported having used an e-cigarette in the past month in 2019 with 1.24 million middle school students reporting the same. For the first time ever, the total number of middle and high school students reporting current use of e-cigarettes surpassed 5 million in 2019.<sup>32</sup>

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<sup>25</sup> Miech R, L. Johnston, P.M. O'Malley, et al., "Trends in adolescent vaping, 2017–2019," New England Journal of Medicine, 381:1490-1491, 2019; DOI:10.1056/NEJMc1910739.

<sup>26</sup> Miech, R. A., Johnston, L. D., O'Malley, P. M., et al., "Monitoring the Future national survey results on drug use, 1975–2018: Volume I, Secondary school students," Ann Arbor: Institute for Social Research, The University of Michigan (2019), available at <http://monitoringthefuture.org/pubs.html#monographs>. For each age group, the increase from 2017 to 2018 was statistically significant ( $p < .001$ ).

<sup>27</sup> Miech R, L. Johnston, P.M. O'Malley, et al., "Trends in adolescent vaping, 2017–2019," New England Journal of Medicine; 381:1490-1491, 2019; DOI:10.1056/NEJMc1910739.

<sup>28</sup> Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., "Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018," Morbidity and Mortality Weekly Report, 67(45):1276-1277, 2018. The NYTS defines e-cigarettes as "battery-powered devices that provide nicotine and other additives to the user in the form of an aerosol."

<sup>29</sup> *Id.*

<sup>30</sup> Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," JAMA, 322(21):2095-2103, 2019. Several improvements were made to the NYTS in 2019, including switching from paper-and-pencil to electronic survey administration, adding skip patterns and example product images, and updating brand examples to reflect the current tobacco marketplace (e.g., adding JUUL), which may affect the comparability of tobacco product use behaviors, including e-cigarette use behaviors, with previous years. Although trend analyses, which use more data points and are not solely dependent on changes during a single year, may be conducted without major shifts in patterns or findings, the exact magnitude of the effect of these survey improvements in 2019 cannot be fully quantified. Thus, direct statistical comparisons between estimates of tobacco product use between 2018 and 2019 were not conducted.

<sup>31</sup> Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," JAMA, 322(21):2095-2103, 2019.

<sup>32</sup> *Id.*

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Disturbingly, these data also indicate that a growing percentage of America’s youth who use e-cigarettes have become frequent e-cigarette users (defined as reporting use on 20 days or more of the prior 30-day period). An increasing number of youth are thus at greater risk of nicotine addiction at a time when the developing brain is particularly susceptible to permanent changes from nicotine use and when almost all nicotine addiction is established.<sup>33</sup> Data from the 2019 NYTS have documented continued frequent youth ENDS use.<sup>34</sup> The proportion of current high school e-cigarette users who reported use on 20 days or more (of the prior 30-day period), and thus were frequent users, was 34.2 percent in 2019.<sup>35</sup> The proportion of current middle school e-cigarette users who reported use on 20 days or more (of the prior 30-day period) was 18.0 percent in 2019.

This builds upon an increase in frequent ENDS use among youth who report using ENDS products observed in 2018. For example, data from the 2018 NYTS showed that the proportion of current high school e-cigarette users who reported use on 20 days or more (of the prior 30-day period) increased by 38.5 percent, from 20.0 percent in 2017 to 27.7 percent in 2018.<sup>36</sup> In a study that collected data from February to May 2018 and focused specifically on 15-to-17-year-old current users of JUUL products (the most commonly used brand, including among youth), 55.8 percent reported using such ENDS products on 3 or more of the previous 30 days, and over a quarter (25.3 percent) reported use on 10 to 30 days of the prior month.<sup>37</sup>

The concerns caused by the sharp increase in the number of youth using ENDS products are compounded by evidence indicating that youth whose first tobacco product is an ENDS product are at an increased risk of becoming cigarette smokers as compared to non-ENDS users. A 2018 report by the National Academy of Sciences, Engineering, and Medicine entitled “Public Health Consequences of E-Cigarettes,” which took into account multiple lines of evidence across different studies and study designs, concluded that “there is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”<sup>38</sup>

FDA is also concerned about the extraordinary popularity of flavored ENDS products with youth. Research has long shown that flavors increase youth appeal of tobacco products,

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<sup>33</sup> Miech R., Johnston L, O’Malley PM, et al., “Adolescent vaping and nicotine use in 2017–2018 — U.S. National Estimates,” *New England Journal of Medicine*; 380:192-3, 2019.

<sup>34</sup> Cullen, K.A., A.S. Gentzke, M.D. Sawdey, “E-cigarette use among youth in the United States, 2019,” *JAMA*, 322(21);2095-2103, 2019.

<sup>35</sup> *Id.*

<sup>36</sup> Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., “Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018,” *Morbidity and Mortality Weekly Report*, 67(45);1276-1277, 2018.

<sup>37</sup> Vallone, D.M., M. Bennett, H. Xiao, et al., “Prevalence and correlates of JUUL use among a national sample of youth and young adults,” *Tobacco Control*, 0:1-7, 2017, doi: 10.1136/tobaccocontrol-2018-05463.

<sup>38</sup> National Academies of Sciences, Engineering, and Medicine, “Public health consequences of e-cigarette,” Washington, DC: The National Academies Press, 2018, doi: <https://doi.org/10.17226/24952>.



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including ENDS.<sup>39</sup> Evidence continues to accumulate, further confirming that youth are particularly attracted to flavored ENDS products. Data from the 2018 NYTS showed that past 30-day use of any flavored e-cigarette increased from 2017 among high school students who reported current e-cigarette use (60.9 percent to 67.8 percent,  $p < 0.05$ ).<sup>40</sup> In the 2016-2017 (Wave 4)<sup>41</sup> Population Assessment of Tobacco and Health (PATH) Study,<sup>42</sup> among youth age 12 to 17 who reported using an ENDS product, 93.2 percent reported that their first ENDS use was with a flavored ENDS product.<sup>43</sup> Data from Wave 4 also showed that 71 percent of current youth ENDS users said they used ENDS products “because they come in flavors I like.”<sup>44</sup>

The NYTS survey instrument groups mint- and menthol-flavored products together, so it is not possible to differentiate youth use of mint and menthol flavors separately based on the NYTS data. The 2018 NYTS data indicate that, among high school students whose only tobacco product use is e-cigarettes, known as exclusive e-cigarette users, the proportion who reported fruit-flavored ENDS use was 75.5 percent in 2018<sup>45</sup> and the proportion who reported mint-and menthol-flavored ENDS use was 38.1 percent.<sup>46</sup> In 2019, in the same population, fruit-flavored ENDS use was 66.1 percent and mint- and menthol-flavored ENDS use was 57.3 percent.<sup>47</sup> Among middle school exclusive e-cigarette users, the 2018 NYTS data indicate that use of fruit-flavored ENDS use was 58.1 percent and mint-and menthol-flavored ENDS use was 20.6

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<sup>39</sup> E.g., Carpenter, C.M., et al., “New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies,” *Health Affairs*, 24(6):1601-1610, 2005; Pepper, J. K., K.M. Ribisl, N.T. Brewer, “Adolescents’ interest in trying flavoured ecigarettes,” *Tobacco Control*, 25:ii62-ii66, 2016; Camenga, D. R., M. Morean, G. Kong, et al., “Appeal and use of customizable e-cigarette product features in adolescents,” *Tobacco Regulatory Science*, 4(2):51-60, 2018; Harrell, M.B., S.R. Weaver, A. Loukas, et al., “Flavored e-cigarette use: characterizing youth, young adult, and adult users,” *Preventive Medicine Reports*, 5:33-40, 2017.

<sup>40</sup> Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., “Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018,” *Morbidity and Mortality Weekly Report*, 67(45):1276-1277, 2018.

<sup>41</sup> Population Assessment of Tobacco and Health (PATH) Study [United States] Restricted Use Files (ICPSR 36231), available at: <https://www.icpsr.umich.edu/icpsrweb/NAHDAP/studies/36231>.

<sup>42</sup> The PATH study is a research study that assesses within-person changes and between-person differences in a large national cohort of participants aged 12 years and older over time. Each wave is a follow-up where the PATH study can examine its objectives, iteratively and cumulatively, to generate a broad body of knowledge about tobacco product use in the USA. Data collection for each wave occurred during the following timeframes: Wave 1 (September 2013-December 2014), Wave 2 (October 2014-2015), Wave 3 (October 2015-2016), and Wave 4 (2016-2017).

<sup>43</sup> Rostron B et al. “Prevalence and Reasons for Use of Flavored Cigars and ENDS among US Youth and Adults: Estimates from Wave 4 of the PATH Study, 2016-2017,” *American Journal of Health Behavior*, 44(1):76-81, 2020.

<sup>44</sup> *Id.*

<sup>45</sup> Cullen, K.A., A.S. Gentzke, M.D. Sawdey, et al., “E-cigarette use among youth in the United States, 2019,” *JAMA*, 322(21):2095-2103, 2019.

<sup>46</sup> Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., “Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018,” *Morbidity and Mortality Weekly Report*, 67(45):1276-1277, 2018.

<sup>47</sup> Cullen, K.A., A.S. Gentzke, M.D. Sawdey, “E-cigarette use among youth in the United States, 2019,” *JAMA*, 322(21):2095-2103, 2019.

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percent.<sup>48</sup> In 2019, in the same population, fruit-flavored ENDS use was 67.7 percent and mint- and menthol-flavored ENDS use was 31.1 percent.<sup>49</sup> Between 2016 and 2019, high school exclusive e-cigarette users who reported mint- and menthol-flavored ENDS use increased from 16.0 percent to 57.3 percent,  $p < 0.05$ .<sup>50</sup> Data for middle school e-cigarette users was inconclusive on this point due to a limited number of middle-school students in the NYTS sample who not only used e-cigarettes within the past 30 days, but whose exclusive tobacco product use in the past 30 days was e-cigarettes.<sup>51</sup> In 2019, the data indicate that more than one million middle and high school exclusive e-cigarette users used mint- or menthol-flavored ENDS in the past 30 days.<sup>52</sup>

However, data from the MTF survey examine mint and menthol JUUL use separately and indicate that youth use of menthol-flavored products is not as high as that for mint- and fruit-flavored products. Specifically, a randomly-selected third of 2019 MTF respondents were asked about their flavored JUUL use.<sup>53</sup> The analytic sample included past 30-day JUUL users who answered the question, “Which JUUL flavor do you use most often?” with response options of Classic Tobacco, Crème, Cucumber, Fruit, Mango, Menthol, Mint, Virginia Tobacco, and Other. Among past 30-day JUUL users in each grade studied (8<sup>th</sup>, 10<sup>th</sup>, and 12<sup>th</sup>), use of mango and mint ranked highest, followed by fruit. Reported use of menthol and tobacco flavors were among the lowest ranked options. Specifically, a number of 8<sup>th</sup> grade past 30-day JUUL users reported use of mango (33.5 percent), while the others reported use of mint (29.3 percent), fruit (16.0 percent), and other (14.8 percent).<sup>54</sup> A large percentage of 10<sup>th</sup> grade past 30-day JUUL users reported use of mint (43.5 percent), while the others reported use of mango (27.3 percent), fruit (10.8 percent), and other (8.4 percent).<sup>55</sup> Close to half of 12<sup>th</sup> grade past 30-day JUUL users reported use of mint (47.1 percent), while the others reported use of mango (23.8 percent), fruit (8.6 percent), other (6.0 percent), menthol (5.9 percent), and cucumber (4.4 percent).<sup>56</sup>

Data from the 2019 NYTS also indicate that youth overwhelmingly prefer cartridge-based ENDS products,<sup>57</sup> and we have found that these products are easy to conceal, can be used discreetly, may have a high nicotine content, and are manufactured on a large scale. The 2019 survey instrument included a measure for the “usual brand” of e-cigarette used in the past 30 days.

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<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> Leventhal A., et al., “Flavors of e-Cigarettes Used by Youths in the United States,” *JAMA*, 322(21):2132-2134, 2019.

<sup>54</sup> The remaining flavors, including tobacco and menthol flavors, each had estimates of  $\leq 2.3\%$ .

<sup>55</sup> The remaining flavors, including tobacco and menthol flavors, each had estimates of  $\leq 3.0\%$ .

<sup>56</sup> The remaining flavors, including tobacco flavors, each had estimates of  $\leq 1.5\%$ .

<sup>57</sup> Cullen, K.A., A.S. Gentzke, M.D. Sawdey, “E-cigarette use among youth in the United States, 2019,” *JAMA*, 322(21):2095-2103, 2019.



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Most youth who were current e-cigarette users reported a cartridge-based e-cigarette as their usual brand.<sup>58</sup> In fact, the leading brand is a cartridge-based product that commands approximately 70 percent of the market.<sup>59</sup>

Of particular concern are the design features that appear to make the cartridge-based products so popular with young people. Attributes typically present in cartridge-based products include a relatively small size that allows for easy concealability, and intuitive and convenient features that facilitate ease of use, including draw activation, prefilled cartridges or pods, and USB rechargeability.

Small products may allow youth to use the product in circumstances where use of tobacco products is prohibited, such as a school.<sup>60</sup> Small size may also allow the user to quickly conceal the product in the palm of one's hand or in a pocket.<sup>61</sup> Small size may allow for product use in a social setting without others' awareness,<sup>62</sup> particularly in conjunction with vaping techniques that may be used to prevent or hide the vapor cloud. Additionally, depending on the size and shape of the product, it may also blend in with other equipment that is expected in that setting (e.g., if the ENDS is shaped like a flash drive, for example, next to a computer, where an actual flash drive would be used), or it may otherwise go undetected because parents, teachers, or coaches do not recognize the product as an ENDS.<sup>63</sup>

Products ready for use immediately after purchase have characteristics that facilitate ease of use among young people. With cartridge-based products, there are no settings to change and very little assembly is required. Research on other tobacco products suggests that ease of use is associated with susceptibility to tobacco product uptake among youth.<sup>64</sup> Additional research among youth suggests that younger adolescents are more likely to use more basic ENDS

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<sup>58</sup> *Id.* Unpublished data from the 2019 survey list other brands that are used by youth, some of which are available in both cartridge-based and non-cartridge-based forms.

<sup>59</sup> Nielsen Total US xAOC/Convenience Database & Wells Fargo Securities, LLC, in Wells Fargo Securities, Nielsen: Tobacco All Channel Data Thru 10/4 – Cig Vol Declines Moderate, October 15, 2019.

<sup>60</sup> See, e.g., Schillo B., et al., "JUUL in School: Teacher and Administrator Awareness and Policies of E-Cigarettes and JUUL in U.S. Middle and High Schools," *Health Promot Pract.*, 21(1):20-24, 2020; "Why 'juuling' has become a nightmare for school administrators," *Kaiser Health News* (March 26, 2018), available at: <https://www.nbcnews.com/health/kids-health/why-juuling-has-become-nightmare-school-administrators-n860106/>; "Juul Is Sued by School Districts That Say Vaping Is a Dangerous Drain on Their Resources," *The New York Times* (October 7, 2019), available at: <https://www.nytimes.com/2019/10/07/us/juul-vaping-schools.html>.

<sup>61</sup> <http://pittsburgh.cbslocal.com/2017/12/13/new-ecigarette-popular-among-kids-easy-to-conceal-from-parents/>

<sup>62</sup> <https://www.npr.org/sections/health-shots/2017/12/04/568273801/teenagers-embrace-juul-saying-its-discreet-enough-to-vape-in-class>

<sup>63</sup> <https://www.excelsiorspringsstandard.com/news/new-vaping-devices-may-go-undetected-by-parents/>

<sup>64</sup> Chaffee B.W., J. Urata, E.T. Couch, S. Gansky, "Perceived flavored smokeless tobacco ease-of-use and youth susceptibility," *Tobacco Regulatory Science*, 3(3):367-373, 2017.

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products than older adolescents.<sup>65</sup> Thus, particularly easy-to-use products, such as cartridge-based products, may have lower barriers to initiation.

Other product features that facilitate ease of use include pre-filled cartridges, which are convenient because they do not require filling prior to use and are easy to dispose of and replace; a draw-activated battery that makes the devices much easier to use than other devices; and rechargeability, an important characteristic for use among youth who recharge via a USB port when connected to a computer or charging adapter from other electronic devices, such as a cellphone.

In the notice of proposed rulemaking for the Deeming Rule, FDA noted that the overall public-health impact of ENDS products would depend crucially upon “who uses the products and how they are used. If such products result in minimal initiation by children and adolescents while significant numbers of smokers quit, then there is a potential for the net public health impact at the population level to be positive. If, on the other hand, there is significant initiation by youth, minimal quitting, or significant dual use of combust[ed] and non-combust[ed] products, then the public health impact could be negative.”<sup>66</sup> The data discussed above demonstrate substantial and increasing initiation of ENDS products by youth, particularly certain flavored, cartridge-based products.

### **C. Additional Relevant Considerations**

In issuing the March 2019 Draft Guidance, FDA solicited public comment generally on the proposed approach and specifically sought information that could help inform its decision-making for each key issue. In developing this Final Guidance, FDA considered information provided in the public comments submitted on the March 2019 Draft Guidance. Overall, out of the over 15,000 public comments FDA received in response to the Draft Guidance, many were related to form letter campaigns, while approximately 294 public comments provided unique and substantive information. In addition to the comments that provided unique and substantive information, FDA received thousands of general comments expressing support or opposition to the guidance and separate provisions within the guidance. These comments express broad policy views and do not address specific points related to the March 2019 Draft Guidance. Additional information regarding significant comments received in response to the March 2019 Draft Guidance and FDA’s responses is described in Appendix A.<sup>67</sup>

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<sup>65</sup> Pepper J.K., A.J. MacMonegle, J.M. Nonnemaker, “Adolescents’ use of basic, intermediate, and advanced device types for vaping,” *Nicotine & Tobacco Research*, 21(1):55–62, 2019.

<sup>66</sup> 79 Fed. Reg. 23141, 23147 (2016).

<sup>67</sup> FDA generally does not respond to comments in guidance documents and, as noted in the preamble to the deeming rule, generally “[a]gency compliance/enforcement policies are not subject to the requirements that govern notice-and-comment rulemaking.” 81 Fed. Reg. at 28,977, 29,010 (citing *Prof’ls & Patients for Customized Care v. Shalala*, 56 F.3d 592 (5th Cir. 1995) (a compliance policy guide is not a substantive rule and not subject to APA’s notice-and-comment rulemaking); *Takhar v. Kessler*, 76 F.3d 995, 1002 (9th Cir. 1996) (FDA compliance policy guides were not required to go through notice-and-comment procedures)). Although FDA is addressing comments here, it does so voluntarily and given the circumstances. By responding to comments here, FDA in no way

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FDA also remains concerned about health and safety issues connected to ENDS products—*e.g.*, cases of lung injuries associated with use of vaping products<sup>68</sup> as well as battery explosions with ENDS products<sup>69</sup>—particularly given that these products have been marketed without premarket evaluation. These current public health issues affirm the importance of the premarket review process, as contemplated by the Tobacco Control Act, to scientifically evaluate products based on a public health standard. For example, FDA review of premarket tobacco product applications considers the risks and benefits of the product to the population as a whole, including tobacco product users and non-users. In reviewing premarket tobacco product applications, FDA will consider, among other things: the product’s components, ingredients, additives, and properties; manufacturing practices; and any studies or investigations into the health risks of the tobacco product.

### **D. Enforcement Priorities for ENDS Products**

In the discussion that follows, we describe our current intent regarding prioritizing our enforcement resources with respect to certain illegally marketed ENDS products.

FDA will prioritize enforcement of flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored products), which are produced primarily by large manufacturers. This policy should have minimal impact on small manufacturers (*e.g.*, vape shops) that primarily sell non-cartridge-based ENDS products, unless they market to youth or fail to take adequate measures to prevent youth access. Specifically, FDA intends to prioritize enforcement regarding the lack of marketing authorization against:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors’ access; and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.

FDA intends to prioritize enforcement beginning 30 days after issuance of this Final Guidance.

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establishes a policy, practice, or precedent requiring the Agency to do so with respect to future iterations of this document or any other guidance document.

<sup>68</sup> See, *e.g.*, Centers for Disease Control and Prevention, “Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping,” available at: [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information); Layden, J. E., I. Ghinai, I. Pray, et al., “Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin – Preliminary Report,” *New England Journal of Medicine*, Sept. 2019; DOI: 10.1056/NEJMoa1911614.

<sup>69</sup> See, *e.g.*, Rossheim, M.E., M.D. Livingston, E.K. Soule, et al., “Electronic Cigarette Explosion and Burn Injuries, US Emergency Departments 2015-2017,” *Tobacco Control*, 2019; 28:472-474, available at: <http://dx.doi.org/10.1136/tobaccocontrol-2018-054518>.

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Further, FDA intends to prioritize enforcement of any ENDS product that is offered for sale after May 12, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).

In addition to violations related to lack of marketing authorization, FDA will continue to take legal action regarding sales of tobacco products to minors and other violations and will closely monitor all sales of ENDS products.

1. Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored product)

FDA intends to prioritize enforcement for lack of marketing authorization against any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product) that is offered for sale in the United States without regard to whether or when premarket application for such product has been submitted.

In its balancing of the different public health considerations regarding ENDS products, the March 2019 Draft Guidance did not include tobacco-, mint- and menthol-flavored ENDS products in its proposed enforcement priorities, based on the data at that time indicating that these flavors were preferred more by adults than youth. The intent was, to the extent possible consistent with protecting population health, to avoid foreclosing one potential means by which some adult smokers might seek to transition completely away from combusted tobacco products to potentially less harmful tobacco products. Moreover, the March 2019 draft did not distinguish between cartridge-based products and other products, and instead focused on how products are sold rather than product characteristics.

As discussed above, evidence shows that youth are particularly attracted to flavored, cartridge-based ENDS products. Data show that, among youth who reported ever using an ENDS product, a large majority reported their first ENDS use was with a flavored ENDS product.<sup>70</sup> Data also show that among current youth ENDS users, a majority of youth respondents stated that they used ENDS products “because they come in flavors I like.”<sup>71</sup> In addition, recent data indicate that flavors preferred by youth include mint. Data from the 2019 MTF survey indicate that youth use of mint- and fruit-flavored JUUL products is higher than that of menthol- and tobacco-flavored JUUL products.<sup>72</sup> Finally, data from the 2019 NYTS indicate that youth overwhelmingly prefer cartridge-based ENDS products.<sup>73</sup> These products are easy to conceal, can be used discreetly, may have a high nicotine content, and are manufactured on a large scale.

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<sup>70</sup> Rostron B et al. “Prevalence and Reasons for Use of Flavored Cigars and ENDS among US Youth and Adults: Estimates from Wave 4 of the PATH Study, 2016-2017,” American Journal of Health Behavior, 44(1);76-81, 2020.

<sup>71</sup> *Id.*

<sup>72</sup> Leventhal A., et al., “Flavors of e-Cigarettes Used by Youths in the United States,” JAMA, 322(21):2132-2134, 2019.

<sup>73</sup> Cullen, K.A., A.S. Gentzke, M.D. Sawdey, “E-cigarette use among youth in the United States, 2019,” JAMA, 322(21);2095-2103, 2019.

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FDA received a number of comments that focused on the popularity of mint- and menthol-flavored ENDS among youth and adult populations. Some commenters suggested that such products would become even more popular if others became less available. They argued that not prioritizing enforcement against mint- and menthol-flavored ENDS products would risk the shift of youth from one flavor of ENDS products to another based on a potential but indeterminate impact on adult consumers. Several comments argued that data suggest that even if youth currently prefer “fruit” and “sweets” to mint and menthol, this does not mean that youth do not still find mint and menthol to be appealing flavors. FDA also received public comments claiming that mint- and menthol-flavored ENDS products help smoking cessation. For example, some commenters focused on the potential role that mint- and menthol-flavored ENDS products could play in helping some adults cease the use of combusted tobacco products.

It is possible that prioritizing enforcement against mint-flavored ENDS products could at least in the short term make fewer products available for some addicted adult smokers seeking to use ENDS products to transition completely away from cigarettes. However, the comments, as well as the recent surge in youth use of ENDS products, and especially the preferences indicated in the 2019 NYTS and 2019 MTF data, have led FDA to reconsider its approach with regard to prioritizing enforcement of mint-flavored ENDS products.

FDA also received multiple comments urging the Agency to further refine its enforcement priorities in consideration of how the design features of certain ENDS products may make them so popular among youth. Some commenters focused on the features of cartridge-based systems, particularly that they may contain high nicotine content and that they are easy to conceal. Similarly, some commenters focused on the potential impact of nicotine salts, which are used in some brands of cartridge-based ENDS products. In contrast, FDA received a comment arguing that the rise of youth use should not be attributed to all cartridge-based products but rather to a single, uniquely prevalent cartridge-based product, and that FDA’s regulatory actions should be tailored accordingly.

As discussed above, data show that flavors are a strong driver for youth use, and that youth overwhelmingly use cartridge-based ENDS products. Moreover, preliminary research indicates that certain effects of nicotine salts in ENDS products (*e.g.*, higher nicotine exposure and faster rate of absorption) may increase the abuse liability of ENDS with nicotine salts, which raises concerns of addiction in youth, particularly due to the vulnerability of the developing adolescent brain. However, for many individual addicted cigarette smokers, the potential for ENDS to act as a substitute for cigarettes, thereby encouraging smokers to seek to switch completely away from combustible cigarettes, may be dependent, in part, upon the product having acceptability and abuse liability more comparable to a cigarette.

FDA has refined its enforcement priorities in the Final Guidance to focus on flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored). This approach strikes an appropriate balance between restricting youth access to such products, while maintaining availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from combusted tobacco products. FDA will, however, continue to evaluate new information and adjust these enforcement priorities, as warranted, in light of the best available data about these products.

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We also note that the March 2019 Draft Guidance proposed to prioritize enforcement for flavored ENDS products that are offered for sale in ways that pose a greater risk for minors to access such products. Several comments discussed the wide availability of these products and the means by which youth gain access. These included comments that expressed concern regarding the availability of flavored ENDS products on the Internet and in vape shops. Other commenters focused on how the enforcement priorities were unclear and difficult for retailers to understand, and how that may negatively affect “potentially compliant” retail locations that attempt to prevent minor access. Others expressed concern that the enforcement priorities were altogether impractical and costly for retailers. While the March 2019 Draft Guidance proposed to focus its enforcement priorities of flavored ENDS products on how the product was sold, after considering the comments, the public health threats, and the new evidence described above, FDA determined that focusing on how the product was sold would not appropriately address youth use of the products that are the most popular among youth—*i.e.*, flavored, cartridge-based products. The reality is that youth have continued access to these products in the face of legal prohibitions and even after voluntary actions by some manufacturers. Moreover, as discussed above, the data show that youth overwhelmingly prefer certain flavors of cartridge-based ENDS products.<sup>74</sup> These products are produced on a large scale, are easy to conceal, can be used discreetly, and are not the products typically produced in vape shops that mix nicotine with e-liquid flavors. Given the urgent need to address the dramatic rise in youth use, this Final Guidance prioritizes enforcement with respect to any flavored, cartridge-based ENDS products (other than a tobacco- and menthol-flavored ENDS product) without regard to the location or method of sale. FDA believes that focusing enforcement on these products is important in addressing the increasing rates of youth use of these flavored, cartridge-based products because this is a primary driver in youth experimentation with, and continued use of, ENDS products.

Accordingly, FDA has recalibrated its balancing of public health considerations in light of the public health threats and the significant new evidence described above. This policy reflects FDA’s balancing of concerns regarding the appeal of certain flavored, cartridge-based ENDS products to youth; the potential public health benefit of noncombusted options by which some adult smokers might seek to transition completely away from combusted tobacco products; and the potential risks created by extended availability of these new tobacco products without scientific review and evaluation under the applicable public health standard.

### 2. All other ENDS products without adequate measures to prevent minors’ access

FDA intends to prioritize enforcement for lack of a marketing authorization for any other ENDS products (*i.e.*, any tobacco-, menthol-, or non-flavored ENDS products and any non-cartridge-based, flavored ENDS products) when the manufacturer has not taken or is not taking adequate measures to prevent minors’ access to these products, without regard to whether or not, or when, a premarket application for such product has been submitted.

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<sup>74</sup> Cullen, K.A., A.S. Gentzke, M.D. Sawdey, “E-cigarette use among youth in the United States, 2019,” *JAMA*, 322(21);2095-2103, 2019.

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In assessing whether a manufacturer is taking (or has taken) adequate measures to prevent minors' access to these ENDS products, factors the Agency intends to consider include, but are not limited to:

- Whether the manufacturer has implemented adequate programs to monitor retailer compliance with age-verification and sales restrictions. Such programs might include, for instance: screening retailers, in advance of establishing or renewing distribution agreements, based on the strength of the retailers' age verification policies; establishing and publicizing a hotline for anonymous reporting of noncompliant sales; implementing a mystery shopper program; requiring use of technology that tracks age-verification practices; or other mechanisms.
- Whether the manufacturer has established and enforces penalties against retailers that fail to comply with age-verification and sales restrictions. For instance, in response to the September 12<sup>th</sup> letters, respondent manufacturers stated that they had mechanisms, such as through distribution agreements, to enforce financial penalties and stop sales to retailers in response to noncompliance. In addition to such mechanisms, FDA may consider whether a manufacturer has implemented a policy of notifying FDA of retailer violations.
- If the manufacturer is also a retailer, factors to adequately prevent underage access might include: whether the manufacturer/retailer has implemented programs to ensure compliance with age-verification and sales restrictions; establishing and publicizing a hotline for anonymous reporting of noncompliant sales; checking identification at the door; or other mechanisms.
- If the manufacturer is also a retailer, whether the manufacturer uses adequate age-verification technology (or requires that retailers who sell its products use such technology) to prevent underage access to its website and to prevent underage sales through the Internet. For instance, adequate age-verification could include use of an independent, third-party age- and identity-verification service that compares customer information against third-party data sources, such as public records; and
- Whether the manufacturer limits (or requires that retailers who sell its products to limit) the quantity of ENDS products that a customer may purchase within a given period of time.

FDA's decision to exercise its enforcement authorities with respect to particular products will be fact-specific and determined on a case-by-case basis.

This prioritization takes into account information that was provided by manufacturers in response to the Agency's September 2018 letters, including measures to address youth use that manufacturers can or have already taken to address youth access to ENDS products, as well as information provided in comments to the March 2019 Draft Guidance.

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As noted, FDA considered comments about the practical concerns of implementing an enforcement policy based on how products are sold. The factors above reflect information FDA received from industry, including information manufacturers shared during meetings with FDA leadership, in response to the September 2018 letters, and public comments submitted in response to the March 2019 Draft Guidance. From this information, FDA understands that manufacturers have the means to monitor and/or control how their products are sold at retail by, for example, including or requiring terms, conditions, or controls in their contracts with downstream distributors (wholesalers, distributors, importers, and/or retailers) to prevent youth access.

The March 2019 Draft Guidance did not propose to prioritize enforcement for tobacco- or menthol-flavored ENDS products and did not propose to distinguish between cartridge-based and other ENDS products. The continued significant increase in youth use of ENDS, as demonstrated in the 2019 NYTS and MTF data, as well as the data showing that youth overwhelmingly use flavored, cartridge-based ENDS products, support a reconsideration of the Agency's approach. As noted in the draft guidance, FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data, and it will continue to do so with respect to these unauthorized ENDS products.

As noted above, FDA received a number of comments arguing that the popularity of menthol-flavored ENDS (as well as mint-flavored ENDS, which are discussed above) had increased among youth and adult populations, and suggesting that such products would become even more popular if other flavored ENDS products became less available. They argued that excluding menthol-flavored ENDS products from prioritization would risk the shift of youth from one flavor of ENDS products to another based on a potential but indeterminate impact on adult consumers. FDA also received comments stating that it should immediately begin enforcing premarket review of all ENDS products, including tobacco-flavored ENDS products.

Other commenters emphasized a need for ENDS products to remain available for former smokers who have transitioned or current smokers who want to transition completely away from combustible products. Menthol is unique compared to other available ENDS product flavors as it is the only characterizing flavor available in cigarettes, and it may reduce the irritation and harshness of smoking.<sup>75</sup> Menthol cigarettes are also used by a substantial portion of the U.S. population, who are addicted to nicotine and may be looking for an alternative product to seek to transition completely away from combusted products.<sup>76</sup> FDA is compelled to act by data that

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<sup>75</sup> See, e.g., Harris, B., "Menthol: A review of its thermoreceptor interactions and their therapeutic applications," *International Journal of Aromatherapy*, 16(3-4):117-131, 2006; Galeotti, N., L.D. Mannelli, G. Mazzanti, et al., "Menthol: a natural analgesic compound," *Neuroscience Letters*, 322(3):145-148, 2002; Nishino, T., Y. Tagaito, Y. Sakurai, "Nasal inhalation of l-menthol reduces respiratory discomfort associated with loaded breathing," *American Journal of Respiratory and Critical Care Medicine*, 156(1):309-313, 1997; Lawrence, D., B. Cadman, A.C. Hoffman, "Sensory properties of menthol and smoking topography," *Tobacco Induced Diseases*, 9 Suppl 1(Suppl 1):S3, 2011; Garten, S. & R.V. Falkner, "Continual smoking of mentholated cigarettes may mask the early warning symptoms of respiratory disease," *Preventive Medicine*, 37(4):291-296, 2003.

<sup>76</sup> See, e.g., United States Department of Health and Human Services. Substance Abuse and Mental Health Services Administration (SAMHSA). Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and



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show youth overwhelmingly prefer certain flavors of cartridge-based ENDS products such as fruit, mint, and candy.<sup>77</sup> At the same time, FDA is aware that approximately 9 million adults currently use e-cigarettes.<sup>78</sup> Studies have shown that the majority of adult e-cigarette users use flavored e-cigarettes and there is some evidence to suggest that flavored e-cigarettes may improve switching from cigarette smoking to using e-cigarettes, compared to non-flavored e-cigarettes.<sup>79</sup>

FDA seeks both (1) to avoid foreclosing, even if temporarily, one potential means by which some adult smokers might seek to transition completely away from combusted tobacco products to potentially less harmful tobacco products; and (2) to prevent minors' access to ENDS products. FDA believes that this policy strikes an appropriate balance between restricting youth access to ENDS products and maintaining availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from combusted tobacco products.<sup>80</sup>

Moreover, the prioritization of flavored, cartridge-based products articulated in Section D.1 above, and the prioritization of all other flavored ENDS product sold without adequate measures to prevent youth access, should have minimal impact on those vape shops that primarily sell non-cartridge-based ENDS products and that ensure purchasers are of the requisite age and not purchasing for resale (*e.g.*, are not purchasing in large quantities). Should evidence indicate to the contrary, the Agency will take appropriate action.

3. Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors

Many ENDS products have been and continue to be marketed to minors through a wide variety of media and technology, and their labels and labeling, print advertising, and/or online advertising are appealing to minors. Unlike combusted cigarettes and smokeless tobacco products, for which advertising through television and radio (and any other medium of electronic

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Health, 2016. Analysis run on October 12, 2018. SAMHSA's public online data analysis system (PDAS). (Original Data Source: NSDUH 2016)

<sup>77</sup> Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," *JAMA*, 322(21);2095-2103, 2019.

<sup>78</sup> Creamer, M.R., "Tobacco Product Use and Cessation Indicators Among Adults- United States 2018," *Morbidity and Mortality Weekly Report*, 68:1013-1019, 2019, available at: <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6845a2-H.pdf>.

<sup>79</sup> Russell, C. et al. "Changing Patterns of First E-Cigarette Flavor Used and Current Flavors Used by 20,836 Adult Frequent E-Cigarette Users in the USA," *Harm Reduction Journal*, 15(1):33-47, 2018; Bonhomme, M.G. et al. "Flavoured Non-Cigarette Tobacco Product Use Among US Adults: 2013–2014," *Tobacco Control*, 25(Suppl 2):4–13, 2016.

<sup>80</sup> FDA notes that no ENDS product has been approved by FDA as a drug for smoking cessation. However, the premarket review process for ENDS products will provide an opportunity for FDA to further examine the potential of an ENDS product to meet the tobacco product premarket authorization standard of "appropriate for the protection of public health," including adult decisions to completely transition away from use of combustible products to potentially less harmful ENDS products or other non-combustible forms of nicotine delivery.

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communication subject to regulation by the Federal Communications Commission) has been prohibited since 1971 and 1986 respectively,<sup>81</sup> ENDS products are advertised through television, radio, and online.<sup>82</sup> Social media accounts are frequently used to electronically share tobacco-product-related content with other minors.<sup>83</sup> Sales of such products to minors are prohibited, and FDA is concerned with actions likely to promote unlawful sales and maintain or increase youth use. FDA has issued joint warning letters with the FTC to four firms that manufacture, advertise and offer for sale or distribution several flavored e-liquid products for violations related to online posts by social media influencers on each company's behalf.<sup>84</sup> This type of marketing is especially concerning because longitudinal data from Waves 1 (2013-2014) and 2 (2014-2015) of the PATH Study show that engagement with online tobacco marketing is a risk factor for adolescent tobacco use, as adolescents who engaged with online tobacco marketing had greater incidences of initiating tobacco use, increased frequency of use and progression to poly-product use, and lower incidences of cessation compared to those who do not engage.<sup>85</sup>

Researchers have found that certain marketing strategies can increase youth appeal, both in general and with respect to tobacco products in particular. FDA has previously issued warning letters for products that resemble kid-friendly foods and drinks or that resemble other non-ENDS products that are often consumed by youth.<sup>86</sup> This includes labeling and/or advertising that results in the product resembling juice boxes, candy, or kid-friendly cereal. Actions by manufacturers to present their ENDS products in this way are likely to promote youth use, and also present a risk of confusion that could be harmful to children, including the risk of accidental poisoning.<sup>87</sup> Other marketing conduct likely to promote youth use includes the use of cartoons as part of e-cigarette manufacturers' and retailers' logos, marketing materials, promotions,<sup>88</sup>

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<sup>81</sup> 15 U.S.C. § 1335 ("It shall be unlawful to advertise cigarettes or little cigars on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission"); 15 U.S.C. § 4402(c) (same, for smokeless tobacco).

<sup>82</sup> U.S. Department of Health and Human Services, "E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General," 2016.

<sup>83</sup> See Chu, K.-H., J.B. Colditz, B.A. Primack, et al., "JUUL: Spreading Online and Offline," *Journal of Adolescent Health*, 63(5), 582-586, 2018.

<sup>84</sup> FDA News Release, "FDA, FTC take action to protect kids by citing four firms that make, sell flavored e-liquids for violations related to online posts by social media influencers on their behalf," June 7, 2019, available at: <https://www.fda.gov/news-events/press-announcements/fda-ftc-take-action-protect-kids-citing-four-firms-make-sell-flavored-e-liquids-violations-related>.

<sup>85</sup> Soneji, S., J. Yang, K.E. Knutzen, et al., "Online Tobacco Marketing and Subsequent Tobacco Use," *Pediatrics*, 141(2):e20172927, 2018; doi:10.1542/peds.2017-2927.

<sup>86</sup> E.g., "E-Liquids Misleadingly Labeled or Advertised as Food Products," available at: <https://www.fda.gov/tobaccoproducts/newsevents/ucm605729.htm>; "FDA In Brief: FDA warns companies to stop making, selling or distributing e-liquids marketed to resemble prescription cough syrups," available at: <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-warns-companies-stop-making-selling-or-distributing-e-liquids-marketed-resemble>.

<sup>87</sup> See, e.g., Kamboj, A., H.A. Spiller, M.J. Casavant, et al., "Pediatric Exposure to E-Cigarettes, Nicotine, and Tobacco Products in the United States," *Pediatrics*, 2016;137(6):e2016004.

<sup>88</sup> Allem, J.-P., T. B. Cruz, J.B. Unger, et al., "Return of cartoon to market e-cigarette-related products," *Tobacco Control*, 0, 1-3, 2018; doi:10.1136/tobaccocontrol-2018-054437 (2018); Jackler, R. K., & Ramamurthi, D.,

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Instagram posts,<sup>89</sup> and video advertisements.<sup>90</sup> Cartoon figures are frequently used on product packaging and in television advertising to promote youth consumption of consumer goods.<sup>91</sup> A common theme discussed in food and beverage industry publications has been using cartoons in marketing and packaging consumer products to target children and teenagers.<sup>92</sup> Another marketing strategy that has been recently employed by manufacturers is labeling, advertising, and/or product design that results in the ENDS product resembling ordinary items that may not draw the attention of adults.<sup>93</sup> Similar marketing conduct likely to promote youth use includes labeling and/or advertising highlighting how the product is ‘stealth’ or ‘secret’ and in the form of ordinary objects that may not be readily recognized by parents or teachers.<sup>94</sup>

Any efforts to entice minors to use tobacco products are of concern to FDA. FDA intends to prioritize its enforcement to focus on products that are targeted to minors or likely to promote use of ENDS by minors. Some examples of such products include:

- Products marketed with labeling and/or advertising that resemble kid-friendly foods and drinks or resemble other non-ENDS products that are often marketed and/or appealing to youth. This includes, for example, labeling and/or advertising that results in the product resembling juice boxes, candy, or kid-friendly cereal; and/or
- Products marketed directly to minors by promoting ease of concealing the product or the nature of the product as a tobacco product from parents, teachers, or other adults; and/or
- Products marketed with youth-appealing cartoon or animated characters, such as those that depict or resemble popular children’s characters; and/or

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“Unicorns cartoons: marketing sweet and creamy e-juice to youth,” *Tobacco Control*, 26(4), 471-475, 2017; doi:10.1136/tobaccocontrol-2016-053206; Kirkpatrick, M. G., T.B. Cruz, N.L. Goldenson, et al., “Electronic cigarette retailers use Pokémon Go to market products,” *Tobacco Control*, 26(e2), e145, 2017; doi:10.1136/tobaccocontrol-2016-053369 (2017); Padon, A. A., E.K. Maloney & J.N. Cappella, “Youth-targeted e-cigarette marketing in the US,” *Tobacco Regulatory Science*, 3(1), 95-101, 2017; doi:10.18001/TRS.3.1.9.

<sup>89</sup> Allem, J.-P., T.B. Cruz, J.B. Unger, et al., “Return of cartoon to market e-cigarette-related products,” *Tobacco Control*, 0, 1-3, 2018; doi:10.1136/tobaccocontrol-2018-054437.

<sup>90</sup> Padon, A. A., Maloney, E. K., & Cappella, J. N., “Youth-targeted e-cigarette marketing in the US,” *Tobacco Regulatory Science*, 3(1):95-101, 2017; doi:10.18001/TRS.3.1.9.

<sup>91</sup> Ethan, D., C.H. Basch, L. Samuel, et al., “An examination of product packaging marketing strategies used to promote pediatric multivitamins,” *Journal of Community Health*, 40(3), 564-568, 2015; doi:10.1007/s10900-014-9972-1; Kraak, V. I., & Story, M., “Influence of food companies' brand mascots and entertainment companies' cartoon media characters on children's diet and health: a systematic review and research needs,” *Obesity Reviews*, 16(2), 107-126, 2015.

<sup>92</sup> Barrey, S., M. Baudrin, & F. Cochoy, “From fun foods to fun stores,” *Young Consumers*, 11(2):138-147, 2010; Cioletti, J., “Cereal thrillers,” *Supermarket Business Magazine*, 56(10):30, 2001; Cioletti, J., “Future of... youth marketing,” *Beverage World*, 122(8), 10 (2003); Cvetan, D., “Active market for active cultures,” *Dairy Field*, 183(4):18, 2000; Fry, J., “Moo kids on the block say they've got more than the white stuff,” *Beverage World*, 114(1596):1, 1995; Landi, H., “High Tea,” *Beverage World*, 130(7):18-22, 2011; Steinriede, K., “The year's best packaging,” *Beverage Industry*, 91(12): 34, 2000; White, L., “A license for profits,” *Professional Candy Buyer*, 19(6):19-21, 2011.

<sup>93</sup> See, e.g., Ramamurthi, D., C. Chau., R.K. Jackler, “JUUL and Other Stealth Vaporisers: Hiding the Habit From Parents and Teachers,” *Tobacco Control*, Sept. 2018, doi: 10.1136/tobaccocontrol-2018-054455.

<sup>94</sup> *Id.*

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- Products marketed, including through paid social media influencers, with popular children’s characters and titles (*e.g.*, popular children’s YouTube channels, television shows, or characters). This includes, for example, the use of minors or people who portray minors on such shows and their associated show titles.
4. Any ENDS product that is offered for sale in the United States after May 12, 2020.

The U.S. District Court for the District of Maryland has ordered that premarket applications for all deemed new tobacco products on the market as of August 8, 2016, be submitted by May 12, 2020. Even in the absence of this court order, FDA would prioritize enforcement of any ENDS product that lacks a premarket application after May 12, 2020, for the reasons described in this guidance. For ENDS products other than those described in D.1 – D.3 above, if premarket applications are submitted by May 12, 2020, FDA intends to continue to exercise enforcement discretion for up to one year pending FDA review, unless there is a negative action by FDA on such application. A negative action would consist of the issuance of a Refuse to Accept (RTA), Refuse to File (RTF), and/or No Marketing Order (NMO); or of a letter administratively closing the application, or cancelling the application if FDA finds that it mistakenly accepted the application or that the application was submitted in error. In addition, the other enforcement priorities discussed in this guidance would apply to such products, regardless of whether or not a premarket application has been submitted for the product.

We note that the March 2019 Draft Guidance had included August 8, 2021, as the date for which FDA would prioritize enforcement for flavored ENDS products that had not submitted premarket applications. A number of comments expressed concern about the impact of the August 2021 date on businesses. For example, several commenters argued that any restriction on the sale or distribution of ENDS products could result in companies going out of business. On the other hand, FDA received many comments suggesting that in light of the problem of increasing youth access and use of ENDS products, FDA should begin enforcing the premarket authorities as applied to deemed new tobacco products earlier than August 8, 2021. Several comments remarked that FDA should have begun enforcing the premarket review requirements against ENDS products already, that FDA’s previous premarket review compliance date extensions enabled some companies to “delay or circumvent areas of regulatory compliance,” and that further delays were contrary to public health.

Although FDA considered the potential impact of the draft compliance policy on businesses large and small, we note that, pursuant to the Tobacco Control Act, as of the effective date of the final deeming rule, ENDS products were required to have premarket authorization prior to marketing. While some deemed new tobacco products remained on the market in light of FDA’s deferred enforcement policy, such policies are subject to change. Manufacturers cannot have settled expectations to market unlawful products, especially in the face of evolving public health concerns. Therefore, FDA believes that manufacturers should have begun contemplating and/or preparing premarket applications no later than the time of the final deeming rule. As discussed in Section II.B of this Final Guidance, FDA has repeatedly publicly discussed the fact that enforcement discretion timelines for deemed tobacco products were under reconsideration and solicited views from stakeholders. Manufacturers may obtain information about the application

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process from the statutory criteria, as well as published guidances, webinars, and marketing orders and their accompanying documentation provided by FDA.<sup>95</sup>

Under the circumstances, FDA believes that earlier enforcement of the premarket review provisions is appropriate for ENDS products. This policy should result in earlier submission of applications and allow FDA to better evaluate whether these products meet the applicable premarket standard, such as whether the products are appropriate for the protection of the public health, considering the risks and benefits to the population as a whole, including users and nonusers of the tobacco product. Because of FDA's concerns regarding youth use of ENDS products, as well as other ongoing health concerns regarding vaping more generally, all described at length above, FDA is prioritizing enforcement of premarket review requirements for ENDS products, as described in this section, and is doing so independently of the court order. This will ensure that FDA has the necessary information to exercise adequate, timely oversight over these relatively novel and potentially harmful products. Enforcing premarket authorization requirements will, consistent with the process set forth in the Tobacco Control Act, ensure that the burden falls on manufacturers of ENDS products to demonstrate that the manufacture and sale of their products is appropriate for the protection of the public health.

### **E. Avoiding a “Black Market”**

FDA is aware of concerns that, given the rise in popularity of ENDS, removal of some of the most popular products from the market may be accompanied by an increase in black market versions of these products that may pose additional health and safety risks to consumers beyond those of the authentic products. Although all newly deemed products currently on the market without premarket authorization are being sold in violation of the Tobacco Control Act, in this section, we use the term “black market” to refer to, for example, products intended to look like another ENDS products that is currently being marketed, products intended to take the place of an ENDS product that a manufacturer has stopped distributing because the product lacks premarket authorization, and ENDS products intended for another country's market but diverted to the U.S. market. Additional risks posed by these products include the potential that they contain harmful chemicals or constituents that are not present in other products, that they are manufactured using comparatively poor quality controls, and that they are designed in ways that facilitate modifications by distributors or users—all of which increase the risk of adverse events.<sup>96</sup> Moreover, to the extent that such products are sold through nontraditional retail

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<sup>95</sup> For more information on premarket tobacco product applications please see Premarket Tobacco Product Applications for [ENDS], Guidance for Industry (June 2019), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends>; Applications for Premarket Review of New Tobacco Products (updated June 2019) available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-premarket-review-new-tobacco-products>. For more information on CTP's other published regulations and guidances, please see <https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance>; for more information on FDA CTP webinars, please see <https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars>; for information on marketing orders and accompanying documentation, please see <https://www.fda.gov/tobacco-products/compliance-enforcement-training>.

<sup>96</sup> *E.g.*, “Amid Vaping Deaths, California Targets Counterfeit Products,” *The New York Times* (Sept. 17, 2019), available at <https://www.nytimes.com/2019/09/16/us/california-vaping.html>; “‘Juul-alikes’ Are Filling Shelves With

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channels, such as social sources or online commercial marketplaces that do not include age-verification requirements, they pose an increased risk of being accessed by minors.

FDA has regulatory tools and enforcement authorities to address ENDS and other tobacco products that are marketed without authorization, that are counterfeit, and/or that are otherwise involved in illicit trade.<sup>97</sup> FDA has previously issued letters to companies suspected of marketing counterfeit or otherwise unauthorized products.<sup>98</sup> Additional potential actions against adulterated or misbranded illicit tobacco could include: (1) issuing a Warning Letter; (2) issuing an import alert and refusing admission of tobacco products imported or offered for import into the United States; and (3) initiating seizure or injunction court actions. Persons engaging in illicit trade in tobacco products may also be criminally prosecuted under the law.

As a result of this policy, FDA will be better situated to combat black market products, including those that are particularly troubling from a public health or safety perspective, such as counterfeit pods entering the country at the border or being sold through illicit, online channels. By prioritizing our focus as outlined in Section IV.D, the Agency can target our supply chain surveillance and investigation resources on the types of ENDS products that are likely to be subject to counterfeiting and/or sale on the black market. As a result, we will be able to more efficiently and effectively deploy our enforcement tools to get counterfeit and black market products off the market. Moreover, FDA believes that there are significant public health benefits of the policy set forth in this guidance, which is aimed at curbing the dramatic rise in youth use of ENDS products and will help address safety issues connected to ENDS products that are not fully understood—*e.g.*, the development of acute or chronic lung injuries associated with use of vaping products as well as battery explosions with ENDS products—particularly given that these products have been marketed without premarket evaluation. These current public health issues affirm the importance of the premarket review process, as contemplated by the Tobacco Control Act, to scientifically evaluate products based on a public health standard.

## **V. PREMARKET REVIEW FOR OTHER DEEMED NEW TOBACCO PRODUCTS**

FDA remains concerned with minors' access to and use of all tobacco products, particularly flavored tobacco products, which appeal to minors and promote initiation.<sup>99</sup> In addition to the

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Sweet, Teen-Friendly Nicotine Flavors” The New York Times (Aug. 13, 2019), available at <https://www.nytimes.com/2019/08/13/health/juul-flavors-nicotine.html>; Omaiye, E.E., I. Cordova, B. Davis, et. al., “Counterfeit Electronic Cigarette Products with Mislabeled Nicotine Concentrations,” *Tobacco Regulatory Science*, 3(3): 347–357, 2017.

<sup>97</sup> See, *e.g.*, sections 301, 902, 903, 905, 910, and 920 of the FD&C Act.

<sup>98</sup> *E.g.*, “Statement from FDA Commissioner Scott Gottlieb, M.D., on forceful new actions focused on retailers, manufacturers to combat youth access to e-cigarettes as part of FDA’s Youth Tobacco Prevention Plan,” available at: <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-forceful-new-actions-focused-retailers-manufacturers>.

<sup>99</sup> U.S. Department of Health and Human Services, “E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General,” 2016; Villanti, A.C., A.L. Johnson, B.K. Ambrose, et al., “Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014),” *American Journal of Preventive Medicine*, 53(2): 139-151, 2017.

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tobacco products covered earlier in this guidance document, FDA has considered revising its enforcement priorities with respect to premarket authorization for other deemed new tobacco products. We note that several comments on the March 2019 Draft Guidance suggested that FDA begin immediately enforcing the premarket requirements for flavored deemed tobacco products such as cigars and other deemed tobacco products.

FDA received numerous comments relating to the proposed policy for flavored cigars in the March 2019 Draft Guidance. Some of the comments were supportive of that proposed policy, although some wanted the Agency to take even more aggressive action. Other comments opposed inclusion of flavored cigars as an enforcement priority and disagreed with the bases for the proposed policy. For example, some commenters argued that flavored cigars are used most commonly by adult users and that the inclusion of flavored cigars as an enforcement priority limits adults' freedom to choose their preferred product. Other commenters argued that FDA did not have the data necessary to support the need for "a drastic and unprecedented change in enforcement priorities." Some commenters also stated that the evidence cited by FDA discussing initiation of youth usage of flavored cigars was inconsistent and inconclusive. After consideration of the data regarding youth use of cigars generally and comments received on this issue, we have decided to not prioritize enforcement of flavored cigars before May 12, 2020. While there is no public health benefit associated with flavored cigars and FDA remains concerned with youth use of flavored cigars, current data indicate that youth are using flavored cigars at a lower rate than they are using flavored ENDS products.

Comments regarding deemed tobacco products other than ENDS products and cigars, such as waterpipe tobacco (hookah) products, also provided data showing the use of such tobacco products among high school students and stating that evidence reflects that flavors for these tobacco products entice youth. However, such data do not appear to raise comparably urgent public health concerns, as the lower prevalence of youth use of these products suggests that they do not appear to be as appealing to youth at this time.

Accordingly, at this time, FDA has decided to prioritize use of its limited enforcement resources to address the sudden and dramatic increase in youth use of ENDS products, as well as to focus on health and safety concerns connected to ENDS products such as vaping-associated lung injuries. While acknowledging that all new tobacco products on the market without the required authorization are marketed unlawfully and are potentially subject to enforcement action, at any time, in FDA's discretion, FDA's primary focus will be to address the sudden and dramatic increase in youth use of ENDS products, and the products covered by this section of the guidance will therefore be a lower priority.

We have decided not to prioritize enforcement of the tobacco products covered by this section before May 12, 2020. Manufacturers of flavored cigars, however, just like manufacturers of all other deemed new tobacco products, will be required to submit marketing applications for those products by May 12, 2020, consistent with the U.S. District Court for the District of Maryland's order directing FDA to require that applications be submitted to the Agency by May 12, 2020, for deemed new tobacco products on the market as of August 8, 2016, or be subject to FDA enforcement actions, in FDA's discretion. As part of the premarket review process, FDA may evaluate, among other things, the product's constituents, ingredients, additives, and properties;

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manufacturing practices; and any studies or investigations into the health risks of the tobacco product. FDA also has stated its intention to issue a regulation that would ban the use of characterizing flavors in cigars, and FDA is actively working towards that proposed rule.

After May 12, 2020, FDA will make enforcement decisions on a case-by-case basis, recognizing that it is unable, as a practical matter, to take enforcement action against every illegally marketed tobacco product, and that it needs to make the best use of Agency resources. FDA intends to prioritize enforcement based on the likelihood of youth use or initiation to make the most efficient use of its resources. In assessing this, factors the Agency intends to consider include, but are not limited to:

- What FDA understands about the number of youth currently using the product or category of product;
- The trends in those numbers, particularly since 2016;
- Whether the product contains added flavors;
- What FDA understands about how the product or category of product is typically sold and how that is likely to impact access and use by minors; and
- What FDA understands about the frequency and other demographics of use by minors.

To illustrate, based on these factors, FDA's lowest priority among these products will include relatively expensive, large hand-rolled cigars that do not have flavors (*e.g.*, fruit, candy, or mint), given what FDA understands to be their comparatively lower youth usage rates.

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FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data, and it will continue to do so with respect to these products. FDA will take appropriate action regarding tobacco products that are marketed without premarket authorization, including as warranted based on changed circumstances, new information, or to better address minors' use of those products.



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**APPENDIX A – SIGNIFICANT COMMENTS RECEIVED IN RESPONSE TO MARCH 2019 DRAFT GUIDANCE AND FDA RESPONSES**

<b>Legal and statutory framework issues</b>	
Comment	Response
<p>FDA should engage in legislative rulemaking process</p> <ul style="list-style-type: none"> <li>• The draft guidance constituted a major rule and FDA has not followed procedures established by the Administrative Procedure Act (APA) governing the promulgation of rules</li> <li>• The Regulatory Flexibility Act requires an analysis of a proposed rule’s impact on small business and FDA has not conducted such an analysis</li> <li>• FDA is bypassing the requirement to conduct a cost benefit analysis by issuing a guidance instead of formal rule</li> <li>• FDA has not considered regulatory alternatives to the approach outlined in the draft guidance</li> <li>• This action would impose costs and adverse effects on industry which constitutes a major rule which should be subject to the requirements under the Congressional Review Act</li> <li>• Though guidance documents are non-binding, the way the guidance is written, retail outlets would need to comply with standards suggested by the draft guidance as though they were law</li> <li>• Engaging in rulemaking would offer more substantial opportunity for stakeholders to provide public comments and would provide clarity on what stakeholders (through the supply and retail chain) needed to do to come into compliance</li> </ul>	<p>The Final Guidance is a statement of policy that discusses the enforcement of premarket authorities already existing in the statute. It does not establish any rights for any person, is not binding on FDA or the public, and is not subject to requirements of the Regulatory Flexibility Act or the notice-and-comment provisions of the APA. Historically, FDA has not analyzed the economic effects of enforcement guidance, including for reasons such as difficulty in predicting such effects. Alternatives such as issuing warning letters and other enforcement techniques have been considered and used by the Agency. Despite this, as shown by the data highlighted in the Final Guidance, the rate of youth use of tobacco products (particularly fruit- and candy-flavored and mint-flavored ENDS products) has dramatically increased. FDA retains discretion to enforce premarket authorities.</p> <p>The relevant substantive requirements are those governing premarket authorization as set forth in Section 910. The Final Guidance does not impose new restrictions, for retailers or manufacturers, but rather discusses FDA’s enforcement priorities for existing statutory requirements. In Section 910, Congress placed the onus on manufacturers to demonstrate that the marketing of a tobacco product is appropriate for the protection of the public health, taking into account, among other things, the likelihood that those who do not use tobacco products will start using them.</p> <p>FDA provided for a 45-day period for comment on the draft guidance, and interested parties may continue to submit comments after publication of the final guidance, providing a substantial opportunity for public input.</p>
<p>FDA is bypassing statutory restrictions on its discretionary enforcement authority and obligations related to rulemaking, by</p>	<p>FDA has discretion to decide how when to enforce its premarket authorization authorities under the FD&amp;C Act. <i>See Heckler v. Chaney</i>, 470 U.S. 821,</p>

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<p>threatening selective enforcement of its premarket authorization authority.</p>	<p>835 (1985). The Final Guidance is a statement of policy that outlines FDA’s enforcement priorities with respect to such requirements.</p>
<p>Guidance should conform to Section 907.</p> <ul style="list-style-type: none"> <li>• Actions in this guidance should conform to Section 907, which obligates FDA to consider factors not addressed by the guidance, including technical achievability and countervailing effects.</li> <li>• FDA should not adopt modifications to compliance policy but should instead follow through with a rule that considers the comments from FDA’s ANPRM on Flavors in Tobacco Products.</li> </ul>	<p>Section 907 refers to tobacco product standards. This Final Guidance is not setting tobacco product standards, such as a tobacco product standard restricting or eliminating the use of flavors in ENDS. Instead, it is explaining FDA’s enforcement priorities for premarket review requirements already included in the Tobacco Control Act. A flavored product could be marketed consistent with this guidance if it meets the statutory standards for authorization. For example, in April 2019, FDA authorized the marketing of a menthol-flavored IQOS heat-not-burn cigarette product through the PMTA pathway.<sup>100</sup></p>
<p>FDA is supposed to be an advisory agency, not a regulatory agency, and its actions are an overreach.</p>	<p>The Tobacco Control Act provides FDA with regulatory authority over tobacco products.</p>
<p>FDA’s proposed actions are arbitrary and capricious because it has failed to provide adequate reasoning/scientific reasoning/used incomplete or incorrect data.</p>	<p>The enforcement priorities explained in the Final Guidance are based upon and supported by, among other things, multiple high-quality scientific data sources (e.g., NYTS, PATH, MTF).</p>
<p>FDA has failed to connect the proposed policy to an official finding that the actions were “appropriate for the protection of public health.”</p>	<p>The Final Guidance discusses the enforcement of premarket authorities already existing in statute. Section 910 places the onus on manufacturers to show that the marketing of a tobacco product would be appropriate for the protection of the public health, not on the FDA to show otherwise. The Tobacco Control Act uses the term “appropriate for the protection of the public health,” in section 910 and several other provisions. The considerations identified in the statute typically include analysis of whether the action would increase or decrease the likelihood that existing users of tobacco products would stop using such products, and whether it would increase or decrease the likelihood that those who do not</p>

<sup>100</sup> For more information please see <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>.

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	use tobacco products will start using the products. The Guidance reflects these considerations.
<p>FDA has been unresponsive/lack of clarity.</p> <ul style="list-style-type: none"> <li>• Manufacturers have been relying on guidance and information since the deeming rule; this is a drastic departure from deeming and guidances issued since deeming.</li> <li>• Difficult to keep track of FDA’s policies and compliance requirements.</li> </ul>	<p>FDA has communicated its concerns regarding the increase in youth access in public statements, the March 2019 draft guidance, and requests for information to manufacturers. FDA has consistently informed industry that its compliance policies will be responsive to changed circumstances. There could be no reasonable reliance on a deferred enforcement policy subject to change at any time. The guidance explains why the changed circumstances warrant this prioritization; <i>i.e.</i>, the substantial increase in youth use of ENDS in addition to other health and safety considerations. FDA has always stated (and the Tobacco Control Act itself is clear) that deemed new tobacco products are required to obtain premarket authorization and that such products that remain on the market without marketing authorization are marketed unlawfully.</p>
<p>FDA has stated it will provide further guidance and issue rules to make the product review process more transparent and predictable but has not done so.</p>	<p>FDA has provided guidance and information to industry on the premarket pathways through publishing guidances and marketing orders, as well as posting information via webinars and public workshops.<sup>101</sup> The statute also informs the public of the information needed in a premarket tobacco product application. Industry members have successfully obtained marketing authorization orders with information currently available.</p>
<p>Draft guidance would have unjustifiable retroactive effects on industry actors who were “in compliance” with FDA’s previous policy.</p>	<p>This Final Guidance would only affect those products that are illegally on the market; none of the products affected by the guidance were ever in compliance with the premarket authorization requirements of the law. FDA has consistently</p>

<sup>101</sup> For more information on premarket tobacco product applications please see Premarket Tobacco Product Applications for [ENDS], Guidance for Industry (June 2019), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends>; Applications for Premarket Review of New Tobacco Products (updated June 2019) available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-premarket-review-new-tobacco-products>. For more information on CTP’s other published regulations and guidances, please see <https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance>; for more information on FDA CTP webinars, please see <https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars>; for information on marketing orders and accompanying documentation, please see <https://www.fda.gov/tobacco-products/compliance-enforcement-training>.

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	<p>informed industry that its compliance policies will be responsive to changed circumstances. As discussed in the guidance, FDA stated in the notice of proposed rulemaking for the Deeming Rule, that the overall public health impact of ENDS products would depend crucially upon “who uses the products and how they are used. If such products result in minimal initiation by children and adolescents while significant numbers of smokers quit, then there is a potential for the net impact at the population level to be positive. If, on the other hand, there is significant initiation by youth, minimal quitting, or significant dual use of combust[ed] and non-combust[ed] products, then the public health impact could be negative.” As such policies are subject to change, manufacturers cannot have settled expectations to market unlawful products, especially in the face of evolving public health concerns. Therefore, FDA believes that manufacturers should have begun contemplating and/or preparing premarket applications at no later than the time of the final deeming rule.</p>
<p>Draft guidance will kill innovation and force industry out of work.</p>	<p>FDA disagrees that the Final Guidance will cause these results. The Final Guidance explains FDA’s enforcement priorities for certain deemed new products that are being marketed without required premarket tobacco product authorization. The Final Guidance would only affect those products that are illegally on the market; none of the products affected by the guidance were ever in compliance with the premarket authorization requirements of the law. In any event, FDA believes that the use of premarket pathways will incentivize development of innovative tobacco products that meet the applicable statutory standards.</p>
<p>Draft guidance policy on marketing practices would violate the First Amendment as it represents an impermissibly broad commercial speech restriction.</p>	<p>FDA disagrees that the Final Guidance violates the First Amendment. Speech regarding an illegal activity – including distribution of a product that requires premarket review under the FDCA – is not protected under the First Amendment. <i>See United States v. Caputo</i>, 517 F.3d 935, 941 (7th Cir. 2008) (unapproved device); <i>United States v. LeBeau</i>, 654 Fed. App’x 826, 831 (7th Cir. 2016)</p>

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	<p>(unapproved drug); <i>United States v. Cole</i>, 84 F. Supp. 3d 1159, 11-66-67 (D. Or. 2015) (unapproved drug). Even if the First Amendment were applicable, the government has a substantial interest in protecting youth from tobacco products, and prioritizing enforcement actions with respect to ENDS products targeted to, or likely to promote use by, minors is a reasonable measure to directly advance that interest. <i>See, e.g., Discount Tobacco City &amp; Lottery, Inc. v. United States</i>, 674 F.3d 509, 536 (6th Cir. 2012). We have provided additional examples for clarity in the Final Guidance.</p>
<b>Modifications to ENDS Compliance Policy – Flavored ENDS except Tobacco, Mint, Menthol</b>	
<b>Comment</b>	<b>Response</b>
<p>There is no evidence/limited evidence to connect liquid nicotine use with harmful health effects in youth.</p>	<p>As discussed in the Final Guidance the studies of the effects of nicotine exposure in the naïve adolescent brain find that the adolescent brain is uniquely vulnerable to nicotine compared to the adult brain. Repeated exposure to nicotine during adolescence induces long-lasting structural and functional changes in brain regions involved in addiction, attention, learning, and memory.<sup>102</sup></p> <p>Studies further suggest that nicotine-induced changes in the adolescent brain can lead to long-lasting effects on cognitive function, such as cognitive deficits following nicotine abstinence, and may contribute to the risk for mood and anxiety disorders. Nicotine is the primary addictive substance in tobacco products, including e-cigarettes and combustible cigarettes. The rate and extent of nicotine delivery significantly impact product abuse liability. Higher nicotine content and faster rates of nicotine delivery increase products’ abuse liability due to the rapid absorption of nicotine into the brain. Some e-</p>

<sup>102</sup> McDonald, C.G., A.K. Eppolito, J.M. Brielmaier, et. al., “Evidence for elevated nicotine-induced structural plasticity in nucleus accumbens of adolescent rats,” *Brain Research*, 1151, 211-218, 2007; doi: 10.1016/j.brainres.2007.03.019; Bergstrom, H.C., R.F. Smith., N.S. Mollinedo, et al., “Chronic nicotine exposure produces lateralized, age-dependent dendritic remodeling in the rodent basolateral amygdala,” *Synapse*, 64(10), 754-764, 2010; doi:10.1002/syn.20783; England, L.J., K. Aagaard, M. Bloch, et al., “Developmental toxicity of nicotine: a transdisciplinary synthesis and implications for emerging tobacco products,” *Neuroscience and Biobehavioral Reviews*, 72:176-189, 2017.

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	cigarettes are capable of achieving similar or greater nicotine delivery as cigarettes. <sup>103</sup>
<p>“Banning” flavors outside of tobacco, mint, and menthol would deter cigarette smokers from quitting or force smokers to restart smoking if they have already quit.</p> <ul style="list-style-type: none"> <li>• Smokers trying to quit smoking avoid tobacco-, mint-, and menthol-flavored products because they are too similar to flavors of a traditional cigarette.</li> <li>• Stricter policies for ENDS products for youth should not come at expense of adult users.</li> </ul>	<p>The Final Guidance does not ban any products but rather identifies FDA’s priorities in connection with the enforcement of the statutory premarket review requirements. Moreover, the policy announced in the Final Guidance does not prioritize any menthol-flavored, tobacco-flavored, or non-flavored ENDS products or any non-cartridge-based flavored ENDS products for enforcement where the manufacturer is taking adequate measures to prevent minors’ access to these products. Additionally, consumers will be able to access ENDS products (including flavored ENDS products) that receive market authorization. Nicotine replacement therapy products also remain available for tobacco product users who may need assistance with withdrawal symptoms and are also available in several flavors.</p> <p>Available research does not support the argument that smokers trying to quit smoking and transition to ENDS products avoid tobacco and menthol-flavored ENDS products because they are too similar to traditional cigarette flavors.</p> <p>FDA has repeatedly emphasized that the availability of non-combustible options should not come at the expense of addicting a generation of children to nicotine through these same delivery vehicles. FDA believes that this policy strikes an appropriate balance between preventing youth</p>

<sup>103</sup> Hiler, M., A. Breland, T. Spindle, et al., “Electronic cigarette user plasma nicotine concentration, puff topography, heart rate, and subjective effects: Influence of liquid nicotine concentration and user experience,” *Experimental and Clinical Pharmacology*, 25(5), 380-392, 2017; doi:10.1037/pha0000140; Lopez, A.A., M.M. Hiler, E.K. Soule, et al., “Effects of Electronic Cigarette Liquid Nicotine Concentration on Plasma Nicotine and Puff Topography in Tobacco Cigarette Smokers: A Preliminary Report,” *Nicotine & Tobacco Research*, 18(5):720-723, 2016; doi:10.1093/ntr/ntv182; Maloney, S. F., A. Breland, E.K. Soule, et al. “Abuse liability assessment of an electronic cigarette in combustible cigarette smokers,” *Experimental and Clinical Psychopharmacology*, 27(5):443-454, 2019; doi:10.1037/pha0000261; O’Connell, G., J.D. Pritchard, C. Prue, et al, “A randomised, open-label, cross-over clinical study to evaluate the pharmacokinetic profiles of cigarettes and e-cigarettes with nicotine salt formulations in US adult smokers,” *Internal and Emergency Medicine*, 14(6):853-861, 2019; doi:10.1007/s11739-019-02025-3; Ramoa, C. P., M.M. Hiler, T.R. Spindle, et al. “Electronic cigarette nicotine delivery can exceed that of combustible cigarettes: a preliminary report,” *Tobacco Control*, 25(e1): e6-9, 2016; doi:10.1136/tobaccocontrol-2015-052447; Yan, X. S., & C. D’Ruiz, “Effects of using electronic cigarettes on nicotine delivery and cardiovascular function in comparison with regular cigarettes,” *Regulatory Toxicology and Pharmacology*, 71(1):24-34, 2015; doi:10.1016/j.yrtph.2014.11.004.

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	<p>access to ENDS products and maintaining availability of potentially less harmful options for current adult smokers who have transitioned or wish to transition completely away from combusted tobacco products.</p>
<p>No basis for prioritizing flavored ENDS products.</p> <ul style="list-style-type: none"> <li>• The policy will not be successful at keeping kids from using these products; kids use anything that is taboo and illegal.</li> <li>• Youth are more attracted to these products due to peer use than flavors.</li> <li>• Youth use ENDS products for nicotine delivery not for flavors.</li> <li>• Only a correlative, not causal, relationship between youth preference for flavors and increased ENDS usage.</li> </ul>	<p>As discussed in the Final Guidance, data from 2018 NYTS as well as from 2019 Monitoring the Future study and 2019 NYTS show a significant increase in youth use of these products. Data also clearly show that flavors are a primary driver in youth experimentation with, and continued use of, ENDS products, and that the flavored ENDS products overwhelmingly used by youth are cartridge-based products. The policy outlined in the Final Guidance prioritizes enforcement of ENDS products that are targeted to minors or likely to promote use of ENDS by minors. FDA expects that this policy and others stated in the guidance will make fewer products available and more difficult for youth to obtain.</p>
<p>No basis for excluding tobacco, mint, and menthol from prioritization.</p> <ul style="list-style-type: none"> <li>• General increasing popularity of mint and menthol ENDS products amongst youth populations.</li> <li>• Mint- and menthol-flavored products drive youth ENDS usage.</li> <li>• Flavors clearly increase appeal of ENDS products and some flavors have toxic effects and documented respiratory toxicity.</li> </ul>	<p>The Final Guidance explains that FDA intends to prioritize mint-flavored, cartridge-based ENDS products (and any other flavored, cartridge-based ENDS product, other than tobacco- or menthol-flavored ENDS products) for enforcement for lack of a marketing authorization. The guidance also explains that FDA intends to prioritize enforcement for lack of a marketing authorization for any tobacco- or menthol-flavored ENDS products and non-cartridge-based flavored ENDS products when the manufacturer is not taking adequate measures to prevent minors’ access to these products. Data shows that tobacco- and menthol-flavored ENDS products are not as appealing to minors as other flavored ENDS products. While the NYTS groups mint- and menthol-flavored products together, a randomly-selected third of respondents to the Monitoring the Future (MTF) study were asked specifically about their preferred flavors of JUUL and reported use of menthol- and tobacco-flavored products were among the lowest ranked options. Based on the available data and FDA’s interest in balancing between preventing youth usage and preserving options for adults trying to transition away from</p>

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	<p>combustible products, FDA is not prioritizing enforcement against tobacco-, menthol-, and non-flavored ENDS products or non-cartridge-based flavored ENDS products except when the manufacturer is not taking adequate measures to prevent minors' access to these products.</p>
<p>Prioritizing flavors for enforcement will create a significant black market for “banned” flavors outside those that are exempted.</p>	<p>By black market flavored products, we assume this could refer to, for example, flavored ENDS products, including e-liquids, put on the market after the guidance, flavored ENDS products diverted from another country's market to the U.S market, and/or flavored ENDS products made to look like another ENDS product that is currently being marketed. FDA has regulatory tools and enforcement authorities to address deemed tobacco products that are marketed without authorization, counterfeit, and/or otherwise involved in illicit trade. <i>See, e.g.</i>, sections 301, 902, 903, 905, 910, and 920 of the FD&amp;C Act.</p> <p>This Final Guidance describes the Agency's enforcement priorities for products that are on the market without the required premarket authorization—it does not ban any tobacco product—and illicit ENDS products are necessarily subject to the enforcement priorities identified in the guidance as they do not have premarket authorization. Thus, FDA believes that this policy will not significantly increase illicit practices or create new illicit markets, and it could help FDA better address such practices. Once products receive premarket authorization, they can legally enter the market.</p> <p>FDA believes that there are significant public health benefits of the policy set forth in the guidance, which is aimed at curbing the dramatic rise in youth use of ENDS products and will help address safety issues connected to ENDS products that are not fully understood—<i>e.g.</i>, lung injuries associated with use of vaping products as well as battery explosions with ENDS products—particularly given that these products have been marketed without premarket evaluation. These current public health issues affirm the importance of the premarket review process, as contemplated</p>



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	<p>by the Tobacco Control Act, to scientifically evaluate products based on a public health standard. FDA believes that by pursuing this policy the Agency will be better able to monitor and identify illicit cartridge-based products that are threats to public health and safety. As flavored, cartridge-based products exit the market until they are able to demonstrate that they meet the applicable public health standard and receive authorization, the number of potential flavored, cartridge-based products that could cause these threats will shrink to a more manageable number for FDA to monitor. Thus, FDA expects that to the extent any illicit markets were to develop with respect to cartridge-based products in an attempt to evade premarket review requirements, this guidance will help FDA better address the public health threats caused by such markets and the overall public health benefits that will likely accrue as a result of the guidance will be greater than any negative effects of increased illicit markets. Moreover, FDA does not believe that the Agency should refrain from enforcing existing statutory authorities merely because regulated entities could find other ways to violate such authorities. The Agency can, and will, continue to monitor the marketing and use of ENDS and other tobacco products, and adjust its policies and approaches as warranted.</p>
<p>Many other harmful products (<i>e.g.</i>, alcohol) are available in various flavors attractive to youth; it is inconsistent to only prioritize for enforcement flavored ENDS products.</p>	<p>The policy expressed in this Final Guidance is limited solely to tobacco products over which FDA has statutory authority. The focus of this guidance and the Agency’s enforcement priorities is tobacco products, specifically certain ENDS products. Moreover, this comment is about flavored alcohol products that are lawfully on the market, whereas this guidance concerns products being sold in violation of the requirement to have premarket authorization, where the product’s ingredients and additives are among the considerations in the premarket review.</p>
<p>FDA should focus its enforcement priorities on products that contain nicotine salts and/or should specify differences between nicotine and nicotine salts.</p>	<p>FDA believes that ENDS products containing nicotine salts will be adequately addressed by the enforcement priorities set in this Final Guidance.</p>

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	<p>Research is ongoing to better understand the abuse liability associated with nicotine-salt based e-liquids and new cartridge-style ENDS products, the potential for initiation in youth and nonusers, and the potential for switching from combusted cigarettes in current smokers from use of these products. Preliminary research indicates that nicotine salts in ENDS products can drive nicotine exposures in users higher than ENDS containing freebase nicotine; these exposures can also be comparable to or potentially higher than cigarettes.<sup>104</sup> In addition to greater nicotine exposures, ENDS with nicotine salts can have faster absorption<sup>105</sup> and potentially faster elimination from the blood.<sup>106</sup> These factors can increase the abuse liability of ENDS with nicotine salts compared to freebase nicotine, and potentially cigarettes.</p> <p>The higher abuse liability of ENDS with nicotine salts compared to freebase nicotine raises concerns of addiction in youth, particularly due to the vulnerability of the developing adolescent brain. However, for many individual addicted cigarette smokers, the potential for ENDS to act as a substitute for cigarettes, thereby encouraging smokers to seek to switch completely away from combustible cigarettes, may be dependent, in part, upon the product having acceptability and abuse liability more comparable to a cigarette.</p> <p>The Final Guidance focuses FDA’s priorities on flavored, cartridge-based ENDS products because</p>
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<sup>104</sup> Goniewicz, M. L., R. Boykan, C.R. Messina, et al., “High exposure to nicotine among adolescents who use Juul and other vape pod systems (‘pods’),” *Tobacco Control*, 28(6), 2019; doi:10.1136/tobaccocontrol-2018-054565; Talih, S., R. Salman, R. El-Hage, et al., “Characteristics and toxicant emissions of JUUL electronic cigarettes,” *Tobacco Control*, 28(6):678-680, 2019; doi:10.1136/tobaccocontrol-2018-054616; Teichert, A., P. Brossard, L.F. Medlin, et al., “Evaluation of Nicotine Pharmacokinetics and Subjective Effects following Use of a Novel Nicotine Delivery System,” *Nicotine Tobacco Research*, 20(4):458-465, 458-465; doi:10.1093/ntr/ntx093.

<sup>105</sup> O’Connell, G., J.D. Pritchard, C. Prue, et al., “A randomised, open-label, cross-over clinical study to evaluate the pharmacokinetic profiles of cigarettes and e-cigarettes with nicotine salt formulations in US adult smokers,” *Internal and Emergency Medicine*, 14:853-861, 2019; doi:10.1007/s11739-019-02025-3.

<sup>106</sup> Bowen, A., & C. Xing, “Nicotine Salt Formulations for Aerosol Devices and Methods Thereof,” United States Patent, Pub. No. US 2015/0020824, 2015, <https://patentimages.storage.googleapis.com/57/f8/7e/2db69f396801d5/US20150020824A1.pdf> (visited Oct 8 2019).

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	<p>data show that flavors are a strong driver for youth use, and that youth overwhelmingly prefer cartridge-based ENDS products. However, FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data, including any data on ENDS products containing nicotine salts, and it will continue to do so with respect to these products.</p>
<p>FDA should focus its enforcement priorities on cartridge-based ENDS products.</p>	<p>FDA is concerned about the rising youth appeal and use of ENDS products. The data show that flavors are a strong driver for youth use, and that youth overwhelmingly use cartridge-based ENDS products. Accordingly, such products are a key focus of the Final Guidance. FDA will, however, take appropriate action regarding ENDS that are marketed without premarket authorization, including as warranted based on changed circumstances, new information, or to better address minors' use of those products.</p>
<p><b>Modifications to ENDS Compliance Policy – Offered for sale in ways that pose a greater risk for minors to access such products</b></p>	
<p>Comment</p>	<p>Response</p>
<p>The Tobacco Control Act prohibits FDA from restricting tobacco sales to a specific category of retail outlets.</p>	<p>FDA is not restricting or even prioritizing enforcement against ENDS products sold in a specific category of retail outlets. Although the March 2019 Draft Guidance proposed to focus its enforcement priorities for flavored ENDS products on how the product was sold (regardless of the type of retail establishment), after considering the comments, the public health threats, and new evidence, FDA determined that focusing on how the product was sold would not be sufficient to address youth use of these products. Given the urgent need to address the dramatic rise in youth use, this Final Guidance prioritizes enforcement with respect to any flavored, cartridge-based ENDS products (other than a tobacco- and menthol-flavored ENDS product) without regard to the location or method of sale.</p> <p>With respect to tobacco-, menthol-, and non-flavored ENDS products as well as flavored cartridge-based ENDS products, the Final Guidance states that FDA does not intend to prioritize enforcement where manufacturers have</p>

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	<p>taken adequate measures to prevent youth access. These types of measures generally are among those that manufacturers have informed FDA that they are capable of implementing for ENDS products and none involve a specific category of retail outlet.</p>
<p>Lack of clarity for retail locations</p> <ul style="list-style-type: none"> <li>• Should retail locations have age verification at their door or a separate room for the sale of any ENDS products?</li> <li>• Can retail locations employ less burdensome alternatives?</li> <li>• Concern that the policy could make traditional cigarette products more easily accessible than ENDS products.</li> <li>• Need clarity on how manufacturers or wholesalers can document adequate measures to prevent youth access.</li> <li>• How are retail outlets supposed to balance space constraints with youth access concerns?</li> <li>• FDA should give existing enforcement mechanisms the chance to succeed or focus on enforcing existing mechanisms before instituting new policy.</li> </ul>	<p>FDA has provided additional details regarding factors that it intends to consider in assessing whether a manufacturer is taking adequate measures to prevent youth access. For example, the Final Guidance lists several different types of programs to monitor compliance with age-verification and sales restrictions, all of which are programs that some manufacturers have stated they are capable of implementing for ENDS products. Unlike the Draft Guidance, it does not include, as a factor for prioritization, whether the product is sold by retailers in a location where minors are able to enter at any time.</p> <p>The March 2019 Draft Guidance proposed to focus its enforcement priorities of flavored ENDS products on how the product was sold (regardless of the type of retail establishment). After considering the comments, the public health threats, and new evidence, FDA determined that, to address youth use of these products, this Final Guidance should prioritize enforcement with respect to any flavored, cartridge-based ENDS products (other than a tobacco- and menthol-flavored ENDS product) without regard to the location or method of sale. The alarming data on the increase in youth use of ENDS products shows that the FDA’s enforcement efforts to date did not adequately address this problem.</p>
<p>Enforcement priorities would effectively ban many retailers from selling ENDS products while allowing sales from vape shops and online retailers.</p> <ul style="list-style-type: none"> <li>• Concerns that many retailers will be forced to close.</li> <li>• Concerns that this will just cause retailers to shift unauthorized products to vape shops and other stores.</li> </ul>	<p>This Final Guidance prioritizes enforcement with respect to any flavored, cartridge-based ENDS products (other than a tobacco- and menthol-flavored product) without regard to the location or method of sale.</p> <p>In addition, the Final Guidance explains that FDA intends to prioritize enforcement for lack of a marketing authorization for tobacco-, menthol-, and non-flavored ENDS products and for non-</p>

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<ul style="list-style-type: none"> <li>Concerns about the rise in youth use of open tank systems and sourcing of e-vapor products at vape shops, as indicated by an analysis of Wave 2 (2014-2015) to Wave 3 (2015-2016) of results from the PATH study.</li> </ul>	<p>cartridge-based flavored ENDS products where the manufacturer is not taking adequate measures to prevent youth access to ENDS products. For example, the Final Guidance lists several different types of programs to foster compliance with age-verification and sales restrictions, all of which are programs that some manufacturers have stated they are capable of implementing for ENDS products.</p> <p>Finally, FDA notes that there has been a dramatic rise in youth use of cartridge-based ENDS products since Wave 3 of the PATH study was completed in 2016, as demonstrated by results from the NYTS in 2018 and 2019. These recent data inform FDA’s serious public health concerns regarding the sale of certain flavored, cartridge-based products without premarket authorization. Moreover, although this Final Guidance should have minimal impact on those vape shops that primarily sell non-cartridge ENDS products and ensure that purchasers are of the requisite age and are not purchasing for resale (<i>e.g.</i>, are not purchasing in large quantities), should evidence indicate to the contrary, the Agency will take appropriate action.</p>
<p>Stricter enforcement of current age verifications rules would be an effective enforcement strategy.</p> <ul style="list-style-type: none"> <li>Lax enforcement is a primary driver of youth ENDS use.</li> <li>FDA should increase penalties to retailers who violate current regulations and sell to minors.</li> <li>Age verification should be as strong as it is for alcohol.</li> <li>There is a need for stricter age verification for online sales of ENDS products.</li> </ul>	<p>As described in the Final Guidance, FDA vigorously enforces the age verification requirements in its compliance check program. FDA has been focusing enforcement efforts on age verification as a strategy to address youth use of tobacco products, and FDA continues to enforce age restrictions. However, FDA believes that age verification alone is not sufficient to address this issue, given the most recent data that youth use of ENDS products continues to increase. FDA determined that focusing on how the product was sold would not be sufficient to address youth use of these products given the many sources of products available for youth access. The reality is that youth have continued access to ENDS products in the face of legal prohibitions and even after voluntary actions by some manufacturers. FDA believes that the policy expressed in the</p>

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	<p>Final Guidance is a more appropriate means to combat youth use of, and access to, these products.</p>
<p>Many companies already comply with age verification requirements.</p> <ul style="list-style-type: none"> <li>• Policies that encourage additional measures would harm law-abiding retailers.</li> </ul>	<p>The Final Guidance does not require additional age verification measures. Instead, it states that FDA intends to prioritize enforcement for lack of a marketing authorization for tobacco-, menthol-, and non-flavored ENDS products as well as non-cartridge-based flavored ENDS products where the manufacturer is not taking adequate measures to prevent youth access to ENDS products.</p>
<p>Online sales of ENDS products should be banned.</p>	<p>This suggested sales restriction is outside of the scope of this guidance, which concerns enforcement of the premarket authorization requirements.</p> <p>At this time, FDA is finalizing this Guidance to address its concerns regarding youth use of ENDS products. The guidance prioritizes enforcement with respect to flavored, cartridge-based ENDS products because data shows that flavors are the primary driver in youth experimentation with, and continued use of, ENDS products, and that youth overwhelmingly use cartridge-based ENDS products. These priorities apply whether the products are sold online or in brick-and-mortar stores. However, the Agency will continue to monitor this issue.</p>
<p>Lack of clarity on what quantity limits for online sales would entail.</p>	<p>Given the data that many youth obtain their ENDS products from friends or sources in their social networks, FDA believes that quantity limits are one measure that a manufacturer could adopt to prevent individuals from purchasing large quantities of ENDS products to then distribute to minors on a secondary market. FDA’s enforcement decisions will be made on a case-by-case basis and depend on many factors, but FDA intends to consider whether a manufacturer limits the quantity of ENDS products that a customer may purchase within a given period of time as a factor in assessing whether a manufacturer is taking adequate measures to prevent youth access. There is wide variation in these types of ENDS products and, based on some of the comments FDA received and the responses to the Agency’s</p>

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	<p>September 12, 2018 letters, FDA believes individual manufacturers are best positioned to know how to set purchase limits for their specific products. Therefore, FDA does not believe that further detail is warranted regarding this issue.</p>
<p>Age to purchase ENDS products should be increased to 21.</p>	<p>On December 20, 2019, the President signed into law legislation that raised the federal minimum age of sale of tobacco products from 18 to 21 years. FDA views this as a major step in protecting the next generation of youth from becoming addicted to ENDS and other tobacco products. FDA believes, however, that this change alone is not sufficient to address the epidemic use of ENDS by youth, especially use of flavored, cartridge-based products (except for tobacco- or menthol-flavored products) that are easily concealed, produced on a large scale, and (in some cases) sold in bulk quantities that has helped enable resale through social or black market sources. As part of the premarket review process for these products, FDA intends to consider measures taken by manufacturers to control youth access to these products.</p>
<p>Purchasing from other adolescents is a major factor driving ENDS usage in youth populations.</p> <ul style="list-style-type: none"> <li>• FDA should increase penalties for individuals who provide products to youth.</li> <li>• This type of behavior should be the responsibility of parents, not the government.</li> <li>• Only specialty vape stores should be permitted to sell ENDS.</li> <li>• Data from CDC’s 2017 Youth Risk Behavior Surveillance System (YRBSS) found that 86.4% of youth who used ENDS did not purchase them at a retail store.</li> <li>• Youth will find ways to purchase restricted flavored products and increased regulations will be ineffective.</li> </ul>	<p>FDA agrees that social sources remain a concern for ENDS and other tobacco products. Given the popularity of social sources, FDA believes that quantity limits could be effective in preventing individuals from purchasing large quantities of ENDS products to then distribute to minors on a secondary market. Accordingly, FDA intends to consider whether a manufacturer limits the quantity of ENDS products that a customer may purchase within a given period of time as a factor in assessing whether a manufacturer is taking adequate measures to prevent youth access.</p>

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<p>Limits on retail or online sales would remove two of the top purchase options for adult ENDS product users.</p>	<p>The priorities in the Final Guidance are addressed to particular products, not retailers. FDA believes that the Final Guidance strikes an appropriate balance between preventing youth access to ENDS products and maintaining availability of potentially less harmful options for current adult smokers who have transitioned or wish to transition completely away from combusted tobacco products. FDA would consider measures taken by manufacturers to control youth access, not adult access, when determining whether to enforce the premarket authorities with respect to these products.</p>
<p>Does not provide adequate reasoning or specificity for manufacturers to understand what marketing actions would prompt enforcement actions.</p>	<p>FDA’s decision to exercise its enforcement authorities with respect to particular products will be determined on a case-by-case basis, informed by the enforcement priorities described in this Final Guidance and any other relevant factors. The Final Guidance provides a number of examples of measures manufactures can take to help prevent youth access to their tobacco products. Such examples reflect information provided by manufacturers in response to the Agency’s September 12, 2018 letters, including measures to address youth use that manufacturers can or have already taken to address youth access to ENDS products, as well as information provided in comments to the March 2019 Draft Guidance.</p>
<p><b>Modifications to ENDS Compliance Policy – flavored ENDS offered for sale after August 8, 2021, without the manufacturer submitting (and FDA receiving) a premarket application</b></p>	
<p>Comment</p>	<p>Response</p>
<p>Moving up the compliance review date would be harmful.</p> <ul style="list-style-type: none"> <li>• Has the potential to impact adults using ENDS products for smoking cessation purposes.</li> <li>• Will harm businesses that have already planned for the initial date.</li> <li>• Will exacerbate an already burdensome premarket review process.</li> <li>• Will be difficult for small businesses to submit complete applications by August 8, 2021.</li> </ul>	<p>The Tobacco Control Act provides that new tobacco products may not be legally marketed without premarket authorization. Accordingly, all deemed new tobacco products on the market without authorization are illegally marketed products. As discussed in the Final Guidance, industry had notice that FDA would revisit its compliance policy if necessary. The Final Guidance announces that FDA intends to prioritize for enforcement ENDS products for which a premarket application has not been submitted by May 12, 2020. FDA understands the concerns expressed by these commenters but believes that it</p>



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	<p>is appropriate for ENDS products to undergo premarket review on a shorter timeframe given the rise in youth use, in addition to other new and continuing public health and safety concerns, such as the outbreak of pulmonary injuries and battery hazards.</p>
<p>Leaving products on the market for this long is problematic.</p> <ul style="list-style-type: none"> <li>• Date is still too far away and will allow harmful products to remain on the market.</li> <li>• Deadline means longer time for products on the market to continue to make unsubstantiated claims without scientific review.</li> <li>• Leaving products on the market is problematic due to lack of evidence justifying later premarket review.</li> </ul>	<p>FDA agrees with these commenters that the proposed August 8, 2021, date would allow products that may be harmful to remain on the market too long, would allow products to market unsubstantiated claims without scientific review, and that the data before the agency does not justify later premarket review. The Final Guidance discusses the date for premarket application submission and the importance of earlier submission of applications to allow for FDA to better evaluate whether these products meet applicable premarket standards, such as whether the products are appropriate for the protection of the public health, considering the risks and benefits to the population as a whole, including users and nonusers of the tobacco product.</p>
<p>Lack of clarity around date for submission of premarket review applications</p> <ul style="list-style-type: none"> <li>• FDA should articulate the status of submitted premarket applications and provide manufacturers opportunity to amend applications in light of changing deadlines.</li> <li>• Still unclear what information must be included in a PMTA and/or SE report</li> </ul>	<p>The Final Guidance discusses dates for submission of applications for premarket review and provides links to application submission information, including where to view marketing orders and accompanying documentation, available at FDA.gov. FDA has provided guidance and information to industry on the premarket pathways through publishing guidances and marketing orders, as well as posting information via webinars and public workshops.<sup>107</sup></p>

<sup>107</sup> For more information on premarket tobacco product applications please see Premarket Tobacco Product Applications for [ENDS], Guidance for Industry (June 2019), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends>; Applications for Premarket Review of New Tobacco Products (updated June 2019) available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-premarket-review-new-tobacco-products>. For more information on CTP’s other published regulations and guidances, please see <https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance>; for more information on FDA CTP webinars, please see <https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars>; for information on marketing orders and accompanying documentation, please see <https://www.fda.gov/tobacco-products/compliance-enforcement-training>.

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<b>Modifications to ENDS Compliance Policy – targeted to minors or likely to promote use of ENDS product by minors</b>	
Comment	Response
<p>FDA should use its authority to require ENDS manufacturers to stop running ads with unsubstantiated claims about smoking cessation and modified risk claims.</p>	<p>This is outside of the scope of the Final ENDS guidance, which addresses premarket review requirements for ENDS products. FDA closely monitors retailer, manufacturer, importer, and distributor compliance with Federal tobacco laws and regulations and takes corrective action when violations occur. When enforcing FDA’s tobacco product authorities, the Agency generally issues a warning letter the first time a compliance check reveals a violation of federal tobacco laws and regulations, including when a manufacturer sells or distributes a product as a modified risk tobacco product without an FDA order in effect. Failure to promptly and adequately correct all violations and ensure compliance with all applicable laws and regulations may lead to enforcement actions, including civil money penalties, seizure, and/or injunction. To the extent that manufacturers are marketing their products for therapeutic purposes, they are subject to FDA’s medical product authorities.</p>
<p>Lack of clarity – it is unclear what ENDS products manufacturers (and other parties that engage in ENDS marketing activities) and retailers can do to avoid concerning marketing activities.</p> <ul style="list-style-type: none"> <li>• Would like to know what specific steps they can take to ensure their marketing reaches adults rather than minors.</li> <li>• Need clarity on what the agency considers targeting or promoting to minors.</li> </ul>	<p>FDA believes the level of detail and examples in the Final Guidance provide sufficient clarity.</p>
<p>FDA should ensure social media platforms are not used as advertising platforms for ENDS products, including monitoring videos that promote ENDS products and limiting the reach of social media influencers who promote products.</p>	<p>To the extent this comment is about the advertising of ENDS products generally, it is outside the scope of the policy. To the extent this comment is about advertising of ENDS products that are targeted to minors or likely to promote use of ENDS by minors, FDA believes the Final Guidance addresses this by indicating that such products will be an enforcement priority.</p>

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<p>A number of ENDS products are designed to be small and discreet, thus promoting ENDS use in minors.</p>	<p>The Final Guidance discusses the Agency’s intent to prioritize its enforcement for products that are targeted to minors or likely to promote use of ENDS by minors. One example of such products includes products marketed directly to minors by promoting ease of concealment.</p>
<p>FDA should support stakeholder partnerships to develop common approach and standards in preventing youth access.</p>	<p>FDA CTP’s Office of Stakeholder Relations regularly connects with stakeholders. Stakeholders also have access to the ombudsman as well.</p>
<p><b>Flavored Cigars</b></p>	
<p>Comment</p>	<p>Response</p>
<p>Enforcing the premarket requirements against flavored cigars would limit adults’ freedom to choose their preferred products.</p>	<p>The Final Guidance does not include a policy to prioritize flavored cigars for enforcement. Instead, as described in the Final Guidance, flavored cigars are treated like all other deemed products that are not ENDS. Flavored cigars may seek premarket authorization from FDA. Manufacturers of flavored cigars, and of other deemed new tobacco products, will be required to submit marketing applications for those products by May 12, 2020, consistent with the U.S. District Court for the District of Maryland’s order, as described in the Guidance.</p>
<p>Eliminating flavored cigars would result in the creation of a black market.</p>	<p>The Final Guidance does not include a policy to prioritize flavored cigars for enforcement. In addition, we do not think development of a black market is likely given that there are a number of “grandfathered” flavored cigars that are lawfully marketed and would remain available to consumers regardless of FDA’s enforcement of premarket authorities.</p>
<p>FDA’s assertion of product migration of youth is an unfounded hypothesis.</p> <ul style="list-style-type: none"> <li>• Concerns that FDA mischaracterizes research and does not cite contrary government findings (citing to CDC reports and PATH data)</li> <li>• FDA’s data on this topic limited to two studies that only recently became available and has not been vetted</li> <li>• There are limitations to the Wave 1-3 PATH data that FDA cites in support</li> </ul>	<p>The Final Guidance does not include a policy to prioritize flavored cigars for enforcement.</p>

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<ul style="list-style-type: none"> <li>• FDA relies on 2018 NYTS data and incorrectly speculates that youth could migrate to flavored cigars</li> <li>• CDC MMWR data and PATH data contradict suggestions that youth usage of cigars is on the rise</li> <li>• Data show decreasing importance of flavors to first time cigar users</li> </ul>	
<p>Only allowing 30 days after guidance is finalized would result in a de facto ban on flavored cigars.</p> <ul style="list-style-type: none"> <li>• Not enough time for manufacturers to submit SE reports.</li> <li>• May not be enough time for retailers to sell off inventory/FDA should include an additional sell off period of time to the compliance guidance.</li> <li>• Should be able to remain on the market until FDA has reviewed and made a determination on the premarket review application.</li> </ul>	<p>The Final Guidance does not include a policy to prioritize flavored cigars for enforcement. In addition, we note that there are a number of “grandfathered” flavored cigars that are lawfully marketed that would remain available to consumers regardless of FDA’s enforcement of premarket authorities.</p>
<p>Guidance should address grandfathered flavored cigar products as well.</p>	<p>The Draft and Final Guidance are about enforcement against products that lack required premarket authorization. Grandfathered tobacco products, which do not require premarket authorization, are outside the scope of the policy.</p>
<p>Lack of clarity</p> <ul style="list-style-type: none"> <li>• Lack of a definition of flavored cigars will lead to confusion and leave retailers misinformed about what constitutes a flavored cigar.</li> <li>• Lack of definition of characterizing flavor.</li> </ul>	<p>The Final Guidance no longer discusses prioritizing enforcement for flavored cigars.</p>
<p>FDA should pursue the flavored cigar enforcement policy addressed in the Draft Guidance.</p>	<p>At this time, FDA has decided to focus this Final Guidance on ENDS products, given the recent surge in youth use and additional considerations such as battery explosions and vaping-related illnesses. Nevertheless, FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data. FDA will take appropriate action regarding tobacco products that are marketed without premarket authorization, including cigars, in accordance with the court’s order in <i>American</i></p>

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	<i>Academy of Pediatrics</i> . FDA also has stated its intention to issue a flavored cigar rule.
<b>Compliance Policy for Other Deemed Products</b>	
Comment	Response
FDA should modify compliance policy for other deemed products. <ul style="list-style-type: none"> <li>• Data on waterpipe tobacco use demonstrates increase in youth use.</li> </ul>	As discussed in the Final Guidance, consistent with the U.S. District Court for the District of Maryland’s order, FDA intends to enforce premarket requirements for these products after May 12, 2020.
FDA should not modify compliance policy for other deemed products.	As discussed in the Final Guidance, consistent with the U.S. District Court for the District of Maryland’s order, FDA intends to enforce premarket requirements for these products after May 12, 2020.
FDA should focus its efforts on menthol cigarettes.	The Final Guidance describes FDA’s policy on enforcing premarket requirements for products subject to the deeming rule. Menthol cigarettes are outside the scope of this policy.