

Modifications to Compliance Policy for Certain Deemed Tobacco Products

Guidance for Industry

DRAFT GUIDANCE

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**U.S. Department of Health and Human Services
Food and Drug Administration
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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 discusses changes to the compliance policies for premarket review requirements for certain deemed tobacco products and 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.

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.

¹ 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.

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II. BACKGROUND

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 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).

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, and other tobacco products that may be developed in the future (81 FR 28974 at 28976 (May 10, 2016)).

Chapter IX of the FD&C Act, including sections 905 (annual registration) and 910 (premarket review requirements), now applies to deemed products. Among other requirements, and as particularly relevant to this draft guidance, these statutory provisions and implementing regulations prohibit sales of tobacco products to minors and impose 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. The preamble to the May 10, 2016, final deeming rule explained that FDA did not intend to initiate 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.²

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.

² 81 FR at 29011.

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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 a matter of enforcement discretion, stated its intention not to begin 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 strike an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes, the Agency announced that it would be providing targeted relief on some timelines described in the preamble to the final deeming rule. The comprehensive plan was announced, in part, to afford the Agency time to explore clear and meaningful measures outside of premarket review to make tobacco products less toxic, appealing, and addictive.

The Agency's July 2017 announcement also indicated that extended compliance periods would allow time for FDA to set out additional rules and guidances and for industry to develop higher quality applications. We are continuing to pursue such regulations and guidances; however, the recent surge in youth use of ENDS products has caused us to reevaluate our priorities and modify the compliance policy for certain products, as set forth in this guidance. With respect to flavored cigars affected by this revised compliance policy, we note that any tobacco product, including cigars, may utilize the appropriate pathway to market, including the SE pathway or an exemption from SE. Manufacturers may obtain information about the application process from the detailed statutory criteria, as well as published guidances, webinars, and the marketing orders and their accompanying documentation provided by FDA.

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"). This revised policy stated that the compliance dates for submitting EX REQs, SE Reports, and PMTAs for newly regulated combustible tobacco products (such as most cigars) would be extended to August 8, 2021, and the compliance dates for submitting EX REQs, SE Reports, and PMTAs for newly regulated noncombustible tobacco products (such as most ENDS products) would be extended to 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. Under this revised compliance policy, FDA established a continued compliance period pending review of those applications. 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 Refuse to Accept) or the application was withdrawn.

However, 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 suggested an alarming increase in the use of ENDS products by middle and high school students. In April 2018, FDA

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conducted a nationwide undercover enforcement effort that resulted in FDA issuing 56 warning letters 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 popular with 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 foreclose 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 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. As a result of the warning letters, all of the firms have stopped selling the violative products.

On September 12, 2018, FDA announced a series of critical actions related to the sale and marketing of ENDS products to minors, 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.

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. FDA also stated 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 this policy with respect to certain flavored products that may be contributing to the rise in youth use and having such products come off the market until they receive premarket authorization and otherwise meet all of their obligations under the law.

In response to the September 12th letters to industry, some manufacturers described safeguards that may help to restrict minors' access to ENDS products sold online. Some of the safeguards described by manufacturers, as well as other measures that have been considered or adopted to address minors' access, include:

- Using independent, third-party age- and identity-verification services that compare customer information against third-party data sources, such as public records;
- Limiting the quantity of ENDS products that a customer may purchase within a given period of time.

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Since September 2018, the Agency has repeatedly publicly discussed³ the fact that these compliance timelines were under reconsideration and has solicited the view of stakeholders—including manufacturers—at many steps along the way. During that period, FDA has continued to receive information underscoring the problem of youth use of ENDS. Data from the 2018 National Youth Tobacco Survey (NYTS), as described throughout this guidance, has documented a significant increase in youth use of ENDS products and revealed the magnitude of the problem. These data have prompted FDA to revise its compliance policies with respect to 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. FDA’s revised compliance policy is informed, in part, by the information received from industry, including information the companies shared during meetings each had with FDA leadership. It is also informed by FDA’s understanding that manufacturers have the means to control the distribution and sale of their products to retail customers 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.

In issuing this Guidance, FDA intends to communicate its enforcement priorities so that the public will understand the Agency’s most pressing public health concerns regarding these products and manufacturers will be prompted to move up their filing of premarket submission for certain deemed tobacco 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 Guidance.

III. DEFINITIONS

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

Cigar means a tobacco product that: (1) is not a cigarette; and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco. 21 C.F.R. 1143.1. This includes all types of cigars including little cigars, cigarillos, and other types of cigars.

Component or *Part* means any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product. 21 C.F.R. 1100.3, 1143.1. The following is a nonexhaustive list of examples of components or parts of ENDS (including e-cigarettes): e-liquids; atomizers; cartomizers (atomizer plus replaceable e-liquid-filled cartridge or pod); clearomizers; tank systems; flavors; and bottles that contain e-liquids.

³ 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 <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>; Scudder, L., “Vaping and E-Cigarettes in Kids: An Unprecedented Epidemic,” Medscape, January 28, 2019, <https://www.medscape.com/viewarticle/908077?faf=1>.

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ENDS refers to electronic nicotine delivery systems and includes 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 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.

Minors refers to individuals under the age of 18.

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. CHANGES TO COMPLIANCE POLICY REGARDING CERTAIN ENDS PRODUCTS

At the time FDA issued the August 2017 Compliance Policy to modify the enforcement discretion policies regarding premarket authorization (included in the preamble to the final deeming rule), data from the NYTS showed a modest decrease in prevalence of current e-cigarette use (i.e., past 30-day use) among high school students, from 13.4 percent in 2014 to

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11.7 percent in 2017.⁴ However, recent data show a significant increase in minors' use of ENDS products, particularly in the past year.⁵ For example, data from the NYTS show that, between 2017 and 2018, current e-cigarette use among high school students increased 78 percent (11.7 percent to 20.8 percent, $p < 0.05$).⁶ These data represent an increase of an estimated 1.32 million high school students reporting past 30-day e-cigarette use in one year. Current e-cigarette use among middle school students also increased by 48 percent over the same time period (3.3 percent to 4.9 percent, $p < 0.05$), an increase of an estimated 180,000 middle school students reporting past 30-day e-cigarette use in one year.⁷ Data from the Monitoring the Future study found similar trends from 2017 to 2018, with current (past 30-day) e-cigarette use increasing from 6.6 percent to 10.4 percent among 8th graders, 13.1 percent to 21.7 percent among 10th graders, and 16.6 percent to 26.7 percent among 12th graders.⁸ For each age group, the increase from 2017 to 2018 was statistically significant ($p < .001$).⁹ During this time period, between 2017 and 2018, the rate of combustible product use among youth remained flat.¹⁰

Recent surveys also provide insight into the increase in the proportion of minors who report using ENDS products frequently. For example, data from the NYTS show 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 2018.¹¹ At the

⁴ 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*, 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."

⁵ *Id.* The statistically significant change from 2017 to 2018 in prevalence of current e-cigarette use in youth cannot be the result of changes in survey methodology. The questions that have been used in NYTS to collect information about ever use and current use of e-cigarettes has been consistent over time. From 2015 to 2018 information about ever and current use of e-cigarettes was collected using the following questions, "Have you ever used an e-cigarette, even once or twice?" and "During the past 30 days, on how many days did you use e-cigarettes?" In 2014, the same core questions were asked, except that they included the name of several e-cigarette brands as well: "Have you ever tried an electronic cigarette or e-cigarette, such as Blu, 21st Century Smoke or NJOY?" and "During the past 30 days, on how many days did you use electronic cigarettes or e-cigarettes such as Blu, 21st Century Smoke or NJOY?" The placement of e-cigarette questions in the survey, sampling methodology, and time of year that the survey was conducted have also remained consistent over time.

⁶ *Id.*

⁷ *Id.*

⁸ Miech, R.A., Schulenberg, J.E., Johnston, L.D., et al., "National Adolescent Drug Trends in 2018." Monitoring the Future: Ann Arbor, MI. Retrieved 01/10/19 from <http://www.monitoringthefuture.org>.

⁹ *Id.*

¹⁰ Gentzke A.S., Creamer M., Cullen K.A., et al., "Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018," *MMWR Morb Mortal Wkly Rep*, 68:157–164 (2019), DOI: <http://dx.doi.org/10.15585/mmwr.mm6806e1>.

¹¹ 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*

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same time, NYTS data also show that among high school students who are current users, frequent cigarette use in 2018 was lower than frequent ENDS use at 23.1 percent and that there was not an increase in frequent cigarette use between 2017-2018.¹² In a study that focused specifically on youth use of one brand of ENDS (i.e., JUUL), among 15-to-17-year-old current users of JUUL products, data collected from February to May 2018 indicate that 55.8 percent reported using such products on 3 or more of the previous 30 days, and over a quarter reported use on 10 to 30 days of the prior month.¹³

Evidence indicates that minors are attracted to flavored ENDS products. In the 2016-2017 (Wave 4) Population Assessment of Tobacco and Health (PATH) Study,¹⁴ among the 6.8 percent of youth age 12 to 17 who initiated use of an ENDS product since their last completed interview or who were new baseline respondents and reported ever ENDS use, 96.1 percent had used a flavored ENDS product the first time they tried the product.¹⁵ In addition, 97.0 percent of current youth ENDS users age 12 to 17 reported that they had used a flavored ENDS product in the past month.¹⁶ Data from Wave 4 also showed that 70.3 percent of current youth ENDS users said they used ENDS products “because they come in flavors I like.”¹⁷ Moreover, 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, $p < 0.05$).¹⁸ This evidence is consistent with earlier research indicating that flavors increase youth appeal of tobacco products.¹⁹

Weekly, 67(45);1276-1277 (2018).

¹² Gentzke A.S., Creamer M., Cullen K.A., et al., “Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018,” *MMWR Morb Mortal Wkly Rep*, 68:157–164 (2019), DOI: <http://dx.doi.org/10.15585/mmwr.mm6806e1>.

¹³ 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* 2018,0:1-7, doi: 10.1136/tobaccocontrol-2018-05463. JUUL is one brand of ENDS product, and it currently maintains the largest market share of the ENDS product market.

¹⁴ 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).

¹⁵ FDA Internal Analysis.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ 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*, 67(45);1276-1277 (2018).

¹⁹ 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., Ribisl, K.M., Brewer, N.T., “Adolescents’

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Recent evidence also indicates that mint- and menthol-flavored ENDS products are preferred more by adults over other flavors, but that other flavors are preferred by minors over mint and menthol flavors. For example, findings from the 2014-2015 (Wave 2) PATH Study indicated that mint- and menthol-flavored e-cigarettes ranked fourth among youth (age 12 to 17 years; 6.1 percent) and first among adults (25 years and older; 37.4 percent); these percentages were statistically significantly different.²⁰ These patterns have remained consistent as Wave 4 of the PATH Study found that, in a combined response option, mint- and menthol-flavored e-cigarettes ranked fourth among youth (age 12 to 17 years), third among young adults (age 18-24 years) and second among adults (age 25 years and older).²¹ These findings are bolstered by other independent studies. A study that compared several samples found that among youth aged 12-17 years, mint/menthol (24 percent) ranked fourth most popular, behind fruit (76 percent), candy/other sweets (57 percent), and other (46 percent) while it ranked third (34-45 percent) in two different samples of young adults (aged 18-29 years), and third (33 percent) in one sample of adults (aged 30+ years) and second (32 percent) in another.²²

A study of 396 adolescents from 5 high schools in Connecticut who reported past-month e-cigarette use completed a survey in 2014 that found that fruit flavors were, by far, the most commonly preferred flavors (52.3 percent preferred fruit while, 16.2 percent preferred candy/dessert, 11.4 percent preferred vanilla, 9.6 percent preferred menthol, 9.1 percent preferred mint, and 4.8 percent preferred tobacco).²³ This same study also surveyed a convenience sample of 590 adults who reported past-month e-cigarette use, and found that the most commonly preferred flavors were fruit (40.0 percent), tobacco flavor (32.0 percent), mint (27.6 percent), and menthol (27.6 percent).²⁴ While minors use mint and menthol ENDS products, it appears that they prefer them substantially less than adults prefer such flavors.

interest in trying flavoured ecigarettes,” *Tobacco Control*, 25:ii62-ii66 (2016).; Camenga, D. R., Morean, M., Kong, G., et al., “Appeal and use of customizable e-cigarette product features in adolescents,” *Tobacco Regulatory Science*, 4(2):51-60 (2018).; Harrell, M.B., Weaver, S.R., Loukas, A., et al., “Flavored e-cigarette use: characterizing youth, young adult, and adult users,” *Preventive Medicine Reports*, 5:33-40 (2017).

²⁰ Schneller, L.M., M. Bansal-Travers, M.L. Goniewicz, et al., “Use of flavored electronic cigarette refill liquids among adults and youth in the US—Results from Wave 2 of the Population Assessment of Tobacco and Health Study (2014-2015),” *PLoS ONE* 13(8): e0202744 (2018), available at: <https://doi.org/10.1371/journal.pone.0202744>.

²¹ FDA Internal Analysis.

²² Harrell, M. B., Weaver, S. R., Loukas, A., et al., “Flavored e-cigarette use: Characterizing youth, young adult, and adult users. *Preventive Medicine Reports*, 5, 33-40, (2017), doi: 10.1016/j.pmedr.2016.11.001

²³ Morean, M.E., E.R. Butler, K.W. Bold, et al., “Preferring more e-cigarette flavors is associated with e-cigarette use frequency among adolescents but not adults.” *PLoS ONE* 13(1): e0189015 (2018), available at: <https://doi.org/10.1371/journal.pone.0189015>.

²⁴ *Id.*

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Minors are accessing such products through brick-and-mortar retailers and through the internet. Existing evidence demonstrates that minors are able to purchase ENDS products in a variety of retail establishments, despite regulations prohibiting sale to individuals under 18 years of age (21 C.F.R. 1140.14(b)(1)).²⁵ Minors' access to these products was evidenced through FDA's undercover enforcement efforts with respect to brick-and-mortar and online stores over the summer of 2018, which resulted in the issuance of more than 1,300 warning letters and CMP complaints to retailers who illegally sold ENDS products to minors. Additionally, according to data from the 2018 NYTS, 14.8 percent of U.S. middle and high school e-cigarette users under 18 years of age reported obtaining e-cigarettes in the past 30 days from a vape shop or other store that sells e-cigarettes and 8.4 percent reported obtaining them from a gas station or convenience store.²⁶

Moreover, the recent increased demand for ENDS products has resulted in minors utilizing online retailers to obtain these products, despite age restrictions. Evidence from Wave 4 of the PATH Study revealed that 7.2 percent of youth (age 12 to 17) past 30-day ENDS product users (who have used ENDS products more than once in their lifetime) reported that they usually get their ENDS products from the Internet.²⁷ Likewise, a recent survey of 1,729 adolescents aged 15 to 17 found that, among adolescents who purchased their vaping device, 32.2 percent of them obtained the products online.²⁸ The 2018 NYTS data also revealed that 6.5 percent of U.S. middle and high school e-cigarette users under age 18 reported obtaining their e-cigarettes in the past 30-days on the Internet.²⁹ Internet sales are particularly concerning due to the lack of a direct, face-to-face exchange between a retailer and a consumer. Minors can easily access websites that offer ENDS products for sale or distribution,³⁰ and many online retailers do not use adequate methods to verify the age of the purchaser.

In light of the public health threat described above, FDA has reconsidered and, in its discretion, plans to modify its August 2017 Compliance Policy as to the premarket authorization requirements for certain ENDS products that were on the market on August 8, 2016, and replace it with a new policy as described below. A goal of this guidance is to encourage more prompt filing of premarket submissions for certain ENDS products. Through the premarket review process, FDA conducts a science-based evaluation to determine whether a new tobacco product

²⁵ Retailers must also follow state and local tobacco laws, even if they are more restrictive. For example, in some states the minimum legal sales age is 21.

²⁶ Liu, S.T., K. Snyder, M. Tynan, et al., "Access to Tobacco Products Among U.S. Middle and High School Students, 2016-2018," [manuscript in progress].

²⁷ FDA Internal Analysis.

²⁸ Pepper, J.K., E.M. Coats, J.M. Nonnemaker, et al., "How Do Adolescents Get Their E-Cigarettes and Other Electronic Vaping Devices?" *American Journal of Health Promotion*, 2018 Aug. 1:890117118790366, doi: 10.1177/08901171190366. [Epub ahead of print]

²⁹ Liu, S.T., Snyder, K., Tynan, M., et al., "Access to Tobacco Products among U.S. Middle and High School Students, 2016-2018," [manuscript in progress].

³⁰ Laestadius, L., and Y. Wang, "Youth access to JUUL online: eBay sales of JUUL prior to and following FDA action," *Tobacco Control*, 2018;0;1-6, doi:10.1136/tobaccocontrol-2018-054499.

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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. In addition, the guidance is aimed at focusing the Agency’s enforcement resources where there is a greater threat to public health, and balancing that public health threat against the potential benefit to providing adult smokers noncombustible options to allow them to completely switch from the use of combustible products.

A. Modification of August 2017 Compliance Policy for Certain ENDS products

FDA plans to modify the August 2017 Compliance Policy for flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol-flavored ENDS products) and ENDS products that are targeted to minors or likely to promote use of ENDS by minors. With respect to such products, beginning 30 days after this guidance is finalized, FDA will prioritize enforcement consistent with its commitment to mitigating the alarming trend of youth use of ENDS. The August 2017 Compliance Policy continues to reflect FDA’s thinking with respect to other deemed products outside the scope of this Guidance, which do not implicate these enforcement priorities.

As noted in section II of this guidance, effective August 8, 2016, ENDS products that were not commercially marketed as of February 15, 2007, are new tobacco products. New tobacco products require premarket authorization before they can be legally marketed. Therefore, new ENDS products are legally required to be subject to an order authorizing their marketing.

FDA intends to prioritize enforcement with regard to certain ENDS products marketed in the United States that do not have required FDA authorization for marketing. Recognizing that we are unable to take enforcement action immediately against all such illegally marketed tobacco products, and that we need to make the best use of Agency resources, we are prioritizing our enforcement efforts as described below.

FDA intends to implement the enforcement priorities described below 30 days after this guidance is finalized. Generally, although prior notice is not required, the Agency generally seeks voluntary compliance by issuing a warning letter to a manufacturer and/or retailer before initiating an enforcement action.

B. Priorities for Use of Enforcement Resources

In the discussion that follows, we describe our approach to prioritizing our enforcement resources with respect to certain illegally marketed tobacco products. FDA intends to prioritize enforcement regarding the lack of marketing authorization against:

- Flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol-flavored ENDS products) that are offered for sale in ways that pose a greater risk for minors to access such products;

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- Flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol-flavored ENDS products) that are offered for sale in the United States after August 8, 2021, without the manufacturer submitting (and FDA receiving) a premarket application (or after action by FDA on that application, as described below); and/or
- All ENDS products that are targeted to minors or likely to promote use of ENDS by minors.

This guidance does not in any way alter the fact that no tobacco product, including those with tobacco, mint, or menthol flavors, may be legally sold to minors. FDA will continue to take legal action regarding sales of tobacco products to minors and will closely monitor all sales of ENDS products. If current trends regarding minors' use of ENDS products persist, the Agency will consider adjusting the approach announced in this guidance.

1. Flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol-flavored ENDS products) that are offered for sale in ways that pose a greater risk for minors to access such products

FDA intends to prioritize enforcement for lack of a marketing authorization against flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol-flavored ENDS products) that are offered for sale in the United States in ways that pose a greater risk for minors to access such products. For example:

- Products sold in locations that minors are able to enter at any time (e.g., the entire establishment or an area within the establishment);
- Products sold through retail establishments and online retail locations that have sold to minors after issuance of the guidance [insert guidance date here]; information about sales to minors identified by FDA is publicly available on FDA's searchable retailer inspection database, located here:
https://www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm;
- Products sold online with no limit on the quantity that a customer may purchase within a given period of time; or
- Products sold online without independent, third-party age- and identity-verification services that compare customer information against third-party data sources, such as public records.

FDA requests comments on other examples of products that are offered for sale in ways that pose greater risk for minors to access such products. In addition, FDA solicits comments on whether there are any technologies or other measures that would also be well tailored to address youth access to ENDS products, as well as any additional data that would be relevant to FDA's formulation of its enforcement priorities.

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FDA's decision to prioritize enforcement of the premarket authorities against a manufacturer and/or retailer with respect to products that are offered for sale in ways that pose a greater risk for minor access will be determined on a case-by-case basis.

2. Flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol-flavored ENDS products) that are offered for sale in the United States after August 8, 2021, without the manufacturer submitting (and FDA receiving) a premarket application (or after action by FDA on that application)

After August 8, 2021, FDA intends to prioritize enforcement for lack of a marketing authorization against flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol-flavored ENDS products) that are offered for sale in the United States and for which the manufacturer has not submitted (and FDA has not received) a premarket application.

After that date, FDA's decision to prioritize enforcement of the premarket authorities against a manufacturer and/or retailer will continue to be determined on a case-by-case basis. FDA intends to prioritize enforcement where a manufacturer has not submitted a premarket application by August 8, 2021, regardless of any steps the manufacturer has taken to prevent minor access and appeal to their products, and whether they would be an enforcement priority as described in other sections of this Guidance. Notwithstanding submission (and FDA receipt) of a premarket application, the enforcement priorities described elsewhere in this guidance will continue to apply.

By promoting submission of premarket applications for flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol-flavored ENDS products) by August 8, 2021, FDA is recalibrating its balancing of public health considerations in light of the public health threats described above. This new policy reflects FDA's balancing of concerns regarding the appeal of certain flavored ENDS products to youth; the potential public health benefit of noncombustible options in helping transition adult smokers completely off of combustible tobacco products; and the uncertainty created by extended availability of these new tobacco products without scientific review and evaluation under the public health standard. FDA requests comments on whether to adjust the premarket review compliance date to August 8, 2021 for all ENDS products, including tobacco-flavored, mint-flavored, and menthol-flavored ENDS products.

3. All ENDS products that are targeted to minors or likely to promote use of ENDS by minors

Many ENDS products are being 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 combustible cigarettes, for which advertising through television and radio has been prohibited since 1971, ENDS products are advertised through television, radio,

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and other media.³¹ Many companies are also utilizing social media to market their tobacco products to minors. Labeling and/or advertising for such products has included the use of youth appealing cartoons as well as the use of minors or people who appear to be minors in multimedia advertisements.³² Social media accounts are frequently used to electronically share such videos with other minors.³³

For example, FDA has previously issued warning letters for products that resemble kid-friendly foods and drinks or resemble other non-ENDS products that are often consumed by youth.³⁴ This includes labeling and/or advertising that results in the product resembling juice boxes, candy, or kid-friendly cereal.

Any efforts to entice minors to use tobacco products is of concern to FDA. At this time, FDA is prioritizing its enforcement to focus on products that are targeted to minors or likely to promote use of ENDS by minors.

FDA requests comments on examples of products that are targeted to minors or likely to promote use of ENDS by minors.

V. CHANGES TO COMPLIANCE POLICY REGARDING FLAVORED CIGARS (OTHER THAN TOBACCO FLAVORED) THAT MEET THE DEFINITION OF A NEW TOBACCO PRODUCT

In addition to reconsidering the compliance policy with respect to submission of premarket applications for ENDS products, in its discretion, FDA has also reconsidered the compliance policy with respect to other deemed tobacco products. At this time, in addition to modifying the compliance policy for ENDS products, FDA is also modifying the August 2017 Compliance Policy for flavored cigars. Beginning 30 days after issuance of a final guidance, FDA will prioritize enforcement of actions with respect to flavored cigars (other than tobacco flavored) that were on the market on August 8, 2016, and that meet the definition of a new tobacco product.

³¹ HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

³² See Padon, A., Maloney, E., Cappella, J., “Youth-Targeted E-cigarette Marketing in the US,” *Tobacco Regulation Science*, 2017, 3(1): 95-101.

³³ See Chu, K.-H., J.B. Colditz, B.A. Primack, et al., “JUUL: Spreading Online and Offline,” *Journal of Adolescent Health*, 2018, 63(5), 582-586, doi: <https://doi.org/10.1016/j.jadohealth.2018.08.002>.

³⁴ E.g., “E-Liquids Misleadingly Labeled or Advertised as Food Products,” available at: <https://www.fda.gov/tobaccoproducts/newsevents/ucm605729.htm>.

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Current information shows that minors continue to use these dangerous combustible tobacco products due, in part, to the availability and appeal of fruit and other flavors.³⁵ Cigars are associated with significant risk and provide no public health benefit. Like other combustible tobacco products, cigars – including flavored cigars – expose users to toxic and carcinogenic chemicals. Although little cigars deliver similar levels of nicotine compared to cigarettes, the levels of some carcinogens in the mainstream smoke exceed those in cigarettes.³⁶ In addition, as described below, FDA is concerned that, in the absence of this adjustment of enforcement priorities, minors who use flavored ENDS products might migrate to flavored cigars after this guidance is finalized, similar to the migration that occurred when the Tobacco Control Act banned cigarettes with characterizing flavors (except menthol). FDA also notes that minors have a tendency to be polytobacco users and, therefore, may switch to other flavored tobacco products like flavored cigars if flavored ENDS are no longer available. In 2018, NYTS data indicate that 2.4 percent of middle school students (or 33.3 percent of current tobacco product users) and 11.3 percent of high school students (or 41.7 percent of current tobacco product users) used two or more tobacco products on at least one day in the past month.³⁷ By modifying its compliance policy regarding flavored cigars that meet the definition of new tobacco products, FDA is helping to limit minors' access to a tobacco product that presents substantial risks and provides no public health benefit.

Existing and emerging evidence illustrates the importance of flavors among cigar users and the fact that such flavored cigars are appealing to minors. Data from the PATH Study (Wave 4 Youth) illustrate the continued importance of flavors among first-time cigar users. Recent data from this study indicate that 25.9 percent of ever traditional cigar youth users reported that their first cigar was flavored, 33.5 percent of ever filtered cigar users reported that their first cigar was flavored, and 56.8 percent of ever cigarillo users said that their first cigarillo was flavored.³⁸ This evidence is consistent with earlier research demonstrating that flavors increase youth appeal of tobacco products.³⁹

While various factors impact the potential for migration to other tobacco products, in the present circumstances, FDA notes that there is a likelihood that reduced availability of flavored ENDS products to minors could result in those minors migrating from flavored ENDS products to

³⁵ See Dai, H., “Changes in Flavored Tobacco Product Use Among Current Youth Tobacco Users in the United States, 2014-2017”, *JAMA Pediatrics*, published online January 2, 2019. doi:10.1001/jamapediatrics.2018.4595.

³⁶ Hamad, S.H., N.M. Johnson, M.E. Tefft, et al., “Little Cigars vs 3R4F Cigarette: Physical Properties and HPHC Yields,” *Tobacco Regulatory Science*, 3(4):459-478, 2017; Goel, R., N. Trushin, S.M. Reilly, et al., “A Survey of Nicotine Yields in Small Cigar Smoke: Influence of Cigar Design and Smoking Regimens,” *Nicotine & Tobacco Research*, 1250-1257, 2018.

³⁷ Gentzke, A.S., M. Creamer, K.A. Cullen, et al., “Vital Signs: Tobacco Product Use Among Middle and High School Students – United States, 2011-2018,” *Morbidity and Mortality Weekly Report*, 68(06), Early Release.

³⁸ FDA Internal Analysis.

³⁹ 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.

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flavored combustible tobacco products, including flavored cigars. Historical evidence suggests that flavored tobacco product users might be willing to move to other flavored tobacco products if their preferred product is no longer available.

For example, due to both the Tobacco Control Act's prohibition on cigarettes with characterizing flavors (except menthol) and the pressure placed on smokers by increased taxation of cigarettes resulting from the 2009 Children's Health Insurance Program Reauthorization Act (CHIPRA) (Pub. L. 111-3), price sensitive cigarette smokers are smoking cigars as a flavored, less expensive alternative to cigarettes.⁴⁰ A review of publicly available internal documents from a clove cigarette company found that the company started to develop a clove cigar product in 2007 in anticipation of the Tobacco Control Act and its ban on flavored cigarettes, including clove-flavored cigarettes.⁴¹ According to these documents, the goal was to be prepared for a product transition to allow for a continual marketing of a clove-flavored combustible tobacco product.⁴² Immediately following the prohibition on cigarette characterizing flavors (except menthol), sales of the clove cigar developed by the company increased more than 1,400 percent between 2009 and 2012,⁴³ strongly suggesting that users of clove cigarettes switched to the clove cigar on the basis of flavor availability.

Similarly, several studies assessed changes in loose tobacco sales following a large tax increase in RYO tobacco and found decreases in RYO tobacco sales as soon as the tax rate changed, but a dramatic increase in pipe tobacco sales.⁴⁴ Researchers analyzing publicly available federal excise tax data from 2000–2015 found that total RYO tobacco sales significantly decreased by 70.0 percent; however, total pipe tobacco sales increased by 556.4 percent.⁴⁵ Researchers also found similar trends in pipe tobacco sales using federal excise tax data; however, self-reported pipe tobacco use, assessed via the National Survey on Drug Use and Health, remained consistent

⁴⁰ See e.g., Gammon, D.G., Loomis, B.R., Dench, D.L., et al., "Effect of price changes in little cigars and cigarettes on little cigar sales: USA, Q4 2011-Q4 2013," *Tobacco Control*, 25(5):538-544 (2016); Courtemanche, C.J., Palmer, M.K., Pesko, M.F., "Influence of the flavored cigarette ban on adolescent tobacco use," *American Journal of Preventive Medicine*, 52(5):e139-e146 (2017).

⁴¹ Casseus, M., J. Garmon, et al., "Cigarette Smokers' Classification of Tobacco Products," *Tobacco Control*, 25: 628-630, 2016.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Agaku, I. T., & Alpert, H. R., "Trends in annual sales and current use of cigarettes, cigars, roll-your-own tobacco, pipes, and smokeless tobacco among US adults," 2002-2012. *Tobacco Control*, 25(4), 451-457, 2016; Morris, D. S., & Tynan, M. A., "Fiscal and policy implications of selling pipe tobacco for roll-your-own cigarettes in the United States." *PLoS One*, 7(5), e36487, 2012; Tynan, M. A., Morris, D., & Weston, T., "Continued implications of taxing roll-your-own tobacco as pipe tobacco in the USA," *Tobacco Control*, 24(e2), e125-127, 2015; Wang, T. W., Kenemer, B., Tynan, M. A., et al., "Consumption of combustible and smokeless tobacco - United States, 2000-2015." *Morbidity and Mortality Weekly Report*, 65(48), 1357-1363, 2016.

⁴⁵ Wang, T. W., Kenemer, B., Tynan, M. A., et al., "Consumption of combustible and smokeless tobacco - United States, 2000-2015." *Morbidity and Mortality Weekly Report*, 65(48), 1357-1363, 2016.

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and RYO consumption increased.⁴⁶ These data indicate that following the implementation of a tobacco control policy, consumers may modify their behavior to adapt to market changes.

Moreover, recent studies regarding the chemical and toxicological evaluations of cigarettes and cigars demonstrate that certain types of cigars (i.e., little cigars and cigarillos) have a chemical and toxicological profile that is similar to that of combustible cigarettes.⁴⁷ As a result, regular users are at increased risk (as compared to nonusers) for many of the same diseases as cigarette smokers, including oral, esophageal, laryngeal, and lung cancer; cardiovascular diseases; and chronic obstructive pulmonary disease (COPD).⁴⁸

FDA is making enforcement a priority with respect to new mint- and menthol-flavored cigars even though the agency plans to continue to exercise its discretion not to take enforcement action with respect to mint- and menthol-flavored ENDS products, consistent with the policy announced in August 2017. FDA is making this distinction because the Agency is aware that some adults may be using mint- and menthol-flavored ENDS products with the goal of ceasing combustible tobacco use to obtain health benefits at the individual level, and such adults may be at risk of migrating back to cigarettes, which continue to be available in menthol flavor, in the absence of access to mint- and menthol-flavored ENDS products. Because regular cigar smokers are at increased risk (as compared to nonusers) for many of the same diseases as cigarette smokers, there is no similar potential public health benefit to new mint- and menthol-flavored cigars remaining on the market.

FDA understands that tobacco-flavored cigars are not as appealing to minors as other flavored cigars.⁴⁹ Accordingly, all tobacco-flavored cigars will continue to be subject to the extended compliance dates announced in the August 2017 Compliance Policy.

FDA requests comments and/or data on the number of currently marketed flavored cigars that were on the market as of February 15, 2007 (i.e. flavored cigars that are not considered “new tobacco products”). In addition, FDA requests comments, including data, research results, and

⁴⁶ Agaku, I. T., & Alpert, H. R., “Trends in annual sales and current use of cigarettes, cigars, roll-your-own tobacco, pipes, and smokeless tobacco among US adults,” 2002-2012. *Tobacco Control*, 25(4), 451-457, 2016.

⁴⁷ E.g., Cecil, T.L., T.M. Brewer, M. Young, and M.R. Holman, “Acrolein yields in mainstream smoke from commercial cigarette and little cigar tobacco products,” *Nicotine & Tobacco Research* 19, 865-870, 2017; Erythropel, H.C., G. Kong, T.M. de Winter, T.M., “Presence of High-Intensity Sweeteners in Popular Cigarillos of Varying Flavor Profiles,” *Journal of the American Medical Association*, 320, 1382-1383 320(13):1380-1383, 2018. doi: 10.1001/jama.2018.11187; Hamad, S.H., N.M. Johnson, M.E. Tefft, et al., “Little Cigars vs 3R4F Cigarette: Physical Properties and HPHC Yields,” *Tobacco Regulatory Science* 3(4):459-478, 2017; Pickworth, W.B., Z.R. Rosenberry, D. Yi, “Cigarillo and Little Cigar Mainstream Smoke Constituents from Replicated Human Smoking,” *Chemical Research in Toxicology*, 31: 251-258, 2018.

⁴⁸ Chang, C.M., C.G. Corey, B.J. Rostron, et al., “Systematic Review of Cigar Smoking and All Cause and Smoking Related Mortality,” *BMC Public Health*, doi: 10.1186/s12889-015-1617-5, 2015.

⁴⁹ E.g., 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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other information, on how FDA should prioritize enforcement of actions with respect to flavored cigars (other than tobacco-flavored) that were on the market on August 8, 2016, and that meet the definition of a new tobacco product.

VI. COMPLIANCE POLICY REGARDING OTHER 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.⁵⁰ In addition to the tobacco products covered in this guidance document, FDA considered revising its enforcement priorities with respect to premarket authorization for other products with significant youth use, like waterpipe tobacco (hookah) products. With respect to waterpipe tobacco, however, due to remaining questions, including questions related to how such products might be used in the absence of flavors, FDA is not changing its compliance policy at this time. Waterpipe tobacco use also does not appear to have the same ease of use particularly on school grounds, as ENDS products and cigars, given the cumbersome nature of the related equipment. Instead, FDA is continuing to study the health effects associated with waterpipe tobacco use, as well as use patterns, to determine whether to modify the current compliance policy for waterpipe tobacco products in the future. Other deemed products, such as pipe tobacco and dissolvables, do not appear to have wide-spread, significant youth use at this time, so FDA is not currently revisiting the compliance policy with respect to such products.

FDA also considered revising the compliance policy for premarket authorization for mint- and menthol-flavored ENDS products. However, current data demonstrate that minors prefer alternative flavors, such as fruit, over mint- and menthol-flavored ENDS products, and it is possible that mint- and menthol-flavored ENDS products may be important to some adults who seek to use specific ENDS products to cease combustible tobacco product use. FDA is committed to continuing to study the long-term health effects associated with mint- and menthol-flavored ENDS product use, as well as minors' use patterns, to evaluate and determine whether to modify the current compliance policy for mint- and menthol-flavored tobacco products in the future.

Further, scientific evidence may shed new insight into the public health concerns related to currently available products. As discussed in FDA's comprehensive plan for tobacco and nicotine regulation, FDA is committed to pursuing policies that strike an appropriate balance between regulation and encouraging development of innovative tobacco products that may have the potential to have a net positive public health impact at the population level. FDA is always 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. Any additional changes to FDA's compliance policies would be announced in future guidance documents. FDA requests comments on whether it should also modify the August 2017 Compliance Policy for other deemed products.

⁵⁰ U.S. Department of Health and Human Services, "E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General, 2016."