FDA U.S. FOOD & DRUG ADMINISTRATION

MAR 13 2019

The Honorable Ron Johnson
Chairman
Committtee on Homeland Security and Governmental Affairs
United States Senate
Washington, D.C. 20510-6250

Dear Chairman Johnson:

Thank you for your letter of January 17, 2019 regarding the Food and Drug Administration's (FDA or the Agency) recent actions and announcements to protect youth from e-cigarettes.

To help explain the Agency's plans to change its compliance policy with respect to certain deemed products, it is helpful to provide background on the regulation of electronic nicotine delivery systems (ENDS), such as e-cigarettes. As you know, in accordance with the Tobacco Control Act, in 2016, FDA issued a final regulation to deem almost all tobacco products subject to its tobacco authorities.

Before the final deeming rule, FDA had no authority to prohibit retailers from selling e-cigarettes to minors. E-cigarettes were unregulated by FDA and sold without any review of their ingredients or how they were made. The regulation directly applied the substantive requirements of chapter IX of the Food, Drug & Cosmetic Act (FD&C Act) and its implementing regulations to ENDS. The Regulatory Impact Analysis (RIA) for the final deeming rule acknowledged the rapidly growing ENDS market. When the deeming rule took effect on August 8, 2016, all "new" tobacco products – i,e., products that were not commercially marketed as of February 15, 2007 – required premarket authorization. The RIA recognized that nearly all ENDS products would be subject to premarket review and that a majority of all ENDS submissions would require a premarket tobacco application (PMTA).

FDA recognized that industry would need time to comply with the new regulatory requirements triggered by the final deeming rule and announced, as a matter of enforcement discretion, a compliance policy with staggered timeframes for compliance. Some of the requirements, such as the Federal minimum age of purchase, took effect immediately when the deeming rule took effect on August 8, 2016, while other requirements, such as premarket review, were subject to an enforcement policy with a longer compliance period. FDA announced it did not intend to enforce the requirements of premarket review against manufacturers of newly-regulated, new tobacco products if they submitted applications seeking marketing authorization within specific timeframes. PMTAs were expected 24 months after the effective date of the rule (i.e., August 8, 2018). Unless FDA had issued an order denying or refusing to accept the submission, manufacturers who submitted applications by this deadline would be subject to a continued compliance period for 12 months. As a result, FDA anticipated many ENDS products would remain on the market for up to three years.

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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.

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 requests for exemption from demonstrating substantial equivalence (EX REQs), reports demonstrating substantial equivalence (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. In response to these complaints, FDA took a series of actions to address youth access to these products. These include the largest coordinated enforcement effort in Agency history that resulted in more than 1,300 warning letters and civil money penalty complaints (fines) to retailers who illegally sold JUUL and other e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores last summer, as well as actions to address products that were misleadingly labeled and/or advertised, including 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.

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. Additionally,

to date, FDA has published several resources to aid industry application submission. For example, FDA published the Tobacco Product Master File Guidance and a Small Entity Compliance Guide for Deeming, and developed educational webinars describing deeming requirements and discussing the draft guidance, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems. FDA published the "PMTA for ENDS" draft guidance, which, when finalized, will describe FDA's current thinking on what products are considered to be ENDS, how FDA intends to review PMTAs for ENDS, and what information FDA recommends that submitters include in their applications. This week, the Agency also published the draft guidance, *Modifications to Compliance Policy for Certain Deemed Tobacco Products*, which 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. A proposed rule that explains how to submit SE Reports is pending review within the Administration. Additionally, FDA's Refuse to Accept Procedures for Premarket Tobacco Product Submissions final rule describes when FDA will refuse to accept a tobacco product submission because the application has not met a minimum threshold for acceptability for FDA review. Under the rule, FDA will refuse to accept a tobacco product premarket review submission, for example, that is not in English, does not pertain to a tobacco product, or does not identify the type of submission. By refusing to accept submissions that have the deficiencies identified in the proposed rule, FDA will be able to focus our review resources on submissions that meet a threshold of acceptability and encourage quality submissions.

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 National Youth Tobacco Survey (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 11.7 percent in 2017.[1] However, recent data show a significant increase in minors' use of ENDS products, particularly in the past year.[2] 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, $p<0.05$).[3] These data represent an increase of an estimated 1.32 million high school students reporting past 30-day e-cigarette use in one year.

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[1] 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."

[2] *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.

[3] *Id.*

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.[4] 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.[5] For each age group, the increase from 2017 to 2018 was statistically significant ($p<.001$).[6] During this time period, between 2017 and 2018, the rate of combustible product use among youth remained flat.[7]

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.[8] At the 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.[9] 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 three or more of the previous 30 days, and over a quarter reported use on 10 to 30 days of the prior month.[10]

Evidence also indicates that minors are attracted to flavored ENDS products. In the 2016-2017 (Wave 4) Population Assessment of Tobacco and Health (PATH) Study,[11] among the 6.8 percent

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[4] *Id.*

[5] 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*.

[6] *Id.*

[7] 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.

[8] 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).

[9] 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.

[10] 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.

[11] 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

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.[12] 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.[13] 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."[14] 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, $p<0.05$).[15] This evidence is consistent with earlier research indicating that flavors increase youth appeal of tobacco products.[16]

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.[17] 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).[18] 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

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(September 2013-December 2014), Wave 2 (October 2014-2015), Wave 3 (October 2015-2016), and Wave 4 (2016-2017)

[12] FDA Internal Analysis.

[13] *Id.*

[14] *Id.*

[15] 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).

[16] *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' 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).

[17] 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.*

[18] FDA Internal Analysis.

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.[19]

A study of 396 adolescents from five high schools in Connecticut, who reported past-month e-cigarette use completed a survey in 2014 that found that fruit flavors are, 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).[20] 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).[21] While minors use mint and menthol ENDS products, it appears that they prefer them substantially less than adults prefer such flavors.

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.[22] 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, as described above, 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.[23]

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.[24] 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

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[19] 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

[20] 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.*

[21] *Id.*

[22] 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.

[23] 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].

[24] FDA Internal Analysis.

obtained the products online.[25] 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.[26] 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,[27] and many online retailers do not use adequate methods to verify the age of the purchaser.

This data highlighted the need for FDA to revisit its compliance policies with respect to the continued marketing of deemed tobacco products that have not obtained premarket authorization, and to call on the industry to do more to keep their products out of the hands of minors. As a result, in November of last year, Commissioner Gottlieb announced several new potential steps the agency could take to curb youth use trends, including:

- Revisit the current premarket review compliance policy for flavored ENDS products (other than tobacco, mint, and menthol flavors or non-flavored products) that are not sold at an age-restricted in-person location.

- Revisit the current premarket review compliance policy for flavored ENDS products (other than tobacco, mint, and menthol flavors or non-flavored products) that are sold online without heightened age verification.

- Revisit the current premarket review compliance policy for any ENDS products that are marketed to kids.

We recognize that additional detail is needed to explain the potential change in the compliance policy for premarket review of deemed products. As such, we are happy to brief your staff on the new compliance policy that has been published for comment.

Thank you for your continued interest in this public health matter. Please let us know if you have further questions or concerns.

Sincerely,

Karas Gross
Associate Commissioner for
Legislative Affairs

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[25] 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]

[26] 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].

[27] 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.