July 15, 2020

The Honorable Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy
Committee on Oversight and Reform
U.S. House of Representatives
Washington, D.C. 20515-6143

Dear Chairman Krishnamoorthi:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the December 4, 2019 hearing before the Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, entitled "The Federal Response to the Epidemic of E-Cigarette Use, Especially Among Children, and the Food and Drug Administration's Compliance Policy." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

Karas Gross

Karas Gross
Associate Commissioner for
Legislative Affairs

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We have restated Representative Krishnamoorthi's questions below in bold, followed by FDA's responses.

The Honorable Raja Krishnamoorthi

1. **OIRA has completed its review of FDA's compliance policy entitled "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Tobacco Products on the Market Without Premarket Tobacco Authorization" ("Compliance Policy"). From a regulatory process standpoint, is there any legal impediment to the Food and Drug Administration (FDA) publishing the Compliance Policy today?**

On January 7, 2020, FDA published a final guidance setting forth enforcement priorities with regard to the marketing of certain deemed tobacco products that do not have premarket authorization.[1] Thus, this question has been superseded by more recent events.

The final guidance announced that FDA intends to prioritize enforcement against certain illegally-marketed ENDS products by focusing on the following groups of products that do not have premarket authorization:

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

As you know, on July 12, 2019, the United States District Court for the District of Maryland ordered FDA to require manufacturers of e-cigarettes, cigars and other deemed new tobacco products that were on the market as of Aug. 8, 2016 to submit applications for premarket review by May 12, 2020.[2] We had steadily been working toward that deadline, but the coronavirus pandemic impaired the ability to adhere to this timeline. Solely as a result of the pandemic and these exceptional and unforeseen circumstances, we requested on March 30, and on April 22, 2020 were granted by the court, a 120-day extension of the May 12 deadline.

Ultimately, the new Sept. 9 deadline will better serve the public health by allowing manufacturers to prepare for, and the Agency to conduct, the thorough scientific review of these products that is required under law and vital to our mission of protecting Americans while reducing or eliminating physical contact during this critical period. FDA has updated the January 2020 enforcement priorities guidance to reflect the new September 9 deadline and continues to independently prioritize earlier enforcement against certain e-cigarette products that are widely used by youth regardless of whether an application is submitted, as discussed in the guidance. In

[1] "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization; Final Guidance" (April 2020), available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market*

[2] Subsequently, on May 4, 2020, the United States Court of Appeals for the Fourth Circuit dismissed an appeal related to the May 12, 2020 deadline.

addition, as noted in the updated final guidance, FDA intends to prioritize enforcement of any ENDS product that is offered for sale in the United States after September 9, 2020, and for which the manufacturer has not submitted a premarket application.

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.

2. **In order for FDA to publish the Compliance Policy, does FDA need additional approval from:**
    a. **The Office of Information and Regulatory Affairs (OIRA)?;**
    b. **The President?;**
    c. **Any other individual or office within the White House other than OIRA or the President, and if so, which individual or office within the White House?;**
    d. **The Department of Health and Human Services (HHS), and if so, which individual or office within HHS?; and/or**
    e. **If you answered "yes" to any of subparts a through d, above, explain how it was conveyed to you that such additional approval would be necessary, and your understanding as to how that approval will be conveyed and by whom.**

As noted, FDA published the final Compliance Policy on January 7, 2020. Accordingly, the policy is not pending approval of any of the individuals or entities listed above.

3. **You explained that "parallel policy discussions" are the reason that the Compliance Policy is not being published. State:**
    a. **When, how, and from whom, you first learned about the "parallel policy discussions";**
    b. **The identity of all individuals involved in the "parallel policy discussions," by both name and office;**
    c. **Whether the substance of the Compliance Policy is final, or whether additional changes to the Compliance Policy are being considered as part of the "parallel policy discussions";**
    d. **How the "parallel policy discussions" impact the finalization of the Compliance Policy, including whether the Compliance Policy cannot be finalized until some other action is decided, and if so, identify the other actions that must be decided; and**
    e. **Whether specific potential rules, executive orders, or legislation are being considered in connection with the Compliance Policy, and if so, state the subject matter of any such rules, executive orders, or legislation.**

As noted, FDA published the final guidance on January 7, 2020. More generally, FDA notes that it developed and issued the final guidance in response to data demonstrating the extraordinary popularity of certain flavored, cartridge-based ENDS products among youth. As detailed in the final guidance, two of the largest surveys of tobacco use among youth, the National Youth Tobacco Survey (NYTS) and the Monitoring the Future (MTF) Study, demonstrated that, in 2019, e-cigarette use among youth had hit the highest levels ever recorded. Data also showed that youth were more likely to use certain flavored, cartridge-based ENDS products. FDA considered this data, as well as information conveyed in public comments submitted to the draft guidance[3] and information about health and safety issues connected to ENDS products (*e.g.*, the harmful effects of nicotine on adolescent brain development; battery explosions with ENDS products) in developing the enforcement priorities articulated in the final guidance.

Publication of the final guidance occurred after the completion of a policy review process that principally included the Department of Health and Human Services (HHS) (including other operating divisions and the Office of the Secretary), the Department of Justice, the Office of Management and Budget (OMB) and other components of the Executive Office of the President. As part of this process, FDA submitted drafts of the final guidance to OMB's Office of Information and Regulatory Affairs (OIRA) on October 25, 2019 and December 26, 2019, consistent with FDA's long-standing practice of submitting guidance documents to OIRA for review that potentially raise novel legal or policy issues. In addition, on November 22, 2019, the White House conducted a Roundtable to solicit information on ENDS from external stakeholders, including representatives of the vaping industry, retailers, public health advocates, and lawmakers. The event was live-streamed, and can be viewed online.[4]

Cumulatively, this policy development and review process led to the publication of the final guidance on January 7, 2020.

4. **When asked if FDA can issue the guidance now that OIRA has completed its review, Mr. Zeller said: "if the complete executive branch review of the policy was done, but there were still, as I said, in parallel, other ongoing policy-related discussions going on."**
    a. **On what grounds is FDA withholding the Compliance Policy until the "complete executive branch review" is complete?**
    b. **Provide citation to the definition of "complete executive branch review."**
    c. **If there is no formal definition of "complete executive branch review, "provide one, as you understand it.**
    d. **Provide all examples of FDA guidance documents that have been withheld pending parallel discussions or "complete executive branch review" beyond that outlined in Executive Order 12866.**

As noted, FDA published the final guidance on January 7, 2020. More generally, FDA notes that, on policy matters that raise potentially novel legal and policy issues, the Agency often

[3] "Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance" (March 2019), available at *https://www.fda.gov/media/121384/download*.
[4] *See https://www.c-span.org/video/?466761-1/president-trump-holds-roundtable-teen-vaping* (last visited on February 17, 2020).

coordinates closely with other components of HHS and the executive branch to ensure alignment with applicable law and Administration priorities.

5. **Explain whether, and how, compliance with Executive Order 13771 is contributing to the delay in publishing the Compliance Policy**.

As noted, FDA published the final guidance on January 7, 2020. Executive Order 13771 did not affect the timing of publication of the final guidance.

6. Explain whether, and how, the Regulatory Reform Task Force is contributing to the delay in publishing the Compliance Policy. Identify the Regulatory Reform Officer.

As noted, FDA published the final guidance on January 7, 2020. The Regulatory Reform Task Force did not affect the timing of publication of the final guidance. FDA's Regulatory Reform Officer is Anna Abram, Deputy Commissioner for Policy, Legislation, and International Affairs.

7. Identify all FDA rules, compliance policies, guidance documents, and regulatory actions that FDA failed to publish in the Federal Register within the first month after OIRA completed its 12866 review of that FDA rule, compliance policy, guidance document, or regulatory action.

Timing between completion of OIRA's review and publication of a document in the *Federal Register* is not a metric FDA tracks, so we are unable to provide a precise response to this question.

8. Identify all FDA rules, compliance policies, guidance documents, and regulatory actions about which you are aware of any president taking meetings after that FDA rule, compliance policy, guidance document, or regulatory action had passed through OIRA review but had not yet been published in the Federal Register.

FDA does not track this type of information, so we are unable to provide a response to this question.

9. Identify all specific FDA rules, compliance policies, guidance documents, and regulatory actions that you are aware of a president publicly supporting, and then opposing and/or actively working against that specific FDA rule, compliance policy, guidance document, or regulatory action after it passed through OIRA review but had not yet been published in the Federal Register.

FDA does not track this type of information, so we are unable to provide a response to this question.

10. State your understanding of the President's ability to change the substance of an FDA rule, compliance policy, guidance document, or regulatory action after it has passed through OIRA review but has not yet been published in the Federal Register.

FDA respectfully suggests that this question be directed to the White House for further response. More generally, publication of the final guidance occurred after the completion of a policy development and review process that continued after the guidance was submitted to OIRA on October 25, 2019. This policy review process principally included the Department of Health and Human Services (HHS) (including other operating divisions and the Office of the Secretary), the Department of Justice, the Office of Management and Budget (OMB) and other components of the Executive Office of the President. As part of this process, FDA submitted drafts of the final guidance to the OMB's Office of Information and Regulatory Affairs (OIRA) on October 25, 2019 and December 26, 2019, consistent with FDA's long-standing practice of submitting guidance documents to OIRA for review that potentially raise novel legal or policy issues. FDA ultimately published a final guidance on January 7, 2020.

11. You have acknowledged that OIRA's review of the Compliance Policy is complete. Therefore, deliberations about that specific Compliance Policy are complete.

- **a. State whether the Compliance Policy that you sent to OIRA on October 25, 2019, proposed to clear the market of all flavors, or if there were any exemptions, including for menthol and/or for vape shops.**
- **b. State whether OIRA made any changes to the Compliance Policy FDA sent to OIRA.**
- **c. State whether any changes made by OIRA to FDA's Compliance Policy added exemptions, and state what those exemptions were, including whether OIRA added exemptions for menthol and/or vape shops.**

As described above, publication of the final guidance occurred after the completion of a policy development and review process that continued after the guidance was submitted to OIRA on October 25, 2019. As part of this process, FDA submitted drafts of the final guidance to OIRA on October 25, 2019 and December 26, 2019, and FDA ultimately published a final guidance on January 7, 2020.

The final guidance announced that FDA intends to prioritize enforcement against certain illegally-marketed ENDS products by focusing on the following groups of products that do not have premarket authorization:

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

In addition, as noted in the current final guidance, FDA intends to prioritize enforcement of any ENDS product that is offered for sale in the United States after September 9, 2020, and for which the manufacturer has not submitted a premarket application. Further, the final guidance explains that 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. The final guidance also

makes clear that FDA 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.

The final guidance was developed using the best available data, including the most current information from nationally representative surveys of youth tobacco product use showing that flavors are a strong driver for youth use, and that youth overwhelmingly use cartridge-based ENDS products. Consistent with that data, including that from both the 2019 NYTS and 2019 MTF surveys, FDA refined its enforcement priorities in the final guidance to focus on flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored). This approach is designed to balance public health considerations by restricting youth access to such products, while maintaining the 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 ENDS products. In addition, FDA intends to prioritize enforcement of any ENDS product (regardless of flavor) that is offered for sale after September 9, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).

12. You testified that "[t]he options that FDA put on the table for consideration, going to what the scope of what this guidance should be, went to the issue of 'menthol in' or 'menthol out."' Having started into that subject matter, describe all other options FDA put on the table, and to whom FDA proposed the options.

Publication of the final guidance occurred after the completion of a policy development process that began with development of the draft guidance, which FDA issued in March 2019. FDA respectfully refers the Committee to sections II and IV of the final guidance, which contain a detailed discussion of the public health and policy considerations that informed FDA's decision-making throughout this process and culminated in FDA's focus on the enforcement priorities articulated therein.

13. Identify dates and times in the next week for Subcommittee staff to conduct an in-camera review of FDA's Compliance Policy sent to OIRA on October 25 and the Compliance Policy OIRA sent back to FDA after completing its review on November 4. As a matter of courtesy, we are willing to make this accommodation, rather than seeking production of those documents.

As noted, FDA published the final guidance on January 7, 2020. We conducted a briefing with Subcommittee staff on February 26, 2020, regarding premarket tobacco product applications (PMTAs) and would be happy to provide another briefing on the final guidance and actions taken since its publication.

14. The United States District Court for the District of Maryland ordered FDA to require PMTA submissions by May 12, 2020. The government has appealed that order. Unless, the order is stayed on appeal, will FDA comply with the order and require Premarket Tobacco Product Applications (PMTA) by May 2020?

FDA is strongly committed its public health mission of protecting and promoting the public health and to preventing kids from using tobacco products. FDA views the dramatic increase in youth use of ENDS products as a problem that requires an urgent response, and FDA issued the final guidance to communicate enforcement priorities with respect to these products. FDA would adopt these enforcement priorities for ENDS regardless of the decision of the U.S. District Court for the District of Maryland in *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al*.

As mentioned above, on July 12, 2019, the United States District Court for the District of Maryland ordered FDA to require manufacturers of e-cigarettes, cigars and other deemed new tobacco products that were on the market as of Aug. 8, 2016 to submit applications for premarket review by May 12, 2020.[5] We had steadily been working toward that deadline, but the coronavirus pandemic impaired the ability to adhere to this timeline. Solely as a result of the pandemic and these exceptional and unforeseen circumstances, we requested on March 30, and on April 22, 2020 were granted by the court, a 120-day extension of the May 12 deadline. The new deadline is now September 9, 2020.

15. The product design of the current generation of e-cigarettes makes them very concealable. They are small and put out small plumes of quickly dissipating aerosol. Does FDA have the authority to regulate device design, including aspects such as size, shape, and color?

Yes, section 907 of the Federal Food, Drug and Cosmetic (FD&C) Act provides FDA authority to adopt a tobacco product standard, including provisions respecting the construction, components and properties of a tobacco product, if the Agency finds that a tobacco product standard is appropriate for the protection of the public health. In making such a finding, FDA must consider scientific evidence concerning: (1) the risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

In addition, section 906(d) of the FD&C Act authorizes FDA to require restrictions on the sale and distribution of a tobacco product. The restrictions on the sale and distribution of a tobacco product may include restrictions on the access to, and the advertising and promotion of, the tobacco product, if FDA determines such restrictions would be appropriate for the protection of the public health. When determining whether such a restriction would be appropriate for the protection of the public health, FDA must consider the restrictions with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account: (a) the increased or decreased likelihood that existing users of tobacco

[5] Subsequently, on May 4, 2020, the United States Court of Appeals for the Fourth Circuit dismissed an appeal related to the May 12, 2020 deadline.

products will stop using such products, and (b) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

16. Identify all instances of FDA being lobbied on the topic of the Compliance Policy and/or on the "parallel policy discussions," and identify all individuals involved.

Although FDA is unclear about the scope of this question, we are providing high-level information about the types of discussions with external stakeholders that informed development of the final guidance.

To begin with, the final guidance was developed in accordance with the Good Guidance Practices regulation set forth at 21 C.F.R. § 10.115(g), including provisions regarding the opportunity for public notice and comment. Those provisions specify that:

- Before FDA prepares a draft of a "Level 1"[6] guidance document, FDA can seek or accept early input from individuals or groups outside the agency. *See* 21 C.F.R. § 10.115(g)(1)(i). As detailed in the draft and final ENDS guidances, FDA undertook a series of actions, beginning in late 2017, after the Agency received a marked increase in the number of complaints about ENDS products. These actions included publicly acknowledging that FDA was reconsidering the compliance timelines for premarket authorization of ENDS products, and soliciting the views of stakeholders including tobacco product manufacturers, retail associations, and public interest organizations. Details regarding meetings conducted with external stakeholders are available on the public calendars of the Commissioner of Food and Drugs, the Director of the Center for Tobacco Products, and other FDA leadership.[7] Specific to the issue of increases in youth e-cigarette use, former Commissioner Scott Gottlieb communicated to the public about meetings he had with leadership from tobacco companies and publicly discussed letters he sent to companies requesting meetings to address FDA's serious concerns with youth tobacco use.[8]
- After FDA prepares a draft of a Level 1 guidance document, FDA will publish a notice in the *Federal Register* announcing that the draft guidance document is available; post the draft guidance document on the Internet and make it available in hard copy; and invite public comment on the draft guidance document. *See* 21 C.F.R. § 10.115(g)(1)(ii). Consistent with this requirement, FDA published a draft ENDS guidance in March 2019. FDA solicited public comment generally on the proposed approach and specifically sought information that could help inform its decision-making for each key issue.
- After providing an opportunity for public comment on a Level 1 guidance document, FDA will review any comments received and prepare the final guidance document that

[6] FDA regulations define a "Level 1" guidance document as one that (i) sets forth initial interpretations of statutory or regulatory requirements; (ii) sets forth changes in interpretation or policy that are of more than a minor nature; (iii) include complex scientific issues; or (iv) covers highly controversial issues. 21 C.F.R. § 10.115(c)(1).

[7] See *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/public-calendar-meetings-fda-officials*

[8] See *https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-meetings-industry-related-agencys-ongoing-policy; https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-data-demonstrating-rising-youth-use-tobacco;* and *https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-forceful-new-actions-focused-retailers-manufacturers.*

> incorporates suggested changes, when appropriate; publish a notice in the *Federal Register* announcing that the guidance document is available; post the guidance document on the Internet and make it available in hard copy; and implement the guidance document. *See* 21 C.F.R. § 10.115(g)(1)(iv). FDA received more than 15,000 comments 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 expressed broad policy views and did not address specific points related to the draft guidance. FDA considered the information provided in these comments as we finalized the enforcement priorities articulated in the final guidance. Information regarding significant comments received in response to the March 2019 draft guidance and FDA's responses is described in Appendix A to the final guidance.

In addition, consistent with standard practice, FDA participated in three meetings facilitated by OIRA after the draft version of the final guidance had been submitted to OIRA for review (commonly referred to as "E.O. 12866 meetings"). Details regarding these meetings can be found on RegInfo.gov.[9]

Finally, FDA notes that former Acting Commissioner Brett Giroir attended the White House roundtable on ENDS use that was conducted on November 22, 2019, and included participation from external stakeholder groups representing members of the vaping industry, retailers, and public health advocates.

17. JUUL publicly stated that it would not lobby against the Compliance Policy. Did JUUL, Altria, or anyone acting on their behalves lobby or otherwise communicate with the administration about the Compliance Policy and/or on the "parallel policy discussions"?

FDA respectfully suggests that this question be directed to OIRA or the White House for further response.

18. Why did FDA choose to make Mint and Menthol one category on the National Youth Tobacco Survey?

In 2016, the NYTS began asking youth about the specific flavors of tobacco products they used in the past 30 days. From 2016-2019, this question was asked about the use of flavors in tobacco products generally and was not asked separately for each product used. Due to limitations on space in the survey and to allow for the response options to be relevant across tobacco product categories, a combined menthol and mint category was used. Part of the rationale for a combined mint/menthol question was the fact that mint flavored cigarettes cannot be legally marketed in the U.S., so having a separate mint option could have been confusing for cigarette smokers and could have led to misleading responses. Beginning in 2020, the question on specific flavors used

[9] See *https://www.reginfo.gov/public/do/eom12866SearchResults?pubId=&rin=0910-ZA56&viewRule=true.*

will be asked individually for each tobacco product used in the past 30 days, with mint and menthol included as separate response options for relevant product categories (e.g. e-cigarettes).

Another national survey, MTF, separates mint and menthol use as part of the survey module that focuses specifically on the use of JUUL e-cigarettes. The module was first included in the survey in 2019. Youth were asked which JUUL flavor they used most often, and the response options were the JUUL flavors that were sold at the time the module was developed—classic tobacco, crème, cucumber, fruit, mango, menthol, mint, and Virginia tobacco. The question also included a response option for "other."

19. On September 11, when the administration promised to clear the market of all flavors, there was a specific effort to add the words "including mint and menthol." Please state whether the following facts factored into the decision to specifically identify mint and menthol:

a. That 63.9% of youth users use mint or menthol?; and/or

b. That JUUL has historically tried to distinguish mint and menthol from other flavors, at one point even claiming that mint and menthol were not flavors at all?

The final Compliance Policy published on January 7, 2020 and included all flavored, cartridge-based ENDS products, other than tobacco- and menthol-flavored, within the enforcement priorities. The decision not to prioritize tobacco and menthol flavored products in the same manner as other cartridge-based products was informed by data from both the 2019 NYTS and 2019 MTF surveys. The 2019 NYTS data indicated that, among high school students whose only tobacco product use is e-cigarettes, known as exclusive e-cigarette users, fruit-flavored ENDS use was 66.1 percent and mint- and menthol-flavored ENDS use was 57.3 percent. Among middle school exclusive e-cigarette users, fruit-flavored ENDS use was 67.7 percent and mint- and menthol-flavored ENDS use was 31.1 percent. However, 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 alone. A further refinement was provided by a 2019 MTF survey, which examined mint and menthol JUUL use separately. 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 (8th, 10th, and 12th), use of mango and mint ranked highest, followed by fruit. Reported use of menthol and tobacco flavors were among the lowest ranked options.

Based on this data, FDA refined its enforcement priorities in the final guidance to focus on flavored ENDS products other than tobacco- and menthol-flavored products. 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. In addition, FDA intends to prioritize enforcement of <u>any</u> ENDS product (regardless of flavor) that is offered for

sale after September 9, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).

20. The Big Vaping Industry is celebrating victory. The President of the American Vaping Association stated quote "it's a great feeling in two months to go from thinking that prohibition was inevitable to actually proving that your issue has resonance with voters to such an extent that the President of the United States takes notice." Emboldened by his presumed victory over public health, the President of the vaping lobby set his sights on FDA's PMTA process, stating quote "we need to make the administration and the reelection team aware that the magnitude of the threat in May 2020 is just as huge and industry-crushing as the flavor ban is today" (emphasis added). He's indicating that Big Vaping again plans to exert political influence on President Trump, this time to interfere with FDA's PMTA process.

- **a. Would you be concerned if the vaping association was meeting with the White House to exercise political pressure on the PMTA process?;**
- **b. Has the White House engaged FDA about how to conduct the PMTA process?;**
- **c. How could the White House, theoretically, exert influence over how FDA conducts the PMTA process?;**
- **d. Will FDA allow the White House to dictate how FDA conducts the PMTA process?; and**
- **e. Do you commit to informing this Subcommittee if the White House engages FDA about weakening the PMTA process?**

Decisions on PMTAs are made by FDA. As of December 31, 2019, FDA had issued 14 PMTA marketing orders and refused to accept over 368 applications because the application had not met a minimum threshold for acceptability for FDA review.

Ensuring new tobacco products undergo a robust premarket evaluation by FDA is a critical part of the Agency's mission to protect the public health, particularly youth, and to reduce tobacco-related disease and death. While authorization of new tobacco products does not mean they are safe, the review process under the PMTA pathway requires applicants to demonstrate that a new tobacco product is "appropriate for the protection of the public health" (the public health standard) using scientific evidence. Determining whether a tobacco product meets this statutorily-based public health standard requires consideration of the risks and benefits to the population as a whole, including users and non-users of tobacco products, and takes into account the increased or decreased likelihood that existing users of tobacco products will stop using such products, and those who currently do not use tobacco products will start using such products. The review process also considers how the products may impact youth use of tobacco products. FDA experts from various scientific fields, including chemistry, toxicology, and epidemiology, consider the body of evidence to determine whether the tobacco product under review meets the public health standard.

To provide transparency and predictability about the PMTA review process for industry and, in turn, to help facilitate the submission of high quality applications, FDA has issued final guidance

for manufacturers submitting PMTAs for ENDS[10] and is in the process of reviewing comments received in response to a proposed rule that would establish content and format requirements for PMTA submissions.[11] Per standard process, FDA sought (or will seek) Administration review of these regulatory documents prior to publication by submitting the materials to OIRA for review and clearance. As illustrated in the guidance and proposed rule, FDA is committed to a thorough scientific and public health review of PMTAs.

FDA would be pleased to provide periodic updates to the Committee about metrics from our PMTA review pathway.

21. Mint and menthol are very similar flavors. We understand that FDA is considering removing, mint-flavored e-cigarettes from the market but allowing menthol-flavored e-cigarettes to remain on the market.

a. Has FDA issued definitions of mint and menthol? If not, how would you define them?

FDA has not defined mint or menthol. Mint is a term that encompasses the Mentha family of plants, including spearmint, peppermint, orange mint, apple mint, pineapple mint, pennyroyal, and many others. Essential oils extracted from Mentha plants are extensively used in food, drinks, and herbal remedies, due to their pleasant flavors and aromas. Each mint flavor has a specific profile of components that is responsible for its characteristic taste and aroma. One of these components is menthol, which is a major component of peppermint oil. Menthol has local anesthetic properties and is primarily used to provide a cooling sensation.

b. If menthol-flavored e-cigarettes are allowed to remain on the market, how will FDA prevent companies from simply renaming their mint products as menthol to keep them on the market?

FDA will monitor the marketplace for products that may be renamed as menthol products to intentionally mislead authorities. FDA's decision as to whether to take action with respect to particular products will be determined on a case-by-case basis, informed by the enforcement priorities described in its compliance policy and any other relevant factors.

Additionally, for unauthorized tobacco-, menthol-, or non-flavored e-cigarette products, FDA intends to keep a close watch on – and prioritize enforcement against – products for which the manufacturer has not taken or is not taking adequate measures to prevent minors' access to these products, or products that are targeted to or whose marketing is likely to promote use by young people.

22. After August 2016, no new e-cigarette could enter the market without undergoing an FDA review. Does FDA have a list of products that were on the market prior to August

[10] "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems; Final Guidance" (June 2019), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends.*

[11] *See* "Premarket Tobacco Product Applications and Recordkeeping Requirements; Proposed Rule," 84 Fed. Reg. 50566 (Sept. 25, 2019).

2016 so that it knows which ones illegally entered the market after that date? If so, provide that list.

FDA does not have a list of deemed products that were on the market prior to August 8, 2016.

FDA requires owners and operators of domestic manufacturing establishments engaged in the manufacturing of tobacco products to register with FDA and submit a list of all tobacco products manufactured for commercial distribution, along with certain accompanying information (including all labeling). Complete product list information must be submitted at the time of first registration; certain changes in the product list must then be submitted biannually. This registration and listing requirement is subject to enforcement and provides one data source that FDA uses when determining if a product first entered the market after August 8, 2016.

Product listings do not indicate the date products were initially commercially marketed in the United States, as that data is not required at the time of initial submission to FDA.

FDA has received complaints that some companies may be marketing new products that first entered the market after August 8, 2016, and have not gone through premarket review. We take these reports very seriously and investigate reports received. Many of the products we have investigated were not introduced after August 8, 2016. Instead, they were products that had changed their labels, including the name of the product, after August 8, 2016, which does not result in a separate new tobacco product entering the market after that date. In its guidance document entitled Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3), the Agency states that a modification to an existing tobacco product's label, standing alone, does not result in a new tobacco product subject to the premarket review provisions of the FD&C Act.

On January 7, 2020, FDA published a final guidance outlining the Agency's enforcement priorities for deemed products that were on the market prior to August 2016. The guidance stated that FDA intends to prioritize enforcement beginning 30 days after issuance (February 6, 2020), against these illegally marketed ENDS products by focusing on the following groups of products that do not have premarket authorization:

- 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.

The current guidance also states that, after September 9, 2020, FDA intends to also prioritize enforcement against any ENDS products that continue to be sold and for which the manufacturers have not submitted a premarket application. For ENDS products other than those in the three groups described above, if premarket applications are submitted by that date, FDA intends to continue to exercise enforcement discretion for up to one year pending FDA review of the applications, unless there is a negative action by FDA on such application or the product is authorized to be marketed by FDA.

There are many ways FDA is monitoring the marketplace to look for violations, such as reviewing product and marketing status data during inspections, following up on complaints, reviewing press announcements, utilizing the Agency's data sources, and requesting information from companies suspected of marketing a new product without authorization.

23. In May of next year, manufacturers of e-cigarettes will have to submit PMTA applications to FDA, and the Center for Tobacco Products will determine whether these products are "appropriate for the protection of public health." Under this "public health" standard, could FDA approve a product that a significant number of youths are currently using?

FDA reviews marketing applications on a case-by-case basis and does not predetermine the result of the review of any category or specific type of product. Nonetheless, the burden will be on each individual company to demonstrate that the product which is the subject of an application warrants marketing authorization. In general, when reviewing a PMTA, the FD&C Act requires FDA to assess the risks and benefits to the population as a whole, including users and nonusers – including youth, young adults, older adults, former smokers, never smokers, and others. Applicants should include information in their submissions that describes the likelihood of product initiation and cessation by both users and nonusers, consumer perceptions and product appeal, abuse liability and addictiveness of the product, and anticipated or observed product use patterns including frequency and topography. The applicant should provide this information for the population as a whole as well as for specific at-risk populations, e.g., youth, former users.

If a PMTA is filed and scientific review begins, FDA will evaluate scientific evidence submitted to determine how the new product compares to currently marketed products with respect to risk to individual users, and whether marketing of the new product will affect the likelihood of nonuser initiation, cessation rates or shifts in user demographics, and an overall decrease in morbidity and mortality from use of tobacco products. As part of this, FDA will need to understand how youth may use or intend to use the proposed product because youth are a population of particular concern for initiating tobacco use in order to assess whether permitting the marketing of a proposed product would be appropriate for the protection of the public health.

FDA will also consider how the applicant intends to minimize the extent to which youth can access the product and are exposed to its marketing. Where FDA determines that restrictions on the sales and distribution of the new tobacco product (including access to, and the advertising and promotion of, the tobacco product) would be appropriate for the protection of the public health, FDA can impose such restrictions under the terms of a marketing order.

Manufacturers that submit a PMTA and receive a marketing order are required to submit postmarket reports to FDA, as FDA requires under its authority in section 910(f) of the FD&C Act to help inform its determination of whether marketing of the product continues to be appropriate for the protection of the public health. This could include, for example, reports regarding the volume of sales, demographics of purchasers, and other sales data, which provide information that can help indicate trends in tobacco use behavior for the product, such as whether nonusers are initiating tobacco product use with the product and current tobacco product users

are using the product. For example, data that indicate higher rates of youth initiation with the tobacco product than anticipated in the PMTA could result in FDA finding that continued marketing of the tobacco product is no longer appropriate for the protection of the public health and the marketing order should be withdrawn under section 910(d)(1)(A) of the FD&C Act.