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Division of Dockets Management
Food and Drug Administration
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Rockville, MD 20852

Re: Regulation of Flavors in Tobacco Products, Advance Notice of Proposed Rulemaking (Docket No. FDA-2017-N-6565)

These comments are submitted on behalf of National Tobacco Company, LP (NTC) in response to the U.S. Food and Drug Administration's (FDA's or the Agency's) March 21, 2018, advance notice of proposed rulemaking (ANPRM) seeking comments, data, research results, or other information about flavors in tobacco products.[1]

NTC manufactures, markets, and distributes traditional tobacco products. NTC's tobacco products include: large cigars (i.e., cigarillos), cigar wrappers, moist snuff, loose leaf chewing tobacco, and pipe tobacco. NTC does not manufacture or sell cigarettes. NTC's brand portfolio includes Zig-Zag®, Stoker's® and Beech-Nut®, each with multiple brand styles. A product standard restricting use of flavors in tobacco products would potentially impact a number of NTC's traditional tobacco products.

This ANPRM seeks comment and information on numerous identified topics and questions related to flavors in tobacco products. As requested by FDA, the following comments identify the Federal Register notice section and question number associated with each point.

As an initial matter, NTC supports the continued availability of flavored products and consumer choice. There is a long history of adult consumer interest in flavored cigars, flavored smokeless tobacco, and flavored pipe tobacco. Traditional tobacco products come in a wide range of flavors and, in most cases, such flavor varieties are not new. Indeed, there are flavored smokeless tobacco products that date back almost one hundred years. Any regulation of flavored tobacco products should take into account the history of flavor varieties and the significant adult

[1] Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294 (Mar. 21, 2018).

use of those products within each tobacco category. Significantly, one of Congress's stated purposes for passing the Family Smoking Prevention and Tobacco Control Act (TCA) was "*to continue to permit the sale of tobacco products to adults* in conjunction with measures to ensure that they are not sold or accessible to underage purchasers."[2]

The TCA authorizes FDA to adopt new tobacco product standards, such as limits on flavors, only where they are appropriate for the protection of the public health taking into account the scientific evidence concerning risks and benefits to the population as a whole, the likelihood that existing users of tobacco products will stop using such products, and the likelihood that those who do not use tobacco products will start using such products.[3] The statute additionally requires FDA to consider information related to the countervailing effects of the tobacco product standard on the health of adolescent and adult tobacco users and non-tobacco users, including the creation of a significant demand for contraband or other tobacco products,[4] as well as the technical achievability of compliance with such standard.[5]

NTC submits that the currently available data and information – including those cited in the ANPRM – do not provide FDA a basis for issuing a tobacco product standard under Section 907 of the Federal Food, Drug, and Cosmetic Act (FFDCA or Act) to restrict flavors in non-cigarette tobacco products. FDA can address its primary concern with respect to flavors – youth and young adult initiation and use –via increased and more-effective enforcement of federal regulations at 21 C.F.R. part 1140, including the prohibition on sales to minors. Importantly, this much more direct approach would present neither the significant illicit trade and concomitant law enforcement problems nor the concerns around so-called do-it-yourself (DIY) flavoring markets that a flavored product standard would create.

Virtually all tobacco products contain added ingredients that have an impact on flavor. Accordingly, if FDA were to issue a product standard restricting flavors in tobacco product – an action for which FDA currently lacks an adequate science base as required by law – the Agency would need to limit the restriction to use of only "characterizing flavors," which must be clearly defined. In the absence of such a precise limitation, a broad ban on flavors would be tantamount to a ban on entire categories of tobacco products (e.g., pipe tobacco, moist snuff), which may contain, for example, casing ingredients that could impact the flavor of the product.[6]

For example, FDA food labeling regulations define a "characterizing flavor" as one where "the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food … designate[s] the type of flavor in the food other than through the statement of ingredients."[7] A product standard

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[2] Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat. 1776 (2009), § 3(7) (emphasis added) (TCA).
[3] Federal Food, Drug, and Cosmetic Act (FFDCA) § 907(a)(3)(B)(i); 21 U.S.C. § 387g(a)(3)(B)(i).
[4] FFDCA § 907(b)(2); 21 U.S.C. § 387g(b)(2).
[5] FFDCA § 907(b)(1); 21 U.S.C. § 387g(b)(1).
[6] For example, we refer FDA to comments filed to this docket by the Pipe Tobacco Council.
[7] 21 C.F.R. § 101.22(i).

restricting use of flavors in tobacco products without such a limitation – for example, a standard that defines a product as "flavored" based on the presence of a particular ingredient or constituent or by the product's "multisensory" experience – would create be an unmanageable morass of implementation and enforcement issues. Such a vague and potentially broad product standard would also raise substantial technical achievability questions. For instance, given FDA's historical position that products modified to comply with product standards must undergo premarket review under section 910 of the FFDCA, a broad standard prohibiting "flavors" in tobacco products could require companies like NTC to reformulate entire categories of their product portfolios and obtain FDA authorization for each product modified to comply with the standard. Likewise, limiting a flavor standard to certain so-called "youth-appealing" flavors would be unsupportable based on existing scientific evidence, impossible to implement, and likely Constitutionally infirm.

A. The Role of Flavors (Other Than Tobacco) in Tobacco Products

1. *Provide studies or information regarding the role of flavors (other than tobacco) generally in tobacco products. If the response relies on research in other areas (e.g., consumer products), discuss the appropriateness of extrapolating from such research to tobacco products.*

B. Flavors (Other Than Tobacco) and Initiation and Patterns of Tobacco Product Use, Particularly Among Youth and Young Adults

2. *Provide studies or information regarding the role of flavors (other than tobacco) in initiation and/or patterns of use of combusted tobacco products, particularly among youth and young adults.*
3. *Provide studies or information regarding the role of flavors (other than tobacco) in initiation and/or patterns of use of noncombusted tobacco products, particularly among youth and young adults.*
4. *Provide studies or information regarding the role of flavors (other than tobacco) in noncombusted tobacco products on initiation of tobacco product use or progression to use of other tobacco products (for example, from noncombusted to combusted tobacco products), particularly among youth and young adults.*

An analysis of the role of flavors in tobacco products must be analyzed in the specific context of each category of tobacco products individually. Flavored tobacco has a long tradition in the United States, particularly in the context of older adult use of traditional flavored smokeless tobacco, pipe tobacco, and cigar products. Many traditional flavors, such as Cherry, Honey, Whiskey, Rum, Apple and Grape, have been available to adult consumers for over one hundred years, and a ban on the sale of these products simply removes the right of adults to enjoy traditionally flavored tobacco products without evidence of any anticipated meaningful reduction in youth or young adult access or use.

NTC is not aware of any reliable scientific data that demonstrate that flavors in loose leaf chewing tobacco, moist snuff, pipe tobacco, cigar wraps, or cigarillos – the flavored products

marketed by NTC – increase abuse liability or youth/young adult initiation or use. NTC acknowledges that the analysis of the role of flavors differ for combustible products such as cigarillos as compared to the analysis for non-combustible products such as smokeless tobacco. However, even within these classes, individual product categories (e.g., moist snuff, loose-leaf chewing tobacco, cigarillos, pipe tobacco, cigar wraps) must be considered independently as the use patterns, user demographics, and risk to users varies by such category. Nevertheless, NTC submits that, even in the context of pipe tobacco, cigarillos, and cigar wraps, there are no category-specific data that indicate that flavors increase abuse liability or youth/young adult initiation or use in any such category.

Without such relevant data, FDA does not have a statutory basis to ban or limit flavors in these products. Under section 907 of the FFDCA, in order to promulgate a tobacco product standard, FDA must demonstrate that the product standard is appropriate for the protection of the public health, taking into account scientific evidence concerning:

1. The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;
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.

FDA's ANPRM does not cite sufficient scientific evidence to support a flavor ban or restriction in any specific category of non-cigarette product, and NTC is not aware that such an evidence base exists for any such category. Given the evidentiary requirements of section 907 of the FFDCA and the Administrative Procedure Act (APA), FDA cannot establish a broad flavored tobacco product standard but rather may promulgate product standards applicable to individual product categories (e.g., cigarettes) if supported by sufficient evidence specific to the product category. Where Congress and FDA have acted in the past to propose or enact a product standard, based on the acknowledged complexity of the issue, the (proposed) standard dealt with each potential concern and respective product category individually.[8]

For example, when Congress merely directed FDA to evaluate the evidence for potentially extending the statutory, partial ban on use of characterizing flavors in cigarettes and their components to include menthol, the Agency had to review only <u>one</u> flavor in <u>one</u> product category and obtained a legally required review by the Tobacco Product Scientific Advisory Committee (TPSAC) of this limited flavor-category combination.[9] Even after review of the 2011 TPSAC report on menthol, FDA's 2013 independent review of the impacts of menthol cigarettes, and the comments submitted to the Agency's 2013 menthol ANPRM docket, FDA has apparently concluded it lacks an appropriate scientific basis to prohibit or restrict use of this

[8] *See* FFDCA § 907(a)(1)(A); 21 U.S.C. § 387g(a)(1)(A) (establishing partial ban on use of characterizing flavors in cigarettes and their components); *see also* Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products, Proposed Rule, 82 Fed. Reg. 8,004 (Jan. 23, 2017).
[9] FFDCA § 907(e); 21 U.S.C. § 387g(e).

flavoring ingredient in cigarettes.[10] FDA must apply the same degree of rigor and specificity in evaluating potential product standards on use of flavors in other categories of tobacco products.

Importantly, FDA has approved numerous flavored nicotine-containing products through the drug premarket review process, apparently concluding that flavors did not increase abuse liability. Nicotine gum is currently marketed in flavors such as "ice mint," "fruit chill", "cinnamon surge," "spearmint burst," "fruit wave," "lively mint," "white ice mint" and "cool mint," while nicotine lozenges are currently marketed in in cherry and mint. The data support that these flavored products do not increase abuse liability. For instance, a 2002 study concluded: "Improved flavor of nicotine gum does not increase abuse liability, but may be associated with enhanced craving reduction."[11] FDA has also approved premarket tobacco applications (PMTAs) for flavored snus products.[12] Likewise, in the context of e-cigarettes, a 2015 study concluded that "[t]he e-cigarette flavors tested appealed more to adult smokers than to nonsmoking teens, but interest in flavors was low for both groups."[13]

Moreover, sales data show that the vast majority of NTC's cigar wraps, cigarillos, loose leaf chewing tobacco, pipe tobacco, and moist stuff are purchased by older adults. As explained below, rather than banning or restricting flavors (an action which is not supported by the evidence), the most direct and effective way to address any youth and young adult initiation and use concerns is to actively enforce existing age restrictions for both brick-and-mortar retailers and online.

C. Flavors (Other Than Tobacco) and Cessation, Dual Use, and Relapse Among Current and Former Tobacco Product Users

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[10] *See* FDA Tobacco Products Scientific Advisory Committee, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* (July 21, 2011), *available at* https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf; Food and Drug Administration, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes* (2013), *available at* https://www.fda.gov/downloads/ucm361598.pdf;; Versar, Inc., *Peer Review Summary Report: External Peer Review of the FDA Scientific Evaluation of the Possible Health Effects of Menthol versus Nonmenthol Cigarettes* (Oct. 18, 2011), *available at* https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM361052.pdf; Menthol in Cigarettes, Tobacco Products; Request for Comments; Advance Notice of Proposed Rulemaking, 78 Fed. Reg. 44,484 (July 24, 2013).

[11] Elisabeth J. Houtsmuller et al., *Flavor improvement does not increase abuse liability of nicotine chewing gum*, 72 Pharmacology Biochemistry & Behavior 559-68 (2002).

[12] In the Technical Project Lead (TPL) Review for the Swedish Match General brand snus PMTAs (PM0000010-PM0000017), FDA observed that "[w]hile flavored smokeless tobacco products are a potential concern of youth initiation, these proposed flavors [flavors such as mint, wintergreen, or tobacco character with citrus] are consistent with traditionally available ST flavors and are not novel flavors that likely increase appeal to youth."

[13] Saul Shiffman et al., *The Impact of Flavor Descriptors on Nonsmoking Teens' and Adult Smokers' Interest in Electronic Cigarettes*, 17 Nicotine & Tobacco Research 1255-62 (2015) (Shiffman 2015).

5. *Provide studies or information regarding the role of flavors (other than tobacco) in helping adult cigarette smokers reduce cigarette use and/or switch to potentially less harmful tobacco products.*
6. *Provide studies or information regarding the role of flavors (other than tobacco) in noncombusted tobacco products on the likelihood of: (1) cessation of combusted tobacco products use, (2) cessation of all tobacco product use, and (3) uptake of dual use of combusted and noncombusted tobacco products among current and former tobacco product users. Include information from, and define, all populations: youth, young adults, and adults (and any subgroup thereof, if applicable).*
7. *Provide studies or information regarding the role of flavors (other than tobacco) in noncombusted products on the likelihood of: (1) delayed or impeded cessation among users who would have otherwise quit combusted tobacco product use, or (2) delayed or impeded cessation among users who would have otherwise quit all tobacco product use. Include information from, and define, all populations: youth, young adults, and adults (and any subgroup thereof, if applicable).*
8. *Provide studies or information regarding the role of flavors (other than tobacco) in noncombusted tobacco products on the likelihood that former combusted tobacco product users relapse. Include information from, and define, all populations: youth, young adults, and adults (and any subgroup thereof, if applicable).*

In light of the established lower risks of individual harm associated with use of noncombusted tobacco products, including smokeless tobacco,[14] FDA should not even consider a ban or limitation on flavors in these products. Both FDA Commissioner Scott Gottlieb and Center for Tobacco Products Director Mitch Zeller have repeatedly emphasized the need to move smokers down the continuum of harm to lower-risk products; it is therefore contrary to FDA's comprehensive nicotine policy and public health approach to impose a flavor standard on noncombusted products such as smokeless. Doing so could make them less attractive and acceptable to smokers, thereby potentially decreasing the rate of migration from combusted products to smokeless products.

D. Additional Public Health Considerations

9. *Provide studies or information regarding the potential toxicity or adverse health effects to the user or others from any flavors (e.g., flavor additives, compounds, or ingredients) in tobacco products. These adverse health outcomes may include, but are not limited to, cancer or adverse respiratory, cardiac, or reproductive/development effects. Of particular interest are studies or information on inhalation exposure to any flavor.*

[14] *See, e.g.*, Peter N. Lee & Jan Hamlin, *Systematic review of the relation between smokeless tobacco and cancer in Europe and North America*, 7 BMC Med. 36 (2009); Scientific Committee on Emerging and Newly Identified Health Risks, *Health Effects of Smokeless Tobacco Products* (EC Health & Consumer Prot. Directorate Gen., Scientific Opinion, 2008), *available at* http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf; David J. Nutt et al., *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, 20 European Addiction Research 218–25 (2014); Tobacco Advisory Group of the Royal College of Physicians, Protecting smokers, saving lives: The case for a tobacco and nicotine regulatory authority at 5 (2002).

Provide studies or information on what, if any, toxic chemicals might be formed from the heating or burning of tobacco products with flavors and the potential toxicity or health risks that might result from these formed chemicals.

With respect to the potential toxicity of certain flavor ingredients in oral-use products (e.g., chewing tobacco, moist snuff), FDA should defer to determinations of safety for food use where existing data establish safety for exposure levels expected from established patterns of use of such oral-use tobacco products. With respect to the potential toxicity of flavor ingredients in combustible products such as pipe tobacco, cigarillos, and cigar wraps, FDA should consider establishing product standards that would prohibit or limit use of only those ingredients or flavor-related manufacturing methods that have been scientifically demonstrated to meaningfully increase the toxicity of specific categories of tobacco products. This should involve a complete scientific assessment of each ingredient, including the ranges of levels used in specific product categories and risk modeling based on established patterns of use for the specific product categories, the toxicity of other ingredients used in each category of product (including tobacco), and the quantities thereof.

This approach should also account for relative-risk considerations, including the product's position on the so-called continuum of risk and how compliance with the proposed standard may impact consumer behavior, including whether removing the flavoring ingredient may cause consumers to initiate or continue use of other products (e.g., cigarettes) that may present greater levels of risk to the individual consumer. For any finalized standards, FDA's implementation period must include sufficient time for industry to reformulate products to comply with applicable product standards. Importantly, for products requiring reformulation to comply, FDA must establish a workable and efficient process to obtain authorization to market products modified to meet the standard.

10. *Provide studies or information on the impact, whether intended or unintended, of public health efforts by local jurisdictions, States, and members of the international community to impose restrictions on the manufacture, marketing, sale or distribution of all or a subset of tobacco products with flavors (other than tobacco), including but not limited to cigars, ENDS, menthol cigarettes, and smokeless tobacco products.*

Under the FFDCA, FDA must consider information concerning the countervailing effects of a tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband, or other tobacco products that do not meet the requirements of the Act, and the significance of this demand. NTC submits that a broad flavor ban would result in serious adverse and unintended consequences, such as the creation of a black market and the concomitant law enforcement concerns.

With black markets come organized crime and violence. For example, an official from New York City, where tobacco taxes are extremely high, described black market cigarettes as the

"principal stoking facility of the engine of organized crime."[15] Some sources have noted that profits from illicit trade in cigarettes in the United States may help fund terrorist organizations, including Hezbollah.[16] Indeed, in 2006, the United States government indicted members of an alleged conspiracy to distribute counterfeit versions of our company's Zig-Zag cigarette papers, the proceeds from which the conspirators would allegedly funnel to Hezbollah.[17] An increase in organized crime and violence would, of course, lead to increased law enforcement burdens and costs as well as decreased public safety.

Moreover, the development of illicit trade channels would drive tobacco product transactions out of legitimate businesses that FDA inspects to ensure compliance with 21 C.F.R. part 1140, including its prohibition on underage sales. If sales of flavored products go underground, the government would have a significantly diminished ability to limit access to those of legal age to purchase. Again, if the primary concern here is youth and young adult access and use, keeping products on the legitimate market and strictly enforcing the minimum purchase age requirements is the most effective and direct way to address this important concern.

As the Agency notes, a number of local jurisdictions (e.g., New York City, San Francisco, Providence, Chicago) have already enacted bans on the sale of, or significant restrictions on the locations where retailers may sell or the types of retailers that may sell, flavored tobacco products. This has resulted in a growing patchwork of local restrictions that lack scientific basis (and, in some cases, raise preemption concerns). Indeed, a review of the administrative records of many of these local restrictions revealed the citation of very little, if any, adequate scientific evidence to support them. Any scientific data cited in these records usually consisted only of flavored/menthol cigarette studies. As part of any further FDA rulemaking process – which must be based on adequate scientific evidence per the FFDCA and APA – FDA should clearly state that any state or local flavor ban or restriction that differs from or exceeds FDA's product standards under Subchapter IX of Chapter 9 of title 21 of the United States Code (or Chapter IX of the FFDCA) is preempted pursuant to section 916 of the FFDCA.[18]

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[15] Patrick Fleenor, *Cigarette Taxes, Black Markets, and Crime Lessons from New York's 50-Year Losing Battle*, (Cato Inst., Policy Analysis No. 468, 2003), *available at* https://www.cato.org/publications/policy-analysis/cigarette-taxes-black-markets-crime-lessons-new-yorks-50year-losing-battle.

[16] Nat'l Research Council, Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences (Peter Reuter & Malay Majmundar, eds., Nat'l Acads. Press 2015); Thomas M. Sanderson, *Transnational Terror and Organized Crime: Blurring the Lines*, 24 SAIS Review of Int'l Affairs 49–61 (2004); Louise I. Shelley & Sharon A. Melzer, *The Nexus of Organized Crime and Terrorism: Two Case Studies in Cigarette Smuggling*, 32 Int'l J. of Comparative & Applied Criminal Justice 43–63 (2008); U.S. Immigration and Customs Enforcement, *News Release: Mohamad Youssef Hammond sentenced to 30 years in terrorism financing case* (Jan. 27, 2011), *available at* https://www.ice.gov/news/releases/mohamad-youssef-hammoud-sentenced-30-years-terrorism-financing-case.

[17] *See, e.g.*, First Superseding Indictment, United States v. Nasser, Crim. No. 03-80406 (E.D. Mich. Mar. 29, 2006); Rule 11 Plea Agreement, United States v. Nasser, Crim. No. 03-80406 (E.D. Mich. Sept. 20, 2006); Judgment, United States v. Nasser, Crim. No. 03-80406 (E.D. Mich. Mar. 27, 2009).

[18] *See* FFDCA § 916(a)(2)(A); 21 U.S.C. § 387p(a)(2)(A). The preemption provision contains a clause that "saves" from preemption state and local requirements "relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion off, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products." FFDCA § 916(a)(2)(B); 21 U.S.C. § 387p(a)(2)(B). However, FDA should consider local laws that expressly or effectively prohibit the sale of any or certain flavored

11. Provide studies or information regarding consumer perceptions of the health risks of tobacco products with flavors (other than tobacco) when compared to other tobacco products, both with and without flavors. Include information from, and define, all populations: Youth, young adults, and adults (and any subgroup thereof, if applicable).

12. Provide studies or information regarding consumer perceptions, if any, of the addictiveness of tobacco products with flavors (other than tobacco). Include information from, and define, all populations: Youth, young adults, and adults (and any subgroup thereof, if applicable).

E. Tobacco Product Standards

13. All Flavors

a. Are there any specific flavors for which FDA should establish a tobacco product standard? If so, which flavors (e.g., flavor additives, compounds, or ingredients) and why?

As noted above, FDA should promulgate a flavor product standard only where specific flavor ingredients or manufacturing processes have been scientifically demonstrated to meaningfully increase the toxicity of particular tobacco products. This process should involve a complete scientific assessment of each ingredient, including the ranges of levels used in specific product categories and risk modeling based on established patterns of use for the specific product categories, the toxicity of other ingredients used in each category of product (including tobacco), and the quantities thereof. This approach should also account for relative-risk considerations, including the product's position on the so-called continuum of risk and how compliance with the proposed standard may impact consumer behavior, including whether removing the flavoring ingredient may cause consumers to initiate or continue use of other products (e.g., cigarettes) that may present greater levels of risk to the individual consumer. In the context of flavor ingredients in oral-use products (e.g., chewing tobacco, moist snuff), FDA should defer to determinations of safety for food use where existing data establish safety for exposure levels expected from established patterns of use of such oral-use tobacco products.

Importantly, where FDA requires reformulation of product to comply with such a standard, the Agency must at the same time ensure there is a workable process to facilitate efficient premarket authorization for products modified to comply with the standard.

b. With respect to your response to the previous question, what level (e.g., maximum, minimum, prohibition) should FDA establish to protect the public health, and why?

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tobacco products as preempted product standards and not permissible restrictions on the sale and distribution of such products.

In order to determine acceptable, toxicity-based limits on flavor ingredients of concern in tobacco products, FDA should follow scientifically-valid processes similar to those used when evaluating the toxicity of ingredients in food or drug products. However, this approach should focus on the extent to which the flavor ingredient's use meaningfully increases the toxicity of particular tobacco products, taking into account other ingredients used in each category of product (including tobacco) as well as the quantities thereof and patterns-of-use-based exposure rates. This approach should also account for relative-risk considerations, including the product's position on the so-called continuum of risk and how compliance with the proposed standard may impact consumer behavior, including whether removing the flavoring ingredient may cause consumers to initiate or continue use of other products (e.g., cigarettes) that may present greater levels of risk to the individual consumer. Moreover, ingredients or combinations thereof that provide a certain flavor profile may have different chemical compositions (e.g., one supplier's cherry flavor may have a completely different chemical profile than another's). Accordingly, FDA should perform this analysis on an ingredient-by-ingredient basis rather than through blanket prohibitions or restrictions on categories of or specific flavors.

14. *If FDA were to establish a tobacco product standard prohibiting or restricting flavors, to which types of tobacco products should the standard apply (e.g., combusted, noncombusted, both), and why?*

As noted above, NTC submits that the primary government interests in this context – addressing youth and young adult tobacco product initiation and use – should be addressed more directly and effectively through implementation and strict enforcement of underage sale restrictions rather than via a tobacco product standard prohibiting or restricting flavors in particular tobacco products. In addition, any flavor standard considered by FDA must be analyzed with respect to each individual category of products (e.g., cigar wraps, cigarillos, pipe tobacco, loose leaf chewing tobacco, moist snuff) with scientific support specifically relevant to that individual category of products. FDA cannot meet its statutory burden by referencing all combusted tobacco products or all noncombusted tobacco products but rather must rely on product-specific data to support its regulatory actions. This reflects how different categories of products within the broader classifications of "combusted" and "noncombusted" have different user demographics and patterns of use. It also reflects how use of flavors in tobacco products can raise different youth and young-adult appeal, initiation, and abuse-liability concerns depending on the subcategory of the product in question.

15. *Menthol Flavor*
    c. *FDA has carefully reviewed the data it received in response to the 2013 ANPRM on menthol in cigarettes (78 FR 44484, July 24, 2013). Provide any additional data or information about the role of menthol in cigarettes, particularly regarding the role menthol plays in smoking initiation and in the likelihood of smoking cessation for all populations (youth, young adult, adult).*
    d. *What additional evidence exists on the likelihood that smokers would completely switch to another tobacco product, or start dual use with another product, in the event of a tobacco product standard prohibiting or limiting menthol in cigarettes?*

e. What is the role, if any, that menthol plays in use of tobacco products other than cigarettes, including, but not limited to, cigars and ENDS.

The existing menthol science, which FDA has apparently found insufficient to support a menthol standard for cigarettes to date, is largely limited to the cigarette category and generally does not apply to cigar or smokeless tobacco products. Because cigar, cigar wrap, and smokeless products have substantially different user demographics and patterns of use relative to cigarettes, among other differences, the cigarette menthol science cannot be extrapolated to these other products. Accordingly, any restriction on use of menthol in cigar, cigar wrap, and smokeless tobacco products must be based on adequate, product-specific scientific evidence.

F. Sale or Distribution Restrictions

16. FDA may consider restrictions on the sale and distribution of flavored tobacco products. Possible restrictions could include restrictions on the advertising and promotion of tobacco products with flavors; on access to tobacco products with flavors; and/or on the label, labeling, and/or packaging of tobacco products with flavors. These restrictions could include requirements to bear warnings or disclosure statements. What such restrictions, if any, should FDA consider and why?

Selling tobacco products—of any variety—to minors is already illegal under Federal law. In addition, in an increasing number of state and local jurisdictions, the age to purchase tobacco products is 19 or 21. Instituting a product standard prohibiting or restricting use of flavors in specific tobacco products such as cigars and smokeless tobacco is not the most effective way to the address the Agency's primary concern about youth/young adult initiation and use. Indeed, banning the sale of tobacco products with certain flavors would inappropriately limit consumer choice to the detriment of the many adult consumers who currently enjoy these legal products[19] As discussed above, it would also risk creating a black market that would drive sales of such products underground or create a do-it-yourself (DIY) flavoring market, increasing the risk of youth access and potential harm.

The most direct and effective way to limit tobacco product initiation and use among youth and young adults is to actively enforce existing age restrictions and strictly limit underage access. Indeed, it appears that underage youth are still purchasing tobacco products in significant amounts at retail despite such legal restrictions. For example, the Truth Initiative® surveyed a national sample of more than 1,000 12- to 17-year-olds in April 2018 and found that 74% of those youth surveyed obtained their JUUL electronic nicotine delivery system flavor pods at a physical retail location.[20] Thus, FDA should first focus its efforts on reducing underage sales at the retail level. In addition, FDA should immediately establish and enforce standards for online

[19] *See* TCA § 3(7) (expressing Congressional intent "to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers" in enacting the TCA).
[20] Truth Initiative, *Where are kids getting juul?* (May 29, 2008), *available at* https://truthinitiative.org/news/where-are-kids-getting-juul.

age-verification procedures, including for third-party distributors like Amazon, eBay and other online marketplaces. Finally, as the National Association of Tobacco Outlets, Inc. (NATO) has repeatedly urged, FDA should engage in educational campaigns – and, in conjunction with local authorities, stepped-up enforcement activities – to address the issue of social sources of tobacco products for underage youth. These approaches would provide more immediate impacts and avoid the complicated Constitutional, scientific and illicit trade issues (and attendant delays) that seeking to address youth access and initiation issues through a flavored tobacco product standard rulemaking would.

Any restrictions on advertising or labeling of flavored products considered by FDA, including warnings or disclosure statements, must be supported by scientific evidence and closely tailored to a demonstrated government interest in order to comply with First Amendment protections.

G. Other Actions and Considerations

17. *To the extent that flavors may pose both (1) potential benefits to adult smokers who might consider switching to a noncombusted flavored tobacco product with lower individual risk and (2) potential risks to nonusers who might initiate use of tobacco products through flavored tobacco products or to current users who might progress to flavored tobacco products with higher individual risks, how should FDA assess and balance these benefits and risks?*
18. *Provide studies or information on the role of tobacco flavor in tobacco products in initiation, patterns of use of tobacco products (particularly with respect to progression from non-combusted to combusted tobacco products or from combusted to non-combusted), reduction in use of combustible tobacco products and cessation of tobacco products. Include information from, and define, all populations: Youth, young adults, and adults (and any subgroup thereof, if applicable).*

In addition to actively enforcing existing age restrictions and strictly limiting underage access both in physical retail locations and online, FDA must clearly and accurately communicate to the public (via, for example, FDA's successful public health education campaigns, which can apparently be specifically targeted to particular demographics) the relative risks of tobacco products so that all consumers can make educated purchasing decisions. This could include any scientifically-supported messages regarding flavors in particular tobacco products. FDA should also defer any action on a flavor standard pending the development of adequate scientific data on the harm-reduction potential of noncombusted flavored tobacco products in order to avoid the unintended consequence of consumers continuing or resuming cigarette smoking due to the unavailability of non-tobacco flavored products.

19. *Provide information on whether manufacturing process(es) affect product flavor. Describe any such manufacturing process(es), including the specific products that use the process(es), as well as specific flavors used in the process(es).*
20. *Provide analyses regarding any other tobacco product standard, regulatory action, or other action that FDA could implement that you believe would more effectively reduce the harms caused by flavors in tobacco products to better protect the public health than*

the tobacco product standards or other regulatory actions discussed in the preceding questions.

21. *Discuss any other tobacco product standard, regulatory action, or other activity that FDA could pursue that would complement or increase the effectiveness of the potential tobacco product standards or other regulatory actions discussed in the preceding questions.*

As noted above, FDA should promulgate a flavor product standard only where specific flavor ingredients or manufacturing processes have been scientifically demonstrated to meaningfully increase the toxicity of specific categories of tobacco products. This should involve a complete scientific assessment of each ingredient, including the ranges of levels used in specific product categories and risk modeling based on established patterns of use for the specific product categories, the toxicity of other ingredients used in each category of product (including tobacco), and the quantities thereof. This approach should also account for relative-risk considerations, including the product's position on the so-called continuum of risk and how compliance with the proposed standard may impact consumer behavior, including whether removing the flavoring ingredient may cause consumers to initiate or continue use of other products (e.g., cigarettes) that may present greater levels of risk to the individual consumer. In the context of flavor ingredients in oral-use products (e.g., chewing tobacco, moist snuff), FDA should defer to determinations of safety for food use where existing data establish safety for exposure levels expected from standard use of such oral-use tobacco products. Importantly, where FDA requires reformulation of product to comply with such a standard, the Agency must at the same time ensure there is a workable process to facilitate premarket authorization for products modified to comply with the standard.[21]

In addition, as discussed above, the most direct and effective way to limit tobacco product initiation and use among youth and young adults is to actively enforce existing age restrictions and strictly limit underage access. FDA should first focus its efforts on reducing underage sales at the retail level. In addition, FDA should immediately establish and enforce standards for online age-verification procedures, including for third-party distributors like Amazon, eBay and other online marketplaces. These approaches would provide more immediate impacts and avoid the complicated Constitutional, scientific and illicit trade issues (and attendant delays) that seeking to address youth access and initiation issues through a flavored tobacco product standard rulemaking would implicate.

[21] In this vein, FDA should consider utilizing enforcement discretion to allow for changes to legally marketed products to comply with product standards via self-certification or notification procedures, short of requiring a full Substantial Equivalence report or Premarket Tobacco Product Application. Such a process could allow regulated parties to alter a product in order to comply with a finalized product standard while allowing FDA to utilize its broad authority to request further information on any changes. Such changes could also be referenced in later-filed SE or PMTA submissions.

22. Are there any flavors that especially appeal to youth, young adults, or other specific age group? If so, how are such flavors distinguished from other flavors?

NTC is aware of no adequate data that could distinguish flavors that especially appeal to youth or young adults from those that appeal to adults. Just as adults frequently purchase and consume all varieties of candy, ice cream, and other flavored products,[22] all kinds of flavored tobacco products are widely purchased and used by all adult demographic groups. Indeed, in the context of e-cigarettes, a 2014 study concluded that "[t]he e-cigarette flavors tested appealed more to adult smokers than to nonsmoking teens…."[23] Limiting a flavor standard to certain so-called "youth-appealing" flavors would be unsupportable by currently available scientific evidence and could prove unfeasible to implement, for example, due to vagueness concerns. Moreover, depending on the flavor, some flavors that may sound more child-friendly may prove less appealing to youth and young adults who are seeking more mature, adult-focused products to seem more grown-up and sophisticated to their peers. Older adult consumers may instead prefer these ostensibly child-friendly flavors due to nostalgia or unrelated hedonic reasons.

23. To the extent that you have identified a tobacco product standard or other regulatory action in response to the prior questions, provide additional information and comments on: (1) The technical achievability of compliance with the tobacco product standard or other regulatory action you identified; and (2) how FDA could maximize compliance and public health benefits.

As explained above, limiting tobacco product initiation and use among youth and young adults is best accomplished by actively enforcing existing age restrictions and strictly limiting underage access. This is by far the most practical and technically achievable approach to achieve the government's interest in this context. FDA should first focus its efforts on reducing underage sales at the retail level. In addition, FDA should immediately establish and enforce standards for online age-verification procedures, including for third-party distributors like Amazon, eBay and other online marketplaces.

Technical achievability, compliance, legal, and public health considerations do not support promulgation of a vague and speculative product standard prohibiting use of flavors deemed "youth-appealing." FDA should also avoid promulgating any a flavor-related product standard that would require the removal from the market of flavored tobacco products currently used in significant numbers by adult consumers. Such drastic action could lead to increased illicit trade, the creation of a DIY flavoring market and increased DIY flavoring practices, and the concomitant law enforcement and public health concerns described above.

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[22] For example, a 2014 study conducted by The Nielsen Company found that 58% of surveyed men age 21 and over like flavored alcoholic beverages and that 73% of surveyed women age 21 and over like flavored alcoholic products. *See* The Nielsen Company (US) LLC, Nielsen QuickQuery Survey, http://www.nielsen.com/us/en/insights/news/2015/americans-have-the-fever-for-flavor-alcoholic-beverages-and-creative-taste-profiles.html (Mar. 16, 2015). This suggests that a majority of legal consumers like flavored alcoholic products based on their personal tastes.

[23] *See* Shiffman 2015.

Finally, on the topic of technical feasibility, if FDA is to promulgate any flavor product standard, it must establish a streamlined process for obtaining marketing authorization for any changes made to products in order to meet that standard.

24. *If FDA were to establish a tobacco product standard prohibiting or restricting flavors in tobacco products, what evidence is there, if any, that consumers would start to flavor their own tobacco products?*

Multi-use flavor ingredients are widely available in the marketplace. Based on the popularity of flavored products, it seems inevitable that a flavored product ban would lead to DIY flavoring. Indeed, even today, there are many websites that promote the sale and/or formulation of DIY flavors for various tobacco products.[24]

25. *What data may be used to assess and analyze the range and variety of flavored tobacco products that are currently available to consumers? How can available sources of information, such as manufacturer registrations and/or product listings with FDA, be used in this assessment?*

Section 905 manufacturer registrations and product listings would present significantly under-inclusive information on the range and variety of flavored tobacco products available to U.S. consumers. This is because the manufacturing establishment registration and product listing requirements do not currently apply to foreign manufacturers. Moreover, a review of product names and labeling in such listings would not necessarily indicate which products are flavored, and existing FDA forms (appropriately) do not require registrants to provide information on whether products are "flavored" or how so.[25] This is one of the reasons that banning "flavored" products would be so complicated and would raise significant issues regarding technical achievability. Is a product "flavored" if it contains an ingredient that may impart flavor? Or is a product "flavored" only if its name or labeling identifies a particular flavor or flavors? In order to promulgate a flavor product standard that is supported by scientific evidence and is technically achievable, FDA must first fully address these questions.

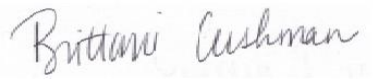
[24] See, e.g., YouTube (approximately 11,900 results for "DIY flavored tobacco"), https://www.youtube.com/results?search_query=DIY+flavored+tobacco (last visited July 18, 2018).

[25] Review of section 904 ingredient listings would provide FDA with data on (compliant) products available to U.S. consumers, regardless of the location of the manufacturer. However, reviewing such submissions for these purposes would also have limitations in that product names alone may not allow FDA to determine the products' "flavored" status. Also, the lack of specific information on the contents of ingredients reported as complex purchased ingredients may give FDA an incomplete picture on the nature of the flavoring ingredients used in a particular product.

* * *

NTC appreciates the opportunity to comment on this ANPRM. Thank you for your review and consideration.

Sincerely,



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