March 7, 2022

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Request to reconsider the exposure modification orders granted to VLN™ and VLN™ Menthol very low nicotine cigarettes

Sent by e-mail.

Dear Director Zeller:

On December 23, 2021, the Food and Drug Administration granted Modified Risk Tobacco Product (MRTP) applications submitted by the 22nd Century Group to make claims for two products, VLN™ and VLN™ Menthol combustible cigarettes, that communicate the products' "very low nicotine levels." As the company had requested, FDA authorized 10 low nicotine claims, including "95% less nicotine" and "greatly reduces nicotine consumption." As part of the exposure modification orders issued for these products, FDA also is requiring that the products' labeling and advertising include the statement "Helps you smoke less."

Although the undersigned organizations have been supportive of various decisions FDA has been making on new product applications, and have filed numerous briefs as *amici curiae* in support of those decisions, after a careful review of the VLN decision, we have determined that it violates the Federal Food, Drug, and Cosmetic Act (FFDCA) because it does not follow the plain language of the statute and essentially erases the clear statutory distinction between subsections (g)(1) and (g)(2) of section 911. As we explain in detail below, for this reason and because of other flaws in the decision, we ask the agency to revoke the decision.[1]

In previously submitted comments on these MRTP applications, we have distinguished the introduction of these products, with claims concerning very low nicotine levels, into the current marketplace, from a marketplace governed by an FDA product standard requiring the nicotine in

[1] Even if FDA does not revoke its modified exposure orders, it should make clear that any rule prohibiting menthol as a characterizing flavor in cigarettes should have the effect of nullifying the order entered as to VLN™ Menthol cigarettes, for all the reasons advanced by the agency in pursuing a rulemaking on a menthol product standard for cigarettes. FDA, News release, *FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers* (Apr. 29, 2021), https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers.

all cigarettes to be reduced to minimally or non-addictive levels.[2] FDA has estimated that reducing nicotine levels in cigarettes to non-addictive levels would prevent more than 33 million youth and young adults from initiating regular smoking by the year 2100.[3] Addressing nicotine levels in tobacco products through comprehensive regulation, rather than on a product-by-product basis, has the best chance of realizing important public health benefits and minimizing unintended consequences.

However, as explained more fully below, the introduction of products like VLN™ and VLN™ Menthol, with claims like those authorized and required by FDA, into a marketplace where highly addictive combustible products remain readily available and are widely promoted, yields none of the public health benefits of a product standard and, indeed, will be a public health detriment. The public health benefits of low nicotine products will be realized only through an industry-wide mandate; they cannot be achieved on a product-by-product basis.

For the following reasons, therefore, we write to urge FDA to reconsider and revoke its exposure modification orders issued for VLN™ and VLN™ Menthol:

(1) By requiring the statement, "Helps you smoke less," the orders exceed the agency's statutory authority;
(2) The authorized MRTP claims will mislead consumers;
(3) The MRTP applications did not demonstrate a potential to benefit the health of the population as a whole;
(4) The MRTP applications offered insufficient evidence on the increased likelihood of tobacco use initiation by non-users, particularly youth;
(5) FDA failed to require consumer perception studies of the applicant's marketing materials prior to granting the application; and
(6) FDA failed to recognize the special risks to certain populations of VLN™ Menthol.

I. THE VLN™ CIGARETTE EXPOSURE MODIFICATION ORDERS EXCEED FDA'S STATUTORY AUTHORITY

Section 911(g) of the FFDCA, 21 U.S.C. § 387k, as enacted by the Family Smoking Prevention and Tobacco Control Act (TCA), outlines the circumstances and manner in which a tobacco product can be marketed as a modified risk tobacco product, and the types of claims that can be made. Under section 911(g)(1), FDA may approve a modified risk claim—such as a claim that the product "presents a lower risk of tobacco-related diseases" or is less harmful than other tobacco products, *see* FFDCA § 911(b)(2)(A)(i)(I)—if it determines that the product, "as . . . actually used by consumers" will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users" and will "benefit the health of the population as a whole." FFDCA § 911(g)(1).

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[2] Comments of American Academy of Pediatrics, et al., in Docket No. FDA-2019-N-0994 (May 18, 2020) at 3-4, https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2020_05_18-Public-Health-Group-Comments.pdf.

[3] Tobacco Product Standard for Nicotine Level of Combusted Cigarettes; Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 11818, 11837 (Mar. 16, 2018) (citing Apelberg, BJ, et al., "Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States," *New England Journal of Medicine*, published online Mar. 15, 2018).

Section 911(g)(2), the part of section 911(g) relied on by FDA to approve the VLN™ products, provides an additional pathway for certain, more limited claims. Entitled the "Special Rule for Certain Products," it is strictly limited to "explicit or implicit representation[s] that [the] tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke." FFDCA § 911(g)(2)(A)(ii). Section 911(g)(2) allows no other type of representation or statement about the product.

To obtain approval under section 911(g)(2), the applicant must also show that approval of the product will "promote the public health," that "scientific evidence is not available . . . without conducting long-term epidemiological studies" showing that the product will significantly reduce the harm and risk of tobacco-related disease to individual tobacco users, and that even without those studies, the scientific evidence that is available "demonstrates that a . . . substantial reduction in morbidity or mortality . . . is reasonably likely in subsequent studies." FFDCA § 911(g)(2)(A). But even if a substantial reduction in morbidity or mortality is reasonably likely, there is no authority under section 911(g)(2) to permit the tobacco company to make such a representation.

When it authorized the VLN™ products, in addition to authorizing the various nicotine reduction claims that 22nd Century had requested, FDA also required that the company state on every label and advertisement that the product "Helps you smoke less," a statement that was not requested by the company. FDA appears to have required this added statement because it determined that it was necessary to instruct consumers how to use the product to obtain its benefits. While a demonstration that the tobacco product "Helps you smoke less" is relevant to whether the product will "significantly reduce . . . tobacco-related disease," FFDCA § 911(g)(1)(A), such a marketing statement is beyond the scope of claims allowed under section 911(g)(2). To make that statement, 22nd Century was required to meet the standards in section 911(g)(1), including the submission of supportive long-term epidemiological studies. By requiring the inclusion of such a statement, without evidence that the standards of section 911(g)(1) have been met, FDA has established a precedent that threatens to undercut and weaken the (g)(1) standards, with adverse public health consequences.

In sum, the "Helps you smoke less" phrase is not authorized under section 911(g)(2), and 22nd Century did not meet (or even attempt to meet) the standards under section 911(g)(1). Accordingly, FDA's orders authorizing the "Helps you smoke less" claim is unlawful.

II. THE AUTHORIZED MRTP CLAIMS WILL MISLEAD CONSUMERS

A. The applicant's consumer perception studies demonstrate that consumers mistakenly believe VLN™ cigarettes are safer.

To obtain a modified exposure order, applicants must have conducted consumer perception studies showing that the reduced exposure claims will not mislead consumers into believing that the product has been shown to be less harmful or to present a lower risk of disease than another tobacco product. *See* FFDCA § 911(g)(2)(B)(iii). As noted in our comments filed in May 2020, the applicant's consumer perception studies confirm that its claims are in fact misleading consumers to believe that VLN™ cigarettes are safer than normal nicotine content (NNC)

cigarettes, consistent with a large body of research finding that many smokers incorrectly link nicotine content with risk for smoking-related disease.[4] This misperception was noted in the Technical Project Lead Review (TPL), which states that, "Indeed, the applicant's quantitative research found that, after viewing VLN™ packs with the proposed modified risk information, participants perceived VLN™ cigarettes as presenting lower risks of tobacco-related disease compared to other cigarettes, including lung cancer and 17 other tobacco-related health effects."[5]

The TPL discounts this harmful misperception by speculating that the respondents were assuming reduced harm due to reduced frequency of smoking, without any cognitive testing to prove this assertion. Given the potential public health harms of such a misperception, mere speculation about how a question was interpreted is wholly insufficient. The TPL asserts that the additional claim—"Helps you smoke less"—will provide further clarification that the health benefits of VLN™ cigarettes are connected to a reduction in smoking, but no research is presented in the publicly available application documents to support this assumption.[6] Moreover, any FDA reliance on this additional claim to counter consumer misperception is misplaced, given the absence of statutory authority to require such a claim.

B. There is insufficient evidence that consumers understand how VLN™ cigarettes can reduce nicotine consumption.

The validity of the approved MRTP claims depends on the extent to which consumers use VLN™ cigarettes in place—and not in addition to—NNC cigarettes. However, this qualifying information is found nowhere on the pack. As we detailed in our May 2020 comments, confusion about how VLN™ cigarettes can reduce your nicotine consumption was identified in the applicant's qualitative studies. Further, Dr. Hatsukami, a leading nicotine reduction scientist, expressed similar concerns at the TPSAC meeting. She stated, "I think what's missing here … is the instruction of completely switching. You know, completely switching, then you'll get the significant reduction in nicotine."[7] She also later noted, "I think one of the gaps is that we really don't know how these smokers are going to use these products when they're given minimal instruction in terms of their use. And so the studies that Dr. Donny and I have conducted were really quite different than what's going to happen on the real marketplace."[8]

These concerns are reiterated in the TPL, which states that, "There are outstanding questions about the manner in which consumers will use VLN™, and if individual tobacco users use VLN™ cigarettes in the same frequency and manner as conventional cigarettes, they will not significantly reduce harm and their risk of tobacco-related disease."[9] The TPL also stated that

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[4] Byron, MJ, et al., "Public misperception that very low nicotine cigarettes are less carcinogenic," *Tobacco Control*, published online Jan. 23, 2018. O'Brien, EK, et al., "U.S. adults' addiction and harm beliefs about nicotine and low nicotine cigarettes," *Preventive Medicine*, 96: 94-100, 2017. Denlinger-Apte, RL, et al., "Low nicotine content descriptors reduce perceived health risks and positive cigarette ratings in participants using very low nicotine content cigarettes," *Nicotine & Tobacco Research*, published online Jan. 18, 2017; Pacek, LR, et al., "Perceived nicotine content of reduced nicotine content cigarettes is a correlate of perceived health risks," *Tobacco Control*, published online July 22, 2017.

[5] FDA, 22nd Century MRTP Scientific Review: Technical Project Lead for MR0000159 and MR0000160, at 14 ("TPL Review").

[6] TPL Review at 15.

[7] TPSAC Meeting Transcript at 198.

[8] TPSAC Meeting Transcript at 296.

[9] TPL Review at 9.

"[t]he social science review found that the proposed LLA [label, labeling, or advertising] include no information on conditions of use, such as how consumers should use VLN™ to reduce their exposure to HPHCs [harmful and potentially harmful constituents] and potential disease risk. In qualitative in-depth interviews, some participants did not appear to understand the conditions of use: after viewing VLN™ cigarette packs with the proposed modified risk labeling, they did not understand the need to cut down or stop smoking in order to benefit from VLN™ cigarettes."[10]

The TPL and decision letter assert that the additional and required claim—"Helps you smoke less"—increased understanding that smokers need to cut down or smoke less to achieve the benefits of nicotine reduction. But, as explained above, FDA lacks the statutory authority to require this claim. Moreover, this research was presumably redacted from the publicly released application materials. It was not available for the public to review and provide comments on and was not a subject of discussion at the TPSAC meeting.

C. FDA's decision contains conflicting information about disclosure statements.

The TPL recommends, but does not suggest requiring, the disclaimer "Nicotine is addictive. Less nicotine does NOT mean safer…." As we discussed in our May 2020 comments, the applicant did not provide evidence that its disclaimer corrected misperceptions about the health risks of VLN™ cigarettes. Further, a large body of evidence has found disclaimers to be ineffective.[11] In the order letter, FDA acknowledged issues with the disclaimer, noting that, "The disclaimer has several features that are inconsistent with expert recommendations for designing disclaimers."[12] Thus, there remains considerable doubt that even if the disclaimer is used, it will have any impact on consumer misperception that the VLN™ cigarettes are safer due to their reduced nicotine.

III. THE VLN™ APPLICATIONS DID NOT DEMONSTRATE A POTENTIAL TO BENEFIT THE HEALTH OF THE POPULATION AS A WHOLE

A. The availability of VLN™ cigarettes with reduced exposure claims will not derive the same benefits as a nicotine product standard.

Absent a reduced nicotine product standard, NNC cigarettes will continue to be readily available and aggressively marketed. This is the reality in which FDA should have assessed this application. There is no strong evidence that very low nicotine content (VLNC) cigarettes can increase smoking cessation outside the context of a nicotine reduction product standard. In the TPL, FDA noted that it "finds it appropriate to bridge data from studies of SPECTRUM NRC102/103 (referred to as "VLNCs") to the proposed MRTPs. In this review, the terms VLNC cigarettes and SPECTRUM NRC102/103 are used interchangeably."[13] While the cigarettes themselves are materially the same, the study conditions in which SPECTRUM cigarettes are used are most often designed to mimic a product standard—participants are generally instructed to

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[10] TPL Review at 14.

[11] Green, KC, Armstrong, JS. (2012). Evidence on the effects of mandatory disclaimers in advertising. *J Public Policy Mark, 31*(2), 293-304; Kesselheim, AS, Connolly, J, Rogers, J, Avorn, J. (2015). Mandatory disclaimers on dietary supplements do not reliably communicate the intended issues. *Health Affairs, 34*(3), 438-446. doi:10.1377/hlthaff.2014.0515.

[12] FDA, 22nd Century MRTP Order Letter for MR0000159 and MR0000160, at 7.

[13] TPL Review at 10.

exclusively smoke the experimental cigarettes and discouraged from using NNC cigarettes. Participants are also given payment for participation and a free supply of VLNC cigarettes. Dr. Hatsukami, an investigator on many of these studies, echoed concerns during the TPSAC meeting that much of the body of research on reduced nicotine cigarettes is not applicable to the context in which regular nicotine cigarettes continue to be available, stating that "I don't think you can really generalize the research that we conducted into what might happen if you have both types of cigarettes on the market."[14]

B. There is insufficient evidence that adult smokers will completely switch to VLN™ cigarettes.

Smokers are unlikely to completely substitute VLN™ cigarettes for NNC cigarettes because VLNC cigarettes have low subjective appeal. Without meaningful uptake among adult smokers, there can be no possible benefit to the public health. FDA's PMTA Scientific Review concluded that "the low subjective appeal, along with increased craving and withdrawal, may prevent current smokers from fully transitioning to VLN™ cigarettes."[15] FDA subsequently reiterated this concern in the MRTP TPL, noting that, "Some model inputs were based on clinical studies; in a real-world setting, the uptake of VLN™ cigarettes among current smokers could be low. Thus, the projected benefits may be overestimated (e.g., high projected market share, dual users of CC and VLN™ cigarettes)."[16] Additionally, the TPL noted that, "There are outstanding questions about the manner in which consumers will use VLN, and if individual tobacco users use VLN cigarettes in the same frequency and manner as conventional cigarettes, they will not significantly reduce harm and their risk of tobacco-related disease."[17]

As noted in our May 2020 comments, if the marketing of VLN™ cigarettes with reduced exposure claims only leads to experimentation and not sustained use among adult smokers, or leads to dual use of the VLN™ cigarettes with NNC cigarettes rather than complete switching or cessation, there is unlikely to be a substantial population health benefit. There was widespread agreement among TPSAC members that dual use will be a likely outcome for adult smokers who try using VLN™ cigarettes.[18] Experimental studies, including those submitted by the applicant, demonstrate low compliance rates and high levels of substitution with NNC cigarettes. Dual use will be significantly more likely when smokers are not receiving the product for free, paid to participate in a study, and instructed to exclusively use VLN™ cigarettes.

C. The availability of VLN™ cigarettes with reduced exposure claims could hinder or delay cessation efforts.

The "Helps you smoke less" claim required by FDA may yield further misperceptions among consumers, given the potential for it to be interpreted as a therapeutic claim. As we noted in our May 2020 comments, the applicant's consumer perception study raises concern that the reduced exposure claims may lead to misperceptions about the role of VLN™ cigarettes in

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14 TPSAC Meeting Transcript at 150.

15 FDA, 22nd Century PMTA Scientific Review: Technical Project Lead for PM0000491 and PM0000492, at 68.

16 TPL Review at 16.

17 TPL Review at 17.

18 TPSAC Meeting Transcript at 203.

smoking cessation. In one phase of its qualitative study, a noted theme was that, "Many expressed confusion as to PARE / VLN's intended category: is it a cigarette or is it nicotine replacement therapy?"[19] This finding suggests that some may view the subject products, even with the proposed claims and disclaimer, as an FDA-approved nicotine replacement therapy (NRT), which could prolong cigarette smoking among those seeking cessation products like NRT. Finally, the applicant's Quantitative Study provides evidence that the proposed claims for VLN™ cigarettes could lead to reduced quit attempts using safer, FDA-approved cessation aids. In that study, exposure to the proposed MRTP claims among smokers with intention to quit was associated with reduced intentions to use NRT.[20] If the MRTP claims do in fact deter smokers that intend to quit from using FDA-approved cessation products, that will result in a net public health harm. As such, it is clear that FDA did not adequately weigh "the risks and benefits to persons from the use of the modified risk tobacco product compared to the use of smoking cessation [drug or device products] approved [by FDA] to treat nicotine dependence" as required by the TCA. FFDCA § 911(g)(4)(d).

IV. THE VLN™ APPLICATIONS CONTAINED INSUFFICIENT EVIDENCE ON THE INCREASED LIKELIHOOD OF TOBACCO USE INITIATION BY NON-USERS, PARTICULARLY YOUTH

The absence of research on this particular issue was a concern noted in FDA's PMTA Scientific Review: "The applicant also did not provide any evidence to address the likelihood that never users who take up VLN™ cigarettes will switch to other tobacco products that present higher levels of individual health risk."[21] These concerns were reiterated by TPSAC members[22] and discussed at length in our comments filed in May 2020.

FDA cannot have a complete picture of the potential public health impact without reliable youth data. These types of evaluations must be done before MRTPs are authorized by FDA, not just in post-marketing surveys and evaluations. Both FDA's Draft Guidance for the preparation of MRTP applications (FDA MRTP Draft Guidance) and the Institute of Medicine's report, *Scientific Standards for Studies on Modified Risk Tobacco Products* (IOM MRTP Report), recommend the inclusion of youth in consumer perceptions studies of promotional material to determine the effect of such modified risk claims on adolescent risk perception or interest in using the product.[23]

The failure by 22nd Century to provide any evidence of the effect of the proposed MRTP claims on adolescent risk perception is an inexplicable omission, against not only FDA's express instructions, but contrary to the statute as well. The consideration of the effects of promotional statements on youth is vitally important in light of the tobacco industry's documented history of

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[19] M/A/R/C® Research, "Qualitative Study to Develop PARE / VLN™ Hypothetical Claims Among U.S. Adult Cigarette Smokers, Adult Former Cigarette Smokers and Adult Never Cigarette Users Phases 1, 2, 3, and 4," at 19.

[20] M/A/R/C® Research, "Quantitative Study to Evaluate VLN Hypothetical Product Messages Among U.S. Adult Cigarette Smokers, Adult Former Cigarette Smokers and Adult Never Cigarette Users," at 113.

[21] FDA, 22nd Century PMTA Scientific Review: Technical Project Lead (TPL) for PM0000491 and PM0000492, at 59.

[22] TPSAC Meeting Transcript at 169.

[23] FDA Draft Guidance, Modified Risk Tobacco Applications, March 2012, at 20; IOM MRTP Report, December 2011, at 165.

marketing tobacco products in ways that attract adolescents and the role that youth initiation has played—and continues to play—in the recruitment of long-term adult smokers.[24]

As relevant here, the TCA requires the applicant to enable FDA to find that its reduced exposure claims are "expected to benefit the health of the population *as a whole*" for the agency to issue an exposure modification order. FFDCA § 911(g)(2)(B)(iv). FDA cannot make this determination without evidence about youth, a key demographic the law sought to protect. Despite the express instructions in FDA's MRTP Draft Guidance and the extensive discussion in the IOM MRTP Report on how research on youth risk perception could appropriately be conducted, 22nd Century has submitted applications that ignore the effects of the proposed modified risk claims on youth. Absent evidence on those effects, the applications cannot possibly establish that the modified exposure product can be expected to benefit the population as a whole.

V. FDA SHOULD REQUIRE TESTING OF VLN™ MARKETING MATERIALS

FDA expressed concerns about the applicant's youth-friendly marketing in its order letter —a concern we also raised in our May 2020 comments—stating that, "FDA found that some of the original advertising submitted with these applications contained potentially youth appealing imagery."[25] While FDA noted that the company subsequently withdrew these marketing materials, it is only recommending, rather than requiring, the company to test future marketing materials, even though FDA acknowledged that the appeal of VLN™ to youth hinges on its marketing materials, noting that "the social science review describes some information suggesting that, *depending on how VLN™ cigarettes are marketed*, effects on youth may be limited."[26] In addition to imagery and themes that attract youth, the applicant's marketing materials will also impact consumer perceptions about the reduced exposure claims, including if claims are read by consumers (e.g., if the ad imagery distracts readers from reading the MRTP claims) and how they are interpreted. For these reasons, the application is seriously defective for lack of the required consumer perception studies of the marketing materials.

VI. FDA FAILED TO RECOGNIZE THE SPECIAL RISKS OF VLN™ MENTHOL CIGARETTES BEYOND THE RISKS POSED BY NON-MENTHOL VLN™ CIGARETTES, PARTICULARLY FOR YOUTH AND COMMUNITIES OF COLOR

In April, 2021, FDA announced that it intended to issue "proposed product standards within the next year to ban menthol as a characterizing flavor in cigarettes and ban all characgerizing flavors (including menthol) in cigars."[27] FDA's then-Acting Commissioner, Dr. Janet Woodcock, stated that such product standards "will help significantly reduce youth initiation, increase the chances of smoking cessation among current smokers, and address health disparities experienced by communities of color, low-income populations, and LGBTQ+ individuals, all of whom are far

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[24] HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, CDC, OSH, 2012, at 530-41, 603-27, and sources cited therein; *U.S. v. Philip Morris*, 449 F. Supp. 2d 1, 561-691 (D.D.C. 2006).

[25] FDA, 22nd Century MRTP Order Letter for MR0000159 and MR0000160, at 7.

[26] TPL Review at 17 (emphasis added).

[27] FDA, News release, *FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers* (Apr. 29, 2021), https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers

more likely to use these tobacco products. All together these actions represent powerful, science-based approaches that will have an extraordinary public health impact."[28]

Given that FDA already has identified the benefits to public health from prohibiting menthol cigarettes, and intends to pursue such a prohibition through its product standard authority, it is incumbent on the agency, before it authorizes reduced exposure claims for a menthol product, to recognize the special risks to public health from menthol cigarettes and to make specific findings that the authorization of the menthol product, with those claims, will not create those public health risks. The applicant here made no showing that its menthol product would not create the special risks long associated with menthol cigarettes and FDA made no findings concerning those risks in issuing its modified exposure order. Thus, the orders issued for VLN™ menthol cigarettes should be rescinded, both for the reasons applicable to the non-menthol cigarettes and because of the absence of any basis for finding that the menthol cigarettes would not create the special risks to particular populations which have led FDA to commit itself to a rulemaking to prohibit menthol as a characterizing flavor in cigarettes.

VII. CONCLUSION

It has now been almost four years since FDA issued an Advance Notice of Proposed Rulemaking seeking comments on a product standard limiting levels of nicotine in combustible tobacco products[29] and no proposed rule has yet been issued.

It is readily apparent that the only way to realize the potential public health benefits of low-nicotine cigarettes is for FDA to establish an industry-wide product standard. Instead, through the reduced exposure orders issued for VLN™ and VLN™ Menthol, FDA is authorizing a product-by-product introduction of very low nicotine cigarettes into the current market, with various authorized and required claims. This actioin is both unlawful and will produce adverse public health consequences. Therefore, we urge FDA to rescind the VLN™ and VLN™ Menthol exposure modification orders.

Thank you for your consideration of our views.

Sincerely,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative

Cc: Dr. Robert Califf, FDA Commissioner
Mark Raza, Acting FDA Chief Counsel

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[28] *Id.*

[29] FDA, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes; Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 11818 (Mar. 16, 2018).