

April 29, 2021

D. Douglas Blanke, JD
Executive Director
Public Health Law Center
Mitchell Hamline School of Law
875 Summit Avenue
Saint Paul, Minnesota 55105

Re: Docket No. FDA-2013-P-0435

Dear Mr. Blanke:

This letter responds to your citizen petition submitted on April 12, 2013, on behalf of the Tobacco Control Legal Consortium¹ and the African American Tobacco Control Leadership Council; American Academy of Pediatrics; American Association for Cancer Research; American Cancer Society – Cancer Action Network; American Heart Association; American Legacy Foundation; American Lung Association; American Public Health Association; Americans for Nonsmokers’ Rights; Asian Pacific Partners for Empowerment, Advocacy and Leadership; Association for the Treatment of Tobacco Use and Dependence; Campaign for Tobacco-Free Kids; Corporate Accountability International; NAATPN, Inc. (parent organization of the National African American Tobacco Prevention Network); National Association of County and City Health Officials; National Latino Alliance for Health Equity; Society for Research on Nicotine and Tobacco; Summit Health Institute for Research and Education, Inc.; and Valerie B. Yerger, N.D.

Your petition requests that the Food and Drug Administration (FDA) prohibit menthol as a characterizing flavor in cigarettes. Specifically, your petition requests that FDA: (1) add menthol to the list of additives and constituents in the prohibition on characterizing flavors in cigarettes and cigarette smoke directed by section 907(a)(1)(A) of the Federal Food, Drug, and Cosmetic

¹ Now known as the Public Health Law Center.

Act (FD&C Act) and (2) work with appropriate entities to provide support to smokers of menthol cigarettes who will quit as a result of the requested prohibition on menthol cigarettes.

On January 14, 2021, you submitted a citizen petition supplement² pursuant to 21 C.F.R. § 10.30(g) to update the administrative record with research developed since 2013 on the impact of menthol in cigarettes. In the supplement, you identify and discuss evidence related to the following topics: menthol's impact on youth initiation, adult and youth cessation, the impact on non-users of menthol cigarettes caused by secondhand smoke exposure, thirdhand smoke exposure, tobacco waste pollution, the disproportionate impact that menthol has had on several subpopulations (e.g., African Americans), evaluation data from several jurisdictions that have implemented prohibitions on menthol, technical achievability, and illicit trade.

FDA has carefully reviewed your petition, January 2021 supplement, and the comments submitted to the petition docket. When a citizen petition requests FDA to issue, amend, or revoke a regulation, the applicable rulemaking procedures apply. *See* 21 C.F.R. § 10.30(f); 21 C.F.R. § 10.40; *see also* the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*; FD&C Act § 907(c) (providing notice and comment procedures for product standard rulemaking). These provisions set forth the procedures for, among other things, developing and issuing a notice of proposed rulemaking, obtaining public comment, and promulgating a final rule. We interpret your petition as a request that the Agency engage in the rulemaking process by proposing a rule to prohibit menthol as a characterizing flavor in cigarettes. As discussed below, FDA intends to take such action. In addition, while FDA generally does not provide direct cessation services, FDA intends to work with the Department of Health and Human Services (HHS) to enlist and collaborate with other entities at the Federal, Tribal, State and Local levels who provide support to menthol smokers who quit or want to quit as a result of a prohibition of menthol as a characterizing flavor in cigarettes going into effect. FDA therefore grants your petition in accordance with 21 C.F.R. § 10.30(e)(3).

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), enacted on June 22, 2009, amended the FD&C Act and gave FDA the authority to regulate tobacco products (Pub. L. 111-31).³ Among other provisions, the Tobacco Control Act established a “Special Rule

² The supplement was submitted on behalf of the following petitioners and other public health organizations: Public Health Law Center; Action on Smoking and Health; African American Tobacco Control Leadership council; American Academy of Pediatrics; American Cancer Society – Cancer Action Network; American Heart Association; American Lung Association; American Medical Association; American Public Health Association; American Thoracic Society; Americans for Nonsmokers' Rights; Association of State and Territorial Health Officials; Campaign for Tobacco-Free Kids; Center for Black Health & Equity; ClearWay MinnesotaSM; Legal Resource Center for Public Health Policy; Massachusetts Association of Health Boards; National LGBT Cancer Network; National Medical Association; Parents Against Vaping E-Cigarettes; Public Health Advocacy Institute; Truth Initiative; and Valerie Yerger, N.D.

³ The Tobacco Control Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. On May 10, 2016, FDA issued the “Deeming Rule,” which extended FDA's tobacco product authority to all tobacco products, other than the accessories of deemed tobacco products, that meet the statutory definition of tobacco

for Cigarettes” that bans cigarettes with characterizing flavors other than tobacco and menthol. The special rule makes clear that it does not limit the authority of the Secretary of HHS to take action on menthol or any other artificial or natural flavor, herb or spice not specified in the special rule (section 907(a)(1)(A) of the FD&C Act).

The FD&C Act does not require or compel FDA to adopt any particular tobacco product standard within any specific time frame. FDA also has broad discretion in deciding whether or not to issue, revise, amend, or revoke an existing product standard (sections 907(a)(2) and 907(d)(4) of the FD&C Act). Section 907 of the FD&C Act also provides that FDA may adopt tobacco product standards if the Secretary of HHS finds that a tobacco product standard is appropriate for the protection of the public health taking into consideration 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 (section 907(a)(3)(B)(i) of the FD&C Act). The FD&C Act grants FDA broad discretion as to the content of tobacco product standards. For example, the FD&C Act provides FDA authority to implement provisions regarding nicotine yields, reduction or elimination of other constituents (including smoke constituents) or harmful components, and provisions for the construction, components, ingredients, additives, constituents (including smoke constituents) and properties of the tobacco product (section 907(a)(4) of the FD&C Act).

In promulgating a product standard, the Agency is required to first issue a proposed rule that, among other things, invites interested persons to submit a draft or proposed tobacco product standard for consideration by the Agency (section 907(c) of the FD&C Act). The Agency is also required to consider information submitted in connection with a proposed standard (section 907(d) of the FD&C Act) including information submitted regarding the technical achievability of compliance with the standard, and information submitted concerning the countervailing effects of the standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband (section 907(b) of the FD&C Act).

In addition, section 907(a)(5) of the FD&C Act requires FDA to “provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.”

II. FDA’s Relevant Regulatory History

In its implementation of the Tobacco Control Act over the past several years, FDA has engaged in close study and careful consideration of the scientific evidence and complex policy issues related to menthol cigarettes.

product. 81 Fed. Reg. 28974 (May 10, 2016), codified at 21 C.F.R. § 1100.1. This includes electronic delivery systems (ENDS), cigars, waterpipe (hookah) tobacco, pipe tobacco, nicotine gels, and dissolvables that were not already subject to the FD&C Act (*id.* at 28976).

In March 2010, FDA's Tobacco Product Scientific Advisory Committee (TPSAC) undertook an extensive review of the available evidence concerning menthol cigarettes and solicited and received input from many public commenters, including researchers, tobacco industry representatives, consultants to the tobacco industry, and public health experts. As required by section 907(e) of the FD&C Act, on March 23, 2011, TPSAC submitted its report and recommendation to the Secretary of HHS on the impact of the use of menthol in cigarettes on the public health, including use among children, African Americans, Hispanics, and other racial and ethnic minorities (TPSAC Report).^{4,5,6} Based on evidence available at that time, TPSAC concluded that removing menthol cigarettes from the market would benefit the public health, and noted that the statute provides a "variety of mechanisms for FDA to consider, if it concludes that it should pursue this recommendation," but it offered "no specific suggestions for FDA to follow-up" on its recommendations (TPSAC Report at 225). TPSAC also noted that, although the FD&C Act requires FDA to consider information submitted on potential countervailing effects of any proposed product standard, such as the creation of a black market, the advisory committee was not "constituted to carry out analyses of the potential for and impact of a black market for menthol cigarettes" and did not analyze that issue (*id.*). Therefore, "FDA would need to assess the potential for contraband menthol cigarettes as required by the [FD&C] Act." (*Id.*). Finally, TPSAC stated that in reviewing the evidence related to its charge, it noticed "gaps in understanding of menthol cigarettes and public health that should be addressed with further research," and recommended that FDA "[s]trengthen the evidence foundation on the public health impact of menthol cigarettes" with research on menthol cigarettes' impact on smoking initiation and cessation and marketing practices. (TPSAC Report at 228).

Shortly thereafter, independent of TPSAC and nonvoting industry representatives to TPSAC, experts within FDA's Center for Tobacco Products (CTP) conducted an evaluation of the available science related to the impact of the use of menthol in cigarettes on public health. This evaluation is entitled "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes" (Preliminary Evaluation)⁷ and has been peer reviewed.⁸ FDA evaluated peer-reviewed literature, tobacco industry submissions and other materials

⁴ Tobacco Products Scientific Advisory Committee, Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations (submitted Mar. 23, 2011, finalized July 21, 2011), *available at* <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>.

⁵ In addition, the nonvoting industry representatives of TPSAC submitted a separate document reflecting the tobacco industry perspective. *See* Non-Voting Industry Representatives on TPSAC and Other Tobacco Industry Stakeholders, The Industry Menthol Report, Menthol Cigarettes: No Disproportionate Impact on Public Health (Mar. 23, 2011), *available at* <https://wayback.archive-it.org/7993/20170406091740/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf>.

⁶ In 2014, the U.S. District Court for the District of Columbia held that TPSAC members were improperly appointed. *Lorillard, Inc. v. FDA*, 56 F. Supp. 3d 37 (D.D.C. 2014). The court ordered FDA to reconstitute TPSAC and enjoined FDA from using the TPSAC menthol report. *Id.* at 57. This holding was vacated by the U.S. Court of Appeals for the D.C. Circuit. *R.J. Reynolds Tobacco Co. v. FDA*, 810 F.3d 827, 832 (D.C. Cir. 2016).

⁷ The Preliminary Evaluation is *available at* <https://www.fda.gov/media/86497/download>.

⁸ 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/media/86018/download>.

provided to TPSAC, secondary data analyses, and CTP's own analyses of relevant large data sets (Preliminary Evaluation at 3). The Preliminary Evaluation concluded the following:

While there is little evidence to suggest that menthol cigarettes are more or less toxic or contribute to more disease risk to the user than nonmenthol cigarettes, adequate data suggest that menthol use is likely associated with increased smoking initiation by youth and young adults. Further, the data indicate that menthol in cigarettes is likely associated with greater addiction. Menthol smokers show greater signs of nicotine dependence and are less likely to successfully quit smoking. These findings, combined with the evidence indicating that menthol's cooling and anesthetic properties can reduce the harshness of cigarette smoke and the evidence indicating that menthol cigarettes are marketed as a smoother alternative to nonmenthol cigarettes, make it likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.

(Preliminary Evaluation at 6).⁹

In July 2013, FDA issued an advance notice of proposed rulemaking (ANPRM) to obtain information related to the potential regulation of menthol in cigarettes, including any data, research, or other information that may inform regulatory actions FDA might take with respect to menthol in cigarettes (78 Fed. Reg. 44484 (July 24, 2013)) (Menthol ANPRM). The Menthol ANPRM also made available the Preliminary Evaluation and an addendum with articles published since the evaluation was submitted for peer review in 2011. (*See id.* at 44485).¹⁰ FDA sought data and information on a number of complex questions, including if FDA established a tobacco product standard for menthol in menthol cigarettes, what level of menthol would be appropriate for the protection of the public health; whether FDA should address menthol in other tobacco products; whether alternatives and substitutes might appear on the market and how those substances might be regulated; whether and how restrictions on advertising and promotion of menthol cigarettes would influence consumer behavior; and whether there was evidence that illicit trade in menthol cigarettes would become a significant problem if menthol cigarettes were banned. (*Id.*). FDA received over 174,000 comments on the ANPRM, with approximately 165,000 of those comments submitted as part of 41 different write-in campaigns.¹¹ FDA has reviewed and closely considered the comments.

In July 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation designed to serve as a "multi-year roadmap to better protect kids and significantly reduce tobacco-related disease and death."¹² The new approach placed nicotine, and the issue of

⁹ The Preliminary Evaluation emphasized that it did "not constitute a decision about what regulatory action, if any, FDA might take with respect to menthol cigarettes" and noted "[t]here is no required deadline or timeline for FDA to make a determination about what regulatory action, if any, is appropriate." (Preliminary Evaluation at 6-7).

¹⁰ The Reference Addendum is available at <https://www.fda.gov/media/86409/download>.

¹¹ *See* Docket: Menthol in Cigarettes, Tobacco Products; Request for Comments, <https://www.regulations.gov/docket/FDA-2013-N-0521>.

¹² Press Release, Food & Drug Admin., FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 27, 2017), <https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death>.

addiction, at the center of the Agency's tobacco regulation efforts, acknowledging that nicotine, while highly addictive, is delivered through products on a continuum of risk.

FDA announced that the Agency would begin a public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels through product standards and further explore how best to protect public health in the evolving tobacco marketplace by seeking input from the public on approaches to regulating kid-appealing flavors in e-cigarettes and cigars. In March 2018, FDA issued three ANPRMs related to the regulation of nicotine in combustible cigarettes,¹³ flavors (including menthol) in tobacco products (Flavors ANPRM),¹⁴ and premium cigars¹⁵.

The Flavors ANPRM requested data and information about, among other things, "how flavors attract youth to initiate tobacco product use and about whether and how certain flavors may help adult cigarette smokers reduce cigarette use and switch to potentially less harmful products" to "inform regulatory actions FDA might take with respect to tobacco products with flavors." (83 Fed. Reg. 12294). With regard to menthol, FDA requested additional data or information about the role of menthol in cigarettes, including the role menthol plays in: (1) smoking initiation, (2) the likelihood of smoking cessation in youth, young adults, and adults, (3) the likelihood that menthol smokers would switch to another tobacco product or start dual use with another tobacco product, instead of quitting smoking, if a tobacco product standard prohibited or limited menthol in cigarettes, and (4) the use of tobacco products other than cigarettes (e.g., ENDS and cigars). (*Id.* at 12299). FDA received over 525,000 comments on the Flavors ANPRM, a large proportion of which were form letters related to 61 different mass mail campaigns.¹⁶ FDA has reviewed and closely considered the comments.

Also in March 2018, FDA announced the availability of a draft concept paper entitled, "Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard," and sought public comment.¹⁷ This paper describes "aspects of the tobacco product market and consumer behavior that may be relevant to the potential development of markets for contraband and nonconforming tobacco products, specifically through illicit trade, after FDA implements a tobacco product standard." (Illicit Trade Paper at 2). The paper analyzes illicit trade by "breaking down the mechanics of an illicit trade market into their various components, and examining the factors that might support or hinder the establishment of a persistent illicit trade market in the face of an FDA tobacco product standard." (*Id.*)

Over the years, the Agency has also invested in scientific research to better understand the effects of menthol. The Menthol and Flavor ANPRMs and internal reviews of the literature have

¹³ Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 83 Fed. Reg. 11818 (Advance Notice of Proposed Rulemaking, Mar. 16, 2018).

¹⁴ Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12294 (Advance Notice of Proposed Rulemaking, Mar. 21, 2018).

¹⁵ Regulation of Premium Cigars, 83 Fed. Reg. 12901 (Advance Notice of Proposed Rulemaking, Mar. 26, 2018).

¹⁶ See Docket: Regulation of Flavors in Tobacco Products, <https://www.regulations.gov/docket?D=FDA-2017-N-6565>.

¹⁷ 83 Fed. Reg. 11754 (Mar. 16, 2018). The draft concept paper is available at <https://www.fda.gov/files/tobacco%20products/published/Illicit-Trade-in-Tobacco-Products-After-Implementation-of-an-FDA-Product-Standard.pdf>.

informed our prioritization of research that will continue to add to the evidence on this issue. Through contracts and interagency agreements with Federal partners, including the National Institutes of Health (NIH), FDA sponsors research on a variety of menthol-related topics. For example, through September 2020, FDA has funded research studying the role of menthol in experimentation and progression to regular use among youth and young adults¹⁸, menthol's impact on dependence in youth¹⁹, the population health impacts and risks of menthol cigarette smoking²⁰, and the effect of menthol use on quitting success²¹. FDA has also funded studies evaluating the impact of a real-world menthol sales restriction in Ontario, Canada.^{22,23} In addition, the Population Assessment of Tobacco and Health Study and national surveys such as the National Youth Tobacco Survey (NYTS) and the Tobacco Use Supplement to the Current Population Survey (TUS-CPS) include questions regarding use, risk perceptions, and attitudes related to menthol tobacco products.^{24,25} More information on specific projects supported by CTP is available at <https://www.fda.gov/tobacco-products/tobacco-science-research/research> (search “menthol” or “flavors”).

III. FDA Response to the Requests in Your Petition

A. *Add menthol to the list of additives and constituents in the prohibition on characterizing flavors in cigarettes and cigarette smoke directed by section 907(a)(1)(A) of the FD&C Act*

1. The request

¹⁸ Villanti, A.C., A.L. Johnson, A.M. Glasser, et al. “Association of Flavored Tobacco Use with Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015.” *JAMA Network Open*, 2(10):e1913804, 2019. Available at <https://doi.org/10.1001/jamanetworkopen.2019.13804>.

¹⁹ Cwalina, S.N., A. Majmundar, J.B. Unger, et al. “Adolescent Menthol Cigarette Use and Risk of Nicotine Dependence: Findings from the National Population Assessment on Tobacco and Health (PATH) Study.” *Drug and Alcohol Dependence*, 206:107715, 2020. Available at <https://doi.org/10.1016/j.drugalcdep.2019.107715>.

²⁰ Le, T.T. and D. Mendez. “An Estimation of the Harm of Menthol Cigarettes in the United States from 1980 to 2018.” *Tobacco Control*, 0:1-5, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2020-056256>.

²¹ Mills, S.D., Y. Hao, K.M. Ribisl, et al. “The Relationship Between Menthol Cigarette Use, Smoking Cessation and Relapse: Findings from Waves 1 to 4 of the Population Assessment of Tobacco and Health Study.” *Nicotine & Tobacco Research*, 2020. Available at <https://doi.org/10.1093/ntr/ntaa212>.

²² Chaiton, M., R. Schwartz, J.E. Cohen, et al. “Prior Daily Menthol Smokers More Likely to Quit Two Years After a Menthol Ban than Non-Menthol Smokers: A Population Cohort Study.” *Nicotine & Tobacco Research*, 2021. Available at <https://doi.org/10.1093/ntr/ntab042>.

²³ Chaiton, M., I. Nicolau, R. Schwartz, et al. “Ban on Menthol-Flavoured Tobacco Products Predicts Cigarette Cessation at 1 Year: A Population Cohort Study.” *Tobacco Control*, 29(3):341-347, 2020. Available at <https://doi.org/10.1136/tobaccocontrol-2018-054841>.

²⁴ See U.S. Department of Health and Human Services. National Institutes of Health. National Institute on Drug Abuse, and U.S. Department of Health and Human Services. Food and Drug Administration. Center for Tobacco Products. Population Assessment of Tobacco and Health (PATH) Study [United States] Restricted-Use Files. Inter-university Consortium for Political and Social Research [distributor], 2020-06-24. <https://doi.org/10.3886/ICPSR36231.v25>.

²⁵ See U.S. Department of Commerce, Census Bureau (2020). National Cancer Institute and Food and Drug Administration co-sponsored Tobacco Use Supplement to the Current Population Survey. 2018-2019. <https://cancercontrol.cancer.gov/brp/tcrb/tus-cps/>.

In your petition, you urge FDA to “prohibit menthol as a characterizing flavor in cigarettes, explicitly including both synthetic (racemic) and natural (l-menthol) menthol.” (Petition at 4-5).²⁶ You assert that FDA has the authority to establish a tobacco product standard for menthol and that Congress “explicitly made menthol a priority” by directing TPSAC to submit a menthol report and recommendations within one year of its establishment. (*Id.* at 7-8). You state that Congress “recognize[d] that the FDA’s decision to regulate menthol should be informed . . . [by] concerns regarding the impact of menthol use on the health of children, African Americans, Hispanics, and other racial and ethnic minorities.” (*Id.* at 8). You state that TPSAC conducted an exhaustive review of the scientific evidence on the public health impact of menthol in cigarettes and made the overall recommendation to FDA that “[r]emoval of menthol cigarettes from the marketplace would benefit the public health in the United States.” (*Id.* at 8-9). You claim that the “strength of the evidence reviewed in the TPSAC Report, and now supplemented by subsequently published evidence, supports the elimination of menthol in cigarettes.” (*Id.* at 9). Finally, you assert that the menthol ban that you propose is “appropriate for the protection of public health” under section 907 of the Tobacco Control Act and present an analysis of the evidence, taking into account the factors in section 907(a)(3)(B)(i) of the FD&C Act, to support your claim that the requested rulemaking would be “appropriate for the protection of public health.” (*Id.* at 8-33).

In your analysis of the evidence, you assert that the existing evidence indicates that mentholated cigarettes increase initiation of smoking and decrease cessation. (*Id.* at 9-10). You cite the TPSAC Report and other studies to demonstrate the prevalence of menthol cigarette use among youth, the appeal of menthol’s minty flavor, and the cooling and anesthetic physiological properties of menthol, which reduce the harshness of cigarette smoke and enhance addiction and discourage cessation. (*Id.* at 11-12, 18-21). You note that, because “nearly 90% of adult smokers start smoking before the age of 18 and nearly 99% start before the age of 25,” banning menthol as a characterizing flavor in cigarettes “would translate to significant benefits for the health of youth and the entire population.” (*Id.* at 14). In addition, you claim that removing mentholated tobacco products from the marketplace would increase the likelihood that current smokers will quit (*id.* at 15-18, 22-24) and would decrease the prevalence of tobacco use in the overall population because “studies have indicated that a portion of smokers who initiate with menthol cigarettes ultimately switch to non-menthol cigarettes” (*id.* at 22). Furthermore, you claim that removing menthol from cigarettes would have a particularly important public health benefit for African Americans and other minority populations. (*Id.* at 24). You cite data indicating that menthol cigarettes are disproportionately used by and targeted to racial and ethnic minority populations, such as African Americans, Native Hawaiian or Pacific Islanders, Hispanics or Latinos, Asian Americans, as well as LGBTQ populations. (*Id.* at 24-28). For example, you state “[t]here is strong evidence of disproportionate use within and targeting of menthol cigarettes to the African American community, as well as evidence of a higher incidence of smoking-related cancer morbidity and mortality as compared to other populations.” (*Id.* at 26).

²⁶ We note that the petition did not provide the exact wording of the proposed regulation, as required by 21 C.F.R. § 10.30(b)(3). For the reasons discussed elsewhere in this response, we interpret your petition to be a request that the Agency engage in the rulemaking process by proposing a rule to prohibit menthol as a characterizing flavor in cigarettes.

Your petition also asserts that the health benefits of a menthol prohibition “would outweigh any perceived challenges.” (*Id.* at 28). You note that the symptoms of withdrawal (e.g., depression, anxiety, and cravings for nicotine) and risk of relapse can be managed and are far outweighed by the immediate and long-term health benefits of quitting smoking. (*Id.* at 28-29). You suggest that a surge in demand for cessation services caused by the removal of menthol tobacco products from the marketplace could be addressed by a notice period or phase-in that would provide additional time to educate the public about the new regulation and available cessation resources, and would give health care organizations and other providers of cessation resources time to prepare for the increased demand for services. (*Id.* at 29). You further suggest that a national effort to “increase access to comprehensive, quality, culturally relevant cessation resources, particularly in underserved communities” will be needed. (*Id.*). Finally, you assert that the risks of expansion of the illicit market have been overstated relative to the health benefits of a menthol prohibition. (*Id.* at 30). You state there is “little evidence to back the tobacco industry’s claims that prohibiting the sale of menthol cigarettes will lead to massive expansion of the illegal market” and cite a study that suggests the vast majority of menthol smokers would try to quit or switch to non-menthol cigarettes if menthol cigarettes were banned. (*Id.* at 30-31). You note that the Prevent All Cigarette Trafficking Act (PACT) of 2009 (Pub. L. 111-154) would make it more difficult to expand the illicit market for cigarettes (*id.* at 31-32) and that FDA could address concerns about illicit markets by expeditiously designing and proposing the track and trace system described in section 920(b) of the Tobacco Control Act (*id.* at 33).

As previously noted, on January 14, 2021, you submitted a citizen petition supplement pursuant to 21 C.F.R. § 10.30(g) to update the administrative record with research developed since 2013 on the impact of menthol in cigarettes. In the supplement, you identify and discuss “seventy-eight relevant sources of information that were not already referenced in the 2013 citizen petition” (Supplement at 3). Many of these sources include peer-reviewed studies that were funded or supported by FDA or other Federal agencies (*id.* at 3-4). The information you provide describes evidence related to menthol’s impact on youth initiation, adult and youth cessation, and the impact on non-users of menthol cigarettes (*id.* at 5, 11-23). You also include information on the disproportionate impact that menthol has had on subpopulations, including youth, young adults, and specific racial/ethnic groups including African Americans (*id.* at 5-11). In addition, you provide evaluation data from several jurisdictions that have implemented prohibitions on menthol, including local jurisdictions in the United States and Canada (*id.* at 5, 16-17). You also suggest that any potential countervailing effects from a menthol product standard can be mitigated by FDA action (*id.* at 5, 24-36).

2. Public comments

FDA received over 2,060 comments on the petition, with approximately 1,618 comments submitted as part of a form letter campaign.²⁷ Comments were received from public health

²⁷ See Docket: Prohibit Menthol as a Characterizing Flavoring in Cigarettes and Cigarette Smoke, <https://www.regulations.gov/docket/FDA-2013-P-0435>. Please note that certain comments submitted to the docket before October 15, 2015 may not be publicly viewable on <http://regulations.gov>. Prior to October 15, 2015, FDA had a long standing practice of not publicly posting on <http://regulations.gov> comments submitted by individuals in

advocacy groups, academics, State and local governments, medical associations, tobacco product manufacturers, and individuals. Most comments expressed support for the petitioners' request to ban menthol as a characterizing flavor in cigarettes, with some of those giving details that were generally in line with what was in your petition.²⁸ A number of comments expressed general opposition to the petitioners' request to ban menthol as a characterizing flavor in cigarettes. However, several comments provided more detailed feedback on opposition to the petition and urged FDA to deny the petition, and these comments are summarized and responded to below.

(Comment 1) Some comments argue that the scientific bases for the petitioners' request are inadequate. These comments state that the petitioners rely heavily on the evidence and conclusions in the TPSAC Report, which the comments state uses a flawed approach to assess the science. In addition, the comments also suggest the other scientific evidence cited by the petitioners is flawed and inadequate. One comment also said the petitioners do not identify the criteria used to identify, evaluate, and assess the strength of the additional evidence they reference, and the petitioners omit evidence FDA should consider as it evaluates the petitioners' request.

(Response) The comments regarding the inadequacy of the petitioners' request were submitted at the time the original citizen petition was submitted to FDA in 2013. The science has evolved since the release of the TPSAC Report. In the intervening eight years, there has been an accumulating evidence base regarding the role menthol in cigarettes plays in regard to facilitating experimentation and progression to regular use, particularly in youth and young adults, greater dependence in youth, and reduced cessation success among current smokers, particularly African American smokers. In January 2021, the petitioners submitted a supplement "to update the administrative record for this citizen petition with the most recent information on the impact of menthol in cigarettes" (Supplement at 1). In addition, since 2013, FDA has engaged in close study and careful consideration of the scientific evidence and complex policy issues related to menthol cigarettes.²⁹ The record before FDA includes, but is not limited to, the following: the citizen petition, the petition supplement which updated the administrative record with research developed since 2013 on the impact of menthol in cigarettes, comments submitted to the petition docket, the TPSAC Report, FDA's Preliminary Evaluation, information and comments received on the 2013 Menthol and 2018 Flavors ANPRMs, and scientific research published since 2013. We believe there is sufficient evidence in the record to support a decision to begin the rulemaking process to prohibit menthol as a characterizing flavor in cigarettes, and the proposed rule may also take into account additional evidence and information not included in the record for this citizen petition. As discussed below, based on our consideration of the existing scientific evidence in the record, FDA believes eliminating menthol as a characterizing flavor in cigarettes would benefit public health and, therefore, the Agency intends to issue a proposed rule to prohibit menthol as a characterizing flavor in cigarettes. As part of the rulemaking process

their individual capacity. For more information, see <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

²⁸ One comment also expressed support for the petitioners' request for FDA to work with appropriate entities to provide support to smokers of menthol cigarettes who will quit as a result of the requested prohibition on menthol in cigarettes. Since most of the comments addressed the petitioners request to ban menthol cigarettes, we have opted to discuss the comments in this section.

²⁹ See *supra* pp. 4-7.

under section 907 of the FD&C Act, the public will have an opportunity to comment on the proposed rule.

(Comment 2) The comments also suggest that the scientific literature supports that menthol cigarettes do not affect population harm differently than non-menthol cigarettes. More specifically, one comment states that studies show that menthol smokers have no greater risks of disease than non-menthol smokers and may have reduced risks of developing some diseases. In addition, the comment states that methodologically sound studies which evaluate smoking cessation and dependence find no difference between menthol and non-menthol smokers and that available data do not establish that menthol cigarettes facilitate smoking initiation.

(Response) As noted in the response to comment 1, these comments were submitted to FDA in 2013 and the science has evolved since then. In January 2021, the petitioners submitted a supplement “to update the administrative record for this citizen petition with the most recent information on the impact of menthol in cigarettes” (Supplement at 1). The supplement cited seventy-eight additional relevant sources of information that were not included in the 2013 citizen petition (Supplement at 3-5). Several of these studies were funded or supported by FDA or other Federal agencies acting in coordination with FDA to inform efforts related to the regulation of tobacco. In addition, as described in the response to comment 1, FDA has engaged in close study and careful consideration of the scientific evidence and complex policy issues related to menthol cigarettes. In assessing the population health impact of menthol cigarettes, the Agency assesses impact on the population as a whole, accounting for impact to both users and non-users of menthol cigarettes. In addition to assessing the risk of dependence and disease, FDA also assesses evidence regarding the potential role of menthol in facilitating experimentation and progression to regular use among youth and young adults, as well as reducing cessation success among smokers, in determining whether restricting menthol in cigarettes is appropriate for the protection of public health. Given the record before the Agency, FDA believes there is sufficient evidence to make a decision regarding the petitioners’ request to begin the rulemaking process to prohibit menthol as a characterizing flavor in cigarettes. As part of the rulemaking process under section 907 of the FD&C Act, the public will have an opportunity to comment on the proposed rule.

(Comment 3) Some comments state that the petitioners fail to fully consider the countervailing effects of a menthol ban (e.g., illicit market for menthol cigarettes, the unregulated design and manufacture of menthol cigarettes, reduced access controls for minors, expansion of criminal enterprises, and declining tax revenue).

(Response) FDA appreciates the commenters concerns about the potential countervailing effects of a menthol product standard. When FDA proposes a product standard, the FD&C Act requires FDA to consider information submitted in connection with a proposed standard including information submitted regarding the potentially countervailing effects of the standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband (section 907(b)(2) of the FD&C Act). Thus, FDA intends to solicit and consider comments regarding the potential for countervailing effects of a proposed

product standard during the rulemaking. Regardless, based on the record, including evidence regarding the potential for countervailing effects, FDA believes it is appropriate to issue this proposed rule.

We note that, although TPSAC did not analyze the “potential for and impact of a black market for menthol cigarettes” in the TPSAC Report (TPSAC Report at 225), since 2013, FDA has engaged in close study and careful consideration of the scientific evidence and complex policy issues related to menthol cigarettes, including the potential countervailing effects of a menthol product standard. As discussed above, FDA made available a draft concept paper entitled, “Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard” and sought public comment on the potential for illicit trade markets to develop in response to a tobacco product standard.³⁰ As part of the rulemaking process under section 907 of the FD&C Act, the public will have an opportunity to comment on the proposed rule, including on the issue of illicit trade and other potential countervailing effects.

3. The response

FDA appreciates your concerns regarding menthol cigarettes and shares your commitment to preventing and reducing the death and disease caused by tobacco products, including menthol cigarettes.

Cigarette smoking is the leading preventable cause of death and disease in the United States.³¹ Due to the “Special Rule for Cigarettes”, menthol cigarettes are the only flavored combusted cigarettes still marketed in the United States.

The Substance Abuse and Mental Health Services Administration (SAMHSA) estimated that in 2019 there were nearly 18.6 million current smokers of menthol cigarettes in the United States.³² Menthol cigarettes are disproportionately used by, and thus have a disproportionately negative impact on, youth and young adults³³, African Americans and other racial and ethnic minority populations³⁴, sexual and gender minorities³⁵, individuals with mental health disorders³⁶, and

³⁰ *Supra* note 17.

³¹ U.S. Department of Health and Human Services. *Smoking Cessation. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

³² United States Department of Health and Human Services. Substance Abuse and Mental Health Services Administration (SAMHSA). Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and Health, 2019. Analysis conducted on December 18th, 2020. SAMHSA’s public online data analysis system (PDAS). <https://pdas.samhsa.gov/>.

³³ *Id.*

³⁴ *Id.*

³⁵ Fallin, A., A.J. Goodin, and B.A. King. “Menthol Cigarette Smoking Among Lesbian, Gay, Bisexual, and Transgender Adults.” *American Journal of Preventive Medicine*, 48(1):93-97, 2015. Available at <https://doi.org/10.1016/j.amepre.2014.07.044>.

³⁶ Hickman, N.J., K.L. Delucchi, and J.J. Prochaska. “Menthol Use Among Smokers with Psychological Distress: Findings from the 2008 and 2009 National Survey on Drug Use and Health.” *Tobacco Control*, 23(1):7-13, 2014. Available at <https://doi.org/10.1136%2Ftobaccocontrol-2012-050479>.

those with lower household income³⁷. Nearly 85% of African Americans who smoke cigarettes smoke menthol cigarettes, whereas about 30% of White smokers are menthol smokers.³⁸ Findings from the 2018 National Youth Tobacco Survey (NYTS) show that, among middle and high school students who had smoked cigarettes in the past 30 days, 51.4% of non-Hispanic Black youth and 50.6% of Hispanic youth reported smoking menthol cigarettes, compared to 42.8% of non-Hispanic White youth.³⁹ This unequal use of menthol cigarettes by race/ethnicity has not changed since 2011.⁴⁰

Characterizing flavors in tobacco products, including menthol, enhance taste and make them easier to use. Menthol masks the harshness and irritation of tobacco smoke among new smokers and facilitates repeated experimentation and progression to regular use, particularly among youth and young adults.^{41,42} Menthol in cigarettes enhances nicotine addiction through a combination of its flavor and sensory effects, which introduce nicotine to new users in a less aversive manner than non-menthol cigarettes, and interacts with nicotine in the brain.^{43,44} Youth who initiate smoking with menthol cigarettes (compared with youth who initiate with non-menthol cigarettes) are at greater risk of progression from experimentation to established smoking and nicotine dependence.^{45,46}

Once a user is addicted, menthol's flavor and sensory effects facilitate continued smoking^{47,48} and menthol makes it harder for them to quit, particularly among daily smokers⁴⁹. This effect is most prevalent among African American menthol smokers, who disproportionately have more difficulty quitting than non-menthol smokers.⁵⁰ Consequently, the continued marketing of

³⁷ Mattingly, D.T., J.L. Hirschtick, R. Meza, et al. "Trends in Prevalence and Sociodemographic and Geographic Patterns of Current Menthol Cigarette Use Among U.S. Adults, 2005-2015." *Preventive Medicine Reports*, 20:101227, 2020. Available at <https://doi.org/10.1016/j.pmedr.2020.101227>.

³⁸ *Supra* note 32.

³⁹ Sawdey, M.D., J.T. Chang, K.A. Cullen, et al. "Trends and Associations of Menthol Cigarette Smoking Among US Middle and High School Students-National Youth Tobacco Survey, 2011-2018." *Nicotine & Tobacco Research*, 22(10), 1726-1735, 2020. Available at <https://doi.org/10.1093/ntr/ntaa054>.

⁴⁰ *Id.*

⁴¹ *Supra* note 18.

⁴² Klausner, K. "Menthol Cigarettes and Smoking Initiation: A Tobacco Industry Perspective." *Tobacco Control*, 20(Suppl. 2):ii12-ii9, 2011. Available at <https://doi.org/10.1136%2Ftc.2010.041954>.

⁴³ *Id.*

⁴⁴ Henderson, B.J., T.R. Wall, B.M. Henley, et al. "Menthol Alone Upregulates Midbrain nAChRs, Alters nAChR Subtype Stoichiometry, Alters Dopamine Neuron Firing Frequency, and Prevents Nicotine Reward." *The Journal of Neuroscience*, 36(10):2957-2974, 2016. Available at <https://doi.org/10.1523%2FJNEUROSCI.4194-15.2016>.

⁴⁵ *Supra* note 19.

⁴⁶ Nonnemaker, J., J. Hersey, G. Homsy, et al. "Initiation with Menthol Cigarettes and Youth Smoking Uptake." *Addiction*, 108(1):171-178, 2013. Available at <https://doi.org/10.1111/j.1360-0443.2012.04045.x>.

⁴⁷ Richter, P., D. Beistle, L. Pederson, et al. "Small-Group Discussions on Menthol Cigarettes: Listening to Adult African American Smokers in Atlanta, Georgia." *Ethnicity & Health*, 13(2): 171-182, 2008. Available at <https://doi.org/10.1080/13557850701784694>.

⁴⁸ Wackowski, O.A., K.R. Evans, M.B. Harrell, et al. "In Their Own Words: Young Adults' Menthol Cigarette Initiation, Perceptions, Experiences and Regulation Perspectives." *Nicotine & Tobacco Research*, 20(9):1076-1084, 2018. Available at <https://doi.org/10.1093/ntr/ntx048>.

⁴⁹ *Supra* note 21.

⁵⁰ Stahre, M., K.S. Okuyemi, A.M. Joseph, et al. "Racial/Ethnic Differences in Menthol Cigarette Smoking, Population Quit Ratios and Utilization of Evidence-Based Tobacco Cessation Treatments." *Addiction*, 105(Suppl. 1):75-83, 2010. Available at <https://doi.org/10.1111/j.1360-0443.2010.03200.x>.

menthol cigarettes raises profound health equity issues. This is true for active smokers as well as nonsmokers. From 2011-2018, the prevalence of secondhand smoke exposure was approximately twice as high among non-Hispanic Black nonsmokers compared to nonsmokers of other races/ethnicities.⁵¹

As evidence shows that menthol facilitates experimentation and progression to regular use among youth and young adults and makes quitting more difficult, particularly in African American smokers, FDA believes eliminating menthol as a characterizing flavor in cigarettes would benefit public health. Based on our consideration of the existing scientific evidence, including that submitted with the citizen petition and supplement, FDA intends to issue a proposed rule to prohibit menthol as a characterizing flavor in cigarettes. This action is consistent with FDA's determination, based on its periodic evaluation of standards pursuant to section 907(a)(5) of the FD&C Act, that the existing tobacco product standard should be changed.⁵²

In order to eliminate menthol as a characterizing flavor in cigarettes, FDA will need to complete "notice and comment rulemaking" in accordance with the Administrative Procedure Act and section 907 of the FD&C Act, and FDA must comply with all other applicable laws and Executive Orders. "Notice and comment rulemaking" is the process that FDA generally uses to create or modify regulations.⁵³ This process involves drafting and publishing a proposed rule in the *Federal Register* that describes the planned regulation and the basis for it (e.g., scientific and policy reasons), and seeks public comment. Section 907 of the FD&C Act also describes the process for proposing and promulgating product standards. Under section 907(c)(4) of the FD&C Act, FDA must provide for a comment period of at least 60 days, but the comment period can be 90 days or longer for more complex rulemakings or if FDA grants an extension request. If, based on all the information, FDA decides to issue a final rule, it would then need to draft a final rule for publication that includes a statement of basis and purpose for the regulation and that discusses the issues raised in public comments.

FDA intends to make this proposed rule one of the Agency's highest priorities. As a proposed rule on menthol will involve important public health issues, FDA expects that there will be substantial interest and input from other agencies and departments across the Government during the rulemaking process. Moreover, as with any rulemaking, the Agency will be facing other priorities, and possibly some unforeseen circumstances. However, FDA is highly committed to issuing this proposed rule.

⁵¹ Shastri, S.S., R. Talluri, and S. Shete. "Disparities in Secondhand Smoke Exposure in the United States: National Health and Nutrition Examination Survey 2011-2018." *JAMA Internal Medicine*, 181(1):134-137, 2021. Available at <https://doi.org/10.1001/jamainternmed.2020.3975>.

⁵² On November 11, 2020, the U.S. District Court of the Northern District of California held that section 907(a)(5) of the FD&C Act "requires that the FDA not only make periodic evaluations, but to make a determination of whether to *modify* the standard, which may include adding menthol cigarettes to the flavor ban." *African Am. Tobacco Control Leadership Council v. U.S. Dep't. of Health & Human Servs.*, No. 20-cv-04012-KAW, Dkt. No. 34 at 4 (N.D. Cal. Nov. 12, 2020) (emphasis in original).

⁵³ For additional information about FDA's rulemaking process, see <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/implementing-tobacco-control-act-through-policy-rulemaking-and-guidance> and <https://www.fda.gov/regulatory-information/fda-rules-and-regulations>.

B. Work with appropriate entities to provide support to smokers of menthol cigarettes who will quit as a result of the requested prohibition on menthol in cigarettes.

Your petition asserts that FDA should collaborate with providers of cessation programs, including those that provide comprehensive cessation services that are accessible to all populations and conduct related public education efforts, to mitigate any potential countervailing effects resulting from the prohibition on menthol as a characterizing flavor in cigarettes and cigarette smoke (Petition at 5).

While FDA generally does not provide direct cessation services, FDA intends to work with HHS to enlist and collaborate with other entities at the Federal, Tribal, State and Local levels who provide support to menthol smokers who quit or want to quit as a result of a prohibition of menthol as a characterizing flavor in cigarettes going into effect. In the meantime, we note that the Agency has developed a range of cessation messaging that aims to educate smokers, including menthol smokers, on the benefits of quitting. We have worked collaboratively with the National Cancer Institute (NCI) to develop a cessation website that features quitting tips, text message programs to help smokers “practice the quit,” and online cessation counseling. We also continue to work with stakeholders and public health partners to further amplify and disseminate cessation messaging through FDA’s Exchange Lab and CDC’s Media Campaign Resource Center. For more information on smoking cessation resources, see <https://www.fda.gov/tobacco-products/health-information/tobacco-public-health-resources>.

IV. Conclusion

For the reasons discussed above, FDA intends to issue a proposed rule to prohibit menthol as a characterizing flavor in cigarettes. In addition, while FDA generally does not provide direct cessation services, FDA intends to work with HHS to enlist and collaborate with other entities at the Federal, Tribal, State and Local levels who provide support to menthol smokers who quit or want to quit as a result of a prohibition of menthol as a characterizing flavor in cigarettes going into effect. FDA therefore grants your petition in accordance with 21 C.F.R. § 10.30(e)(3).

Regards,



May D. Nelson
Director, Office of Regulations
Center for Tobacco Products
Food and Drug Administration