DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1162

[Docket No. FDA–2021–N–1349]

RIN 0910–AI60

Tobacco Product Standard for Menthol in Cigarettes

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes. Tobacco use is the leading preventable cause of death and disease in the United States. Menthol's flavor and sensory effects increase appeal and make menthol cigarettes easier to use, particularly among youth and young adults. There are over 18.5 million menthol cigarette smokers ages 12 and older in the United States. This proposed product standard would reduce the appeal of cigarettes, particularly to youth and young adults, and thereby decrease the likelihood that nonusers who would otherwise experiment with menthol cigarettes would progress to regular smoking. In addition, the proposed tobacco product standard would improve the health and reduce the mortality risk of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation. FDA is taking this action to reduce the tobacco-related death and disease associated with menthol cigarette use. The proposed standard also is expected to reduce tobacco-related health disparities and advance health equity.

DATES: Submit either electronic or written comments on the proposed rule by July 5, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 5, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–1349 for ''Tobacco Product Standard for Menthol in Cigarettes.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beth Buckler or Eric Mandle, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 877–287–1373, *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes. In developing this proposed rule, FDA carefully considered the scientific evidence and complex policy issues related to menthol cigarettes. As described in the preamble of this rule, FDA has conducted multiple scientific reviews related to menthol cigarettes, issued two advance notices of proposed rulemaking (ANPRMs) to solicit data and information about menthol cigarettes, considered a citizen petition requesting that FDA ban menthol as a characterizing flavor in cigarettes, and sponsored research on a variety of menthol-related topics.

Each year, 480,000 people die prematurely from a smoking-attributable disease, making tobacco use the leading cause of preventable death and disease in the United States. In 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) banned characterizing flavors in cigarettes, other than tobacco or menthol, based on their appeal to youth, in order to reduce the number of children and adolescents who smoke cigarettes. As a result, menthol cigarettes are the only cigarettes with a characterizing flavor still marketed in the United States.

In 2019, there were more than 18.5 million current smokers of menthol cigarettes ages 12 and older in the United States. Although menthol cigarette smoking is widespread in the United States, menthol cigarettes are used at a particularly high rate by youth, young adults, and certain other vulnerable populations such as African American and other racial and ethnic groups. Menthol is a flavor compound added to cigarettes, which produces a minty taste and cooling sensation when inhaled. Menthol's flavor and sensory effects reduce the harshness of cigarette smoking and make it easier for new users, particularly youth and young adults, to continue experimenting and progress to regular use. In addition, data show that menthol cigarettes contribute to greater nicotine dependence in youth and young adults than non-menthol cigarettes. By prohibiting menthol as a characterizing flavor in cigarettes, this proposed product standard would reduce the appeal of cigarettes, particularly to youth and young adults, who are more likely to try a menthol cigarette as their first cigarette than a non-menthol cigarette. And because almost all daily smokers started smoking before the age of 25, it would thereby decrease the likelihood that nonusers who would otherwise experiment with menthol cigarettes would progress to regular smoking. By prohibiting menthol as a characterizing flavor in cigarettes, FDA expects a significant reduction in the likelihood of youth and young adult initiation and progression to regular cigarette smoking, which is expected to prevent future cigarette-related disease and death.

In addition, the proposed tobacco product standard would improve the health and reduce the mortality risk of current menthol cigarette smokers by substantially decreasing cigarette consumption and increasing the likelihood of cessation. Published modeling studies have estimated a 15.1 percent reduction in smoking prevalence within 40 years if menthol cigarettes were no longer available in the United States. These studies also estimate that 324,000 to 654,000 smoking attributable deaths overall (92,000 to 238,000 among African Americans) would be avoided within 40 years. FDA expects the public health benefit of this rule to be particularly pronounced among vulnerable populations, including youth and young adults, as well as Black smokers, who have the highest prevalence of menthol cigarette smoking and experience a disproportionate burden of the related harms. For the reasons discussed in the preamble of this proposed rule, FDA finds that the proposed tobacco product standard would be appropriate for the protection of the public health. Additionally, this proposed product standard is expected to substantially decrease tobacco-related health disparities and to advance health equity across population groups.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would prohibit the use of menthol as a characterizing flavor in cigarettes and cigarette components and parts, including those that are sold separately to consumers. Specifically, the rule would provide that a cigarette or any of its components or parts (including the tobacco, filter, wrapper, or paper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, menthol that is a characterizing flavor of the tobacco product or tobacco smoke. Under the proposed rule, no person may manufacture, distribute, sell, or offer for distribution or sale, within the United States a cigarette or cigarette component or part that is not in compliance with the product standard. Among the factors that FDA believes are relevant in determining whether a cigarette has a characterizing flavor are:

- The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;
- The multisensory experience (*i.e.,* taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts;
- Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of tobacco products; and
- Any other means that impart flavor or represent that the tobacco products has a characterizing flavor.

FDA is proposing that any final rule that may issue based on this proposed rule become effective 1 year after the date of publication of the final rule. Therefore, after the effective date, no person may manufacture, sell, or offer for sale or distribution within the United States a cigarette or any of its components or parts that is not in

compliance with part 1162. This regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumers for possession or use of menthol cigarettes. FDA's enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. State and local law enforcement agencies do not independently enforce the Federal Food, Drug and Cosmetic Act (FD&C Act). These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA's behalf. We recognize concerns about how State and local law enforcement agencies enforce their own laws in a manner that may impact equity and community safety and seek comment on how FDA can best make clear the respective roles of FDA and State and local law enforcement.

C. Legal Authority

Section 907 of the FD&C Act (21 U.S.C. 387g) prohibited characterizing flavors, other than menthol and tobacco, in cigarettes. Section 907 expressly preserved FDA's ability to prohibit menthol as an exercise of FDA's authorities to revise or issue tobacco product standards, including provisions that would require the reduction or elimination of a constituent (including a smoke constituent), or harmful component of tobacco products; and provisions respecting the construction, components, ingredients, additives, constituents (including smoke constituents), and properties of the tobacco product (section 907(a)(2), (a)(3), (a)(4)(A)(ii), and (a)(4)(B)(i) of the FD&C Act). FDA's authorities related to the sale and distribution of tobacco products are established under sections 907(a)(4)(B)(v) and 906(d) (21 U.S.C. 387f(d)) of the FD&C Act.

D. Costs and Benefits

The quantified benefits of this proposed rule come from lower smoking-attributable mortality in the U.S. population due to diminished exposure to tobacco smoke for both users and nonusers of cigarettes. The costs of this proposed rule are those to firms to comply with the rule, to consumers impacted by the rule, and to the government to enforce this product standard. In addition to benefits and costs, this rule will cause transfers from State governments, Federal Government, and firms to consumers in the form of reduced revenue and tax revenue.

We estimate that the annualized benefits over a 40-year time horizon will equal $220 billion at a 7 percent discount rate, with a low estimate of $102 billion and a high estimate of $334 billion, and $232 billion at a 3 percent discount rate, with a low estimate of $108 billion and a high estimate of $353 billion.

Over a 40-year time horizon, we estimate that the annualized costs will equal $307 million at a 7 percent discount rate, with a low estimate of $16 million and a high estimate of $601 million, and $291 million at a 3 percent discount rate, with a low estimate of $9 million and a high estimate of $573 million.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
Addiction Review	Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980–2021.
ANPRM	Advance notice of proposed rulemaking.
CARDIA	Coronary Artery Risk Development in Young Adults.
CFR	Code of Federal Regulations.
CPS II	Cancer Prevention Study II.
CTP	FDA's Center for Tobacco Products.
EE	Expert Elicitation.
ENDS	Electronic Nicotine Delivery Systems.
E.O.	Executive order.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
FR	Federal Register.
FTC	Federal Trade Commission.
HHS	U.S. Department of Health and Human Services.
HTP	Heated Tobacco Product.
IOM	Institute of Medicine.
LGBTQ+	Lesbian, gay, bisexual, transgender, or queer.
Nav Guide	Navigation Guide Systematic Review Methodology.
NCI	National Cancer Institute.
NHANES	National Health and Nutrition Examination Survey.
NHIS	National Health Interview Survey.
NRC	National Research Council.
NSDUH	National Survey on Drug Use and Health.
NYC	New York City.
NYAHS	National Young Adult Health Survey.
NYTS	National Youth Tobacco Survey.
PATH	Population Assessment of Tobacco and Health.
PRIA	Preliminary Regulatory Impact Analysis.
RYO	Roll-your-own.
SAVM	Smoking and Vaping Model.
SGR	Surgeon General Report.
SIDS	Sudden infant death syndrome.
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act.
TPSAC	Tobacco Product Scientific Advisory Committee.
TUS–CPS	Tobacco Use Supplement to the Current Population Survey.
YRBS	Youth Risk Behavior Survey.

III. Background

A. Need for the Regulation

FDA is proposing to prohibit menthol as a characterizing flavor in cigarettes. Cigarette smoking is the leading cause of preventable death and disease in the United States and is responsible for more than 480,000 premature deaths per year (Ref. 1). Menthol is a flavor compound that is added to cigarettes, which produces a minty taste and cooling sensation when inhaled (Ref. 2). These sensory properties contribute to smoker perceptions that menthol cigarettes are easier to inhale, are less irritating, have a better taste, are smoother and more refreshing than non-menthol cigarettes (Refs. 3–5). Menthol's flavor and sensory effects reduce the harshness of cigarette smoking among new users and facilitate experimentation and progression to regular smoking of menthol cigarettes, particularly among youth and young adults (Refs. 6–7, 5, 8). As a result, the brain is repeatedly exposed to nicotine and susceptible to nicotine addiction (Ref. 9).

In addition to its flavor and sensory effects, menthol contributes to a greater risk of nicotine dependence by enhancing the addictive effects of nicotine in the brain by affecting mechanisms involved in nicotine addiction (Refs. 10–13). Clinical data show that menthol cigarette smokers have higher levels of brain nicotinic receptors compared to non-menthol smokers (Ref. 14). Studies demonstrate that menthol, like nicotine, binds to nicotinic receptors in the brain (Refs. 15 and 16), and menthol alone can increase the number of nicotinic receptors in the brain (Refs. 10 and 11). Evidence demonstrates that the combined effects of menthol and nicotine in the brain are associated with behaviors indicative of greater addiction to nicotine compared to nicotine alone (Refs. 10 and 12).

Youth and young adults are particularly susceptible to becoming addicted to nicotine. Due to its ongoing development, the adolescent brain, which continues to develop until about age 25, is more vulnerable to nicotine's effects than the adult brain (Refs. 17–19). The combined effects of nicotine and menthol in the developing brain make youth who smoke menthol cigarettes particularly vulnerable to the effects of menthol on nicotine dependence.

Data from multiple studies across different populations and time periods demonstrate that menthol cigarettes contribute to greater nicotine dependence in youth and young adults [1] than non-menthol cigarettes (Refs. 20–28). Menthol is a significant contributor to experimentation and progression to regular cigarette smoking among this population (Refs. 25, 29–31, 8). This is of particular concern since the vast majority of smoking initiation occurs during adolescence (Refs. 32, 8, 31, 33) and youth and young adults are more likely to try a menthol cigarette as their first cigarette than a non-menthol cigarette (Refs. 8, 31, and 33).

In addition to the impacts on progression to regular use and dependence, menthol contributes to reduced cessation success, particularly among Black smokers [2] (Refs. 34–41) (see section IV.D of this document). A number of nationally representative studies among young adult and adult smokers show that menthol in cigarettes contributes to reduced cessation success (Refs. 34–35, 42, 36–38, 40, 43). Among Black smokers, this effect is consistent across large nationally representative studies, smaller clinical studies of smokers, reviews of the menthol and cessation literature, and meta-analyses, which examined outcomes from multiple menthol and cessation studies. Although findings among smokers in the general population produce more mixed results than findings specific to Black smokers, the strongest studies on the general population support an effect of menthol on reduced cessation. For example, two recent studies using data from the nationally representative longitudinal Population Assessment of Tobacco and Health (PATH) study found that menthol is associated with reduced smoking cessation across multiple years of followup (Refs. 40 and 43).

In 2019, there were more than 18.5 million current smokers of menthol cigarettes ages 12 and older in the United States (Ref. 44). Data show that menthol cigarettes are used at a particularly high rate by youth (aged 12–17), young adults (aged 18–25), and other vulnerable populations [3] such as African American and other racial and ethnic groups (Ref. 44). Prohibiting menthol as a characterizing flavor in cigarettes would help to decrease the nicotine addiction resulting from menthol cigarette use, and thereby, decrease disease and death.

In 2009, the Tobacco Control Act established the ''Special Rule for Cigarettes'' (section 907(a)(1)(A) of the FD&C Act (Special Rule for Cigarettes).[4] The Special Rule for Cigarettes banned characterizing flavors in cigarettes, other than tobacco or menthol, based on their appeal to youth, in order to reduce the number of children and adolescents who smoke cigarettes (see H.R. Rep. No. 111–58, pt. 1, at 37 (2009)). As a result, menthol cigarettes are the only cigarettes with a characterizing flavor still marketed in the United States.

In establishing the Special Rule for Cigarettes, Congress noted that, ''[g]iven the number of open questions related to menthol cigarettes, the legislation authorizes the Secretary to ban or modify the use of menthol in cigarettes based on scientific evidence'' (H.R. Rep. No. 111–58, pt. 1, at 39 (2009)). Specifically, the Tobacco Control Act authorizes FDA to adopt or revise product standards where FDA determines that such standard is appropriate for the protection of the public health (section 907(a)(2) and (3) of the FD&C Act).

After careful consideration of the scientific evidence, FDA is proposing to prohibit the use of menthol as a characterizing flavor in cigarettes in

[1] Though age ranges for youth and young adults vary across studies, in general, ''youth'' or ''adolescent'' encompasses those 11–17 years of age, while those who are 18–25 years old are considered ''young adults'' (even though, developmentally, the period between 18–20 years of age is often labeled late adolescence); those 26 years of age or older are considered ''adults'' or ''older adults'' (Ref. 32).

[2] Throughout the preamble of this proposed rule, FDA uses both the terms ''Black'' and ''African American.'' The term ''African American'' is used to describe or refer to a person of African ancestral origins or who identifies as African American. ''Black'' is used to broadly describe or refer to a person who identifies with that term. Though both of these terms may overlap, they are distinct concepts (*e.g.,* a Black person may not identify as African American). As a result, FDA relies on the specific term used by researchers when citing to specific studies. FDA uses the term ''Black'' when not citing to a specific study.

[3] Throughout the preamble of this proposed rule, the term ''vulnerable populations'' refers to groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation. Examples of vulnerable populations include those with lower household income and educational attainment, certain racial or ethnic populations, individuals who identify as LGBTQ+, underserved rural populations, those pregnant or trying to become pregnant, those in the military or veterans, or those with behavioral health conditions or substance use disorders.

[4] Section 907(a)(1)(A) of the FD&C Act states that beginning 3 months after the date of enactment of the Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph (section 907(a)(1)(A) of the Tobacco Control Act) shall be construed to limit the Secretary of HHS's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this section.

order to reduce the death and disease caused by cigarette use. For the reasons described in the preamble of this rule, FDA finds that this product standard would be appropriate for the protection of the public health because it would prohibit menthol cigarettes, which will reduce initiation rates of smoking cigarettes, particularly for youth and young adults, and thereby decrease the likelihood that nonusers of cigarettes who experiment with these tobacco products would progress to regular cigarette smoking. Additionally, the proposed tobacco product standard is anticipated to improve the health of current smokers of menthol cigarettes by decreasing cigarette consumption and increasing the likelihood of cessation among this population. Published modeling studies have estimated that 324,000 to 654,000 smoking attributable deaths would be avoided by the year 2060 if menthol cigarettes were no longer available in the United States (Refs. 45 and 46). These figures significantly understate the public-health benefits because they undercount lives saved of youth and young adults who, as the result of the menthol ban, do not begin to smoke. Beyond averted deaths, societal benefits would include reduced smoking-related morbidity and health disparities, diminished exposure to secondhand smoke among non-smokers, decreased potential years of life lost, decreased disability, and improved quality of life among former smokers. FDA expects the public health benefit of this rule to be particularly pronounced among vulnerable populations, including youth and young adults, as well as Black smokers, who have the highest prevalence of menthol cigarette smoking and experience a disproportionate burden of the related harms.

This proposed product standard is also expected to substantially decrease tobacco-related health disparities and to advance health equity across population groups. Tobacco-related health disparities are the differences observed in population groups regarding: The patterns (*e.g.,* initiation, dual or polyuse, cessation), prevention, and treatment of tobacco use; the risk, incidence, morbidity, mortality, and burden of tobacco-related illness; and in capacity and infrastructure (*e.g.,* political systems, educational institutions), access to resources (*e.g.,* health services and programs), and environmental secondhand smoke exposure (Refs. 47–49). Tobacco-related health disparities affect those who have systematically experienced greater obstacles to health based on group membership due to the inequitable distribution of social, political, economic, and environmental resources (Refs. 50, 49, and 51). Health equity is the attainment of the highest level of health for all people (Ref. 51). It is achieved by equally valuing all individuals regardless of group membership; removing social, economic, and institutional obstacles to health; and addressing historical and contemporary injustices (Refs. 51–53). The advancement of health equity is integral to the reduction and elimination of tobacco-related health disparities, which result from denied opportunity and access to economic, political, and social participation (Refs. 49 and 54).

Despite significant declines in cigarette smoking since 1964, ''very large disparities in tobacco use remain across groups defined by race, ethnicity, educational level, and socioeconomic status and across regions of the country'' (Ref. 1). Menthol cigarettes contribute to these disparities in cigarette use (Refs. 55–56, 21–24, 57–59) and the resulting disparities in health outcomes (Refs. 60–63, 50, 49). Members of underserved communities,[5] such as African American and other racial and ethnic populations, individuals who identify as LGBTQ+, pregnant persons, those with lower household income or educational attainment, and individuals with behavioral health disorders are more likely to report smoking menthol cigarettes than other population groups (Refs. 64–67, 55, 57–59, 68–69, 44, 70–71). Due to this increased prevalence of menthol cigarette smoking, members of underserved communities bear a disproportionate burden of tobacco-related morbidity and mortality (see section V.C of this document). This proposed product standard is anticipated to promote better public health outcomes across population groups.

B. Relevant Regulatory History of Menthol Cigarettes

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. FDA has conducted multiple scientific reviews related to menthol cigarettes, issued two ANPRMs to solicit data and information about menthol cigarettes, considered a citizen petition requesting that FDA ban menthol as a characterizing flavor in cigarettes, and sponsored research on a variety of menthol-related topics through contracts and interagency agreements with Federal partners, including the National Institutes of Health (NIH).[6] Among other things, FDA has considered the comments and information received in response to the scientific reviews, ANPRMs, and citizen petition in developing this proposed rule.

1. Scientific Reviews

In March 2010, FDA's Tobacco Product Scientific Advisory Committee (TPSAC) undertook a 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 populations (Ref. 72).[7] [8] In addition, the nonvoting

[5] As defined by Executive Order (E.O.) 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' (86 FR 7009, January 25, 2021) the term ''underserved communities'' refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life. In the context of tobacco products and tobacco-related health disparities, such communities may include populations disproportionately impacted by marketing and promotion targeted on the basis of such shared characteristics.

[6] Information on specific projects supported by FDA is available at *https://www.fda.gov/tobacco-products/tobacco-science-research/research* (search ''menthol'' or ''flavors'').

[7] 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 (Ref. 72 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 (Ref. 72). Therefore, ''FDA would need to assess the potential for contraband menthol cigarettes as required by the [FD&C] Act.'' (Ref. 72).

[8] Two tobacco companies challenged the TPSAC menthol report in court, alleging that certain TPSAC members had conflicts of interest that led them to shape the recommendations in a manner that injured the tobacco companies. 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

industry representatives of TPSAC submitted a separate document reflecting the tobacco industry perspective (Ref. 73).

Shortly thereafter, independent of TPSAC's work and report, including the nonvoting industry representatives' report, 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 titled ''Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes'' (Preliminary Evaluation) and has been peer reviewed (Ref. 74). FDA evaluated peer-reviewed literature, tobacco industry submissions and other materials provided to TPSAC, secondary data analyses, and CTP's own analyses of relevant large data sets (Ref. 74). The Preliminary Evaluation concluded that menthol in cigarettes is likely associated with increased smoking initiation and progression to regular smoking, increased dependence, and reduced cessation success, particularly among African American smokers (Ref. 74).

As the body of evidence has continued to grow, FDA recently undertook an updated robust review of the science on menthol in cigarettes. This review, titled ''Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980–2021'' (Ref. 75) (Addiction Review), covers the peer-reviewed, publicly available literature spanning the period from 1980 to April 30, 2021, and focuses on the impact of menthol cigarettes on outcomes related to addiction, including progression to regular use, dependence, and cessation. The Addiction Review has been peer reviewed by independent external experts. Taking into consideration comments from this peer review (Ref. 76), FDA revised the Addiction Review, and the final peer-reviewed document is available in the docket for this proposed rule (Ref. 75).

FDA's process for this scientific evaluation is described in detail in the Addiction Review (see Ref. 75). In sum, FDA used several scientific publication databases to retrieve articles published between 1980 and April 30, 2021, and developed a screening process, including eligibility criteria, to identify articles for inclusion in the final review (Ref. 75). FDA scored the individual quality of each study using the ''QualSyst'' systematic review tool (Ref. 75). For the weight of evidence approach, FDA adapted and used the Navigation Guide Systematic Review Methodology (NavGuide), an integrated Cochrane-style risk of bias analysis and weight of evidence approach (Ref. 75). The NavGuide approach was selected due to the rigor of its systematic review methods (*e.g.,* specifying explicit study questions, conducting a comprehensive search, rating the quality and strength of the evidence according to consistent criteria). The approach also allowed for combining the results of clinical and nonclinical evidence into a single conclusion about the effects of menthol on the outcomes of interest (Ref. 75). This weight of the evidence approach allowed FDA to assess the quality of the available evidence and determine the role of menthol in cigarettes on the sensory effects of smoking, as well as the impact of menthol in cigarettes on the progression to regular use, dependence, and cessation.

The Addiction Review found the totality of evidence from 1980 to 2021 supports that: (1) The sensory effects of menthol are associated with positive subjective smoking experiences, such as those that mask and reduce the harshness of cigarette smoking; these effects facilitate continued smoking, (2) menthol is associated with progression to regular cigarette smoking in youth and young adults, (3) menthol in cigarettes is associated with greater dependence among youth, (4) menthol is likely associated with reduced cessation success among the general population, and (5) menthol in cigarettes is associated with reduced cessation success among African American cigarette smokers (Ref. 75). FDA has considered the Addiction Review conclusions based on weighted scientific evidence in the development of this proposed product standard.

In addition, FDA undertook a review of scientific evidence related to the potential impacts of a menthol product standard. This review, titled ''Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes'' (Ref. 77) (Evaluation of Potential Impacts), is comprised of three distinct evaluations. Section 1 describes the results of a reproducible, transparent, and documented review of the scientific evaluation literature regarding the tobacco use behaviors of young people, tobacco use behaviors of adults, sales of tobacco products, illicit sales of tobacco products, and user modification of tobacco products (Ref. 77). Section 2 describes the scientific evidence relevant to consumers' product choices and intended use behaviors in response to a hypothetical menthol cigarette ban (Ref. 77). And section 3 summarizes and evaluates modeling studies that quantify the effects of a menthol cigarette ban to inform an assessment of the potential behavioral responses to a menthol product standard (Ref. 77).

The Evaluation of Potential Impacts has been peer reviewed by independent external experts. Taking into consideration comments from this peer review (Ref. 76), FDA revised the Evaluation of Potential Impacts, and the final peer-reviewed document is available in the docket for this proposed rule (Ref. 77). As with the Addiction Review, FDA has considered this scientific review in the development of this proposed product standard.

2. ANPRMs

In July 2013, FDA issued an 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 FR 44484, July 24, 2013) (Menthol ANPRM). FDA sought data and information on a number of complex questions, including whether FDA should consider establishing a tobacco product standard for menthol in menthol cigarettes; if so, what level of menthol would be appropriate for the protection of 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

menthol report. Id. at 57. This holding was vacated by the U.S. Court of Appeals for the D.C. Circuit on the ground that the tobacco companies failed to show any imminent injury from the report. *R.J. Reynolds Tobacco Co.* v. *FDA,* 810 F.3d 827, 832 (D.C. Cir. 2016).

Because of the pendency of this lawsuit at the time FDA began to develop the Preliminary Evaluation discussed below, FDA did not rely on the findings in the TPSAC menthol report in conducting its independent review of the scientific evidence related to menthol. Similarly, in connection with developing this proposed rule, FDA has reviewed the TPSAC menthol report, as well as the industry perspective document submitted by the non-voting industry representatives on TPSAC, but did not rely directly on any findings or recommendations in the TPSAC menthol report. Although the conclusions reached in the TPSAC menthol report are generally consistent with the determinations reached by FDA in support of this proposed rule, FDA conducted an independent analysis of the scientific evidence, including evidence that has developed since the report issued more than 10 years ago. FDA also notes that it has reviewed but did not rely on an additional analysis that builds on modeling prepared in connection with the TPSAC menthol report. That evidence is discussed in the Evaluation of Potential Impacts.

cigarettes were banned (78 FR 44484 at 44485). The Menthol ANPRM also requested comment on the Preliminary Evaluation and made available an addendum with articles published since the evaluation was submitted for peer review in 2011 (id.).

In July 2017, FDA announced a comprehensive approach to tobacco and nicotine regulation to protect youth and reduce tobacco-related disease and death (Ref. 78). As part of the public dialogue on the comprehensive approach, in March 2018, FDA issued three ANPRMs related to the regulation of nicotine in combustible cigarettes (83 FR 11818, March 16, 2018), flavors (including menthol) in tobacco products (83 FR 12294, March 21, 2018) (Flavors ANPRM), and premium cigars (83 FR 12901, March 26, 2018). In addition, FDA announced the availability of a draft concept paper titled ''Illicit Trade in Tobacco Products after Implementation of a Food and Drug Administration Product Standard,'' and sought public comment (83 FR 11754, March 16, 2018). This paper analyzes the potential for illicit trade markets to develop in response to a tobacco product standard (Ref. 79 at 2).

The Flavors ANPRM requested data and information about the role that flavors play in tobacco products (83 FR 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.,* electronic nicotine delivery systems (ENDS) and cigars) (83 FR 12294 at 12299).

3. Comments to the ANPRMs

While the Menthol ANPRM and the Flavors ANPRM discussed two different potential product standards and a range of product types, both specifically requested public input on the role of menthol in cigarettes. FDA received over 174,000 comments on the Menthol ANPRM, with approximately 165,000 of those comments submitted as part of 41 different organized campaigns. FDA also received over 525,000 comments on the Flavors ANPRM, a large proportion of which were form letters related to 61 different organized campaigns. Some of the issues raised in the comments to the ANPRMs are highlighted below.

Comments generally in support of any proposed menthol product standard stated that a product standard would protect the health of smokers and non-smokers, provide current menthol cigarette smokers an incentive to quit smoking, and protect youth, African Americans, and other vulnerable populations from the dangers of menthol cigarettes. FDA received many comments suggesting a specific, nonzero allowable level of menthol in cigarettes; many comments suggested a prohibition on menthol at any level and noted this would be the easiest standard to enforce. Other comments, without specifying a specific level or amount, argued that FDA should determine the nonzero allowable level of menthol in cigarettes. Many others urged FDA to adopt a product standard prohibiting menthol as a characterizing flavor in cigarettes without specifying a specific level or amount. Many of the comments in favor of prohibiting menthol as a characterizing flavor stated that FDA should be responsible for determining the definition of ''characterizing flavor'' to avoid reliance on industry practices or standards. Regardless of the formulation of a product standard, many comments stated that any menthol product standard is technically achievable and noted the prior ban on other characterizing flavors (other than tobacco and menthol) in cigarettes.

Many comments stated that a product standard should apply to menthol (natural or artificial) and any additive, constituent, artificial or natural flavor, component, or insert which conveys menthol or flavoring to cigarettes or cigarette smoke, including through the tobacco or something other than the tobacco itself. These commenters often noted that there are additives beyond natural and synthetic menthol that can create a similar flavor and sensation in cigarettes.

FDA also received comments from individuals and members of the tobacco industry generally opposing the establishment of any product standard for menthol cigarettes. These comments generally stated there was insufficient scientific evidence to support a menthol product standard. Industry comments also argued menthol cigarettes do not present a greater health risk when compared to non-menthol cigarettes, arguing that menthol does not increase the risk of disease or increase markers for dependence and addiction. Some comments opposed to a menthol product standard stated it would not be appropriate for the protection of the public health, as a standard would not lead to an increase in cessation and would result in consumers adding menthol to non-menthol cigarettes or the use of illicit or unregulated products.

Many comments received from industry noted concern with how FDA would define ''characterizing flavors,'' arguing that any such definition must use clear and science-based criteria. Some comments argued that, without a definition for ''characterizing flavors,'' it could be difficult for industry to comply with a menthol product standard. FDA also received comments from industry suggesting that any standard apply only to known natural or synthetic menthol additives currently used in the manufacture of cigarettes, stating that it was not logical for a product standard to apply to unknown additives or additives not currently in use.

FDA has reviewed and closely considered the comments to the ANPRMs, as well as additional evidence and information not available at the time of the ANPRMs, in developing this proposed rule.

4. Citizen Petition

On April 12, 2013, the Tobacco Control Legal Consortium (now known as the Public Health Law Center) submitted a citizen petition on behalf of themselves, several other public health organizations, and an individual requesting that FDA ban menthol as a characterizing flavor in cigarettes (Ref. 80). FDA issued an interim response in 2013, stating that the Agency had not yet reached a decision on the petition ''because it raises significant, complex issues requiring extensive review and analysis by Agency officials'' (Ref. 81).

In 2020, the African American Tobacco Control Leadership Council and several other public health organizations filed a lawsuit alleging that FDA unreasonably delayed addressing menthol as a characterizing flavor in cigarettes and responding to the citizen petition. Compl., *African Am. Tobacco Control Leadership Council* v. *U.S. Dep't. of Health & Human Servs.,* No. 20–cv–04012 (N.D. Cal. June 17, 2020), ECF No. 1. Before any action by the court, FDA committed to responding to the petition by a date certain. Subsequently, the U.S. District Court of the Northern District of California held that section 907(a)(5) of the FD&C Act ''does not necessarily require that FDA modify the [Special Rule for Cigarettes], but a *determination* of whether the [Special Rule for Cigarettes] should be modified is required by the statute.'' Order Granting in Part and Denying in Part Motion To Dismiss, *African Am. Tobacco Control Leadership Council* v. *U.S. Dep't. of*

Health & Human Servs., ECF No. 34 at 8 (emphasis in original).

On January 14, 2021, the Petitioners submitted a citizen petition supplement pursuant to 21 CFR 10.30(g) to update the administrative record with research developed since 2013 on the impact of menthol in cigarettes. The supplement identified and discussed 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 populations (*e.g.,* African Americans), evaluation data from several jurisdictions that have implemented prohibitions on menthol, technical achievability, and illicit trade (Ref. 82).

On April 29, 2021, FDA issued its final response to the citizen petition and included in its response a determination that the Special Rule for Cigarettes should be changed to include menthol (Ref. 83). In its response, FDA stated that it interpreted the 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.'' FDA granted the request, stating it intends to issue a proposed rule to prohibit menthol as a characterizing flavor in cigarettes (Ref. 83). FDA also stated that it 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 (Ref. 83). To reach this decision, the Agency considered, among other things, the petition, the January 2021 supplement filed by the Petitioners that updated the administrative record with research developed since 2013 on the impact of menthol cigarettes, and the comments submitted to the petition docket (Ref. 83).

C. Legal Authority

1. Product Standard Authority Generally

The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products to protect the public health, including reducing tobacco use by youth (Pub. L. 111–31). Section 901 of the FD&C Act (21 U.S.C. 387a) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco as well as any other tobacco product FDA deemed by regulation.

Among the tobacco product authorities provided to FDA is the authority to revise or-adopt tobacco product standards where FDA determines that such standard is appropriate for the protection of the public health (section 907(a)(2) and (3) of the FD&C Act). This includes a tobacco product standard to prohibit the use of menthol as a characterizing flavor. To establish a tobacco product standard, section 907(a)(3)(A) and (B) of the FD&C Act requires that FDA find that the standard is appropriate for the protection of the public health, taking into consideration scientific evidence concerning:

- The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;
- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

2. Authority To Prohibit Menthol as a Characterizing Flavor in Cigarettes

The Tobacco Control Act established the Special Rule for Cigarettes that prohibited cigarettes or any of its component parts from containing, as a constituent (including smoke constituent) or additive, an artificial or natural flavor or an herb or spice that is a characterizing flavor of the tobacco product or tobacco smoke (section 907(a)(1)(A) of the FD&C Act). This rule exempted menthol from the prohibition but stated that ''nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol'' (id.). Further, section 907(a)(2) states that FDA ''may revise'' the Special Rule in accordance with the rulemaking provisions outlined in section 907 of the FD&C Act.

Section 907 of the FD&C Act authorizes FDA to issue tobacco product standards that are appropriate for the protection of the public health, including provisions that would require the reduction or elimination of a constituent (including a smoke constituent), or harmful component of tobacco products and provisions respecting the construction, components, ingredients, additives, constituents (including smoke constituents), and properties of the tobacco product (section 907(a)(3), (a)(4)(A)(ii), and (a)(4)(B)(i) of the FD&C Act). This includes the authority to issue a new product standard prohibiting characterizing flavors in tobacco products pursuant to section 907(a)(3) and (4) and to amend or revoke an existing product standard pursuant to section 907(d)(4) of the FD&C Act. Section 907(a)(4)(B)(v) also authorizes FDA to include in a product standard a provision restricting the sale and distribution of a tobacco product to the extent that it may be restricted by a regulation under section 906(d) of the FD&C Act. Similar to section 907(a)(4)(B)(v), section 906(d) of the FD&C Act gives FDA authority to require restrictions on the sale and distribution of tobacco products by regulation if the Agency determines that such regulation would be appropriate for the protection of the public health. Section 701 of the FD&C Act (21 U.S.C. 371) provides FDA with the authority to ''promulgate regulations for the efficient enforcement of'' the FD&C Act.

Pursuant to section 907(a)(2) and (3) and (c) of the FD&C Act, FDA is proposing this tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes, because it would reduce the tobacco-related death and disease associated with menthol cigarette use, and FDA has found the standard to be appropriate for the protection of the public health consistent with section 907(a)(3), (a)(4)(A)(ii), and (a)(4)(B)(i). In addition, this proposed rule would prohibit the distribution, sale, and offer for distribution or sale of cigarettes with menthol as a characterizing flavor. This sale and distribution restriction would also assist FDA in enforcing the standard and would ensure that manufacturers, distributors, and retailers are selling product that complies with the standard. For these reasons, the Agency has found such restriction to be appropriate for the protection of the public health consistent with sections 907(a)(4)(B)(v) and 906(d) of the FD&C Act. FDA's analysis showing that the proposed tobacco product standard is appropriate for the protection of the public health is discussed in section V of this document.

D. FDA's Consideration of Health Equity

Advancing health equity is a policy priority and an important component of fulfilling FDA's mission to protect and promote public health. FDA and the Federal Government now recognize the advancement of health equity as ''both a moral imperative and pragmatic policy,'' as E.O. 13995 states.

Considerations related to health equity helped inform FDA's decision to

prioritize this proposed product standard. In particular, FDA took into account the disproportionate toll menthol cigarettes have taken on certain population subgroups. We note that the expected health benefits of this proposed standard are expected to be greater in these subgroups than in the population more generally.

This proposed product standard easily clears the threshold of being appropriate for the protection of the public health, due to the large health benefits from the expected reduced initiation and increased cessation when looking at the population generally. We make this finding even without taking into account the specific expected greater health benefits from this product standard among certain population subgroups.

IV. Menthol Cigarette Use Is Common, Addictive, and Harmful

A. Background

Menthol is a flavor additive widely used in consumer and medicinal products, including cigarettes (Refs. 1 at 782, 84). It is a compound that can be derived from plants or synthetically produced and has a minty taste and cooling properties (Refs. 84 and 2). Menthol is added to cigarettes in a variety of ways (*e.g.,* sprayed on the cut tobacco during blending; placed in a capsule in the filter) and eventually diffuses throughout the cigarette (Refs. 84–86). Menthol may be present in cigarettes not labeled as menthol cigarettes (Refs. 87, 84–85, 88–89).

The first menthol cigarette was marketed in the late 1920s, and the menthol share of the cigarette market has continued to increase since then (Refs. 90–92). Federal Trade Commission (FTC) data on market share of the largest cigarette manufacturers indicate that the menthol cigarette market increased from 16 percent in 1963 to 29 percent in 1979 (Ref. 92). From 1980 to 2009, it remained relatively constant ranging from 25 to 29 percent (Ref. 92) and, from 2010 to 2019, it increased from 31 to 37 percent (Ref. 92). Market trend research evaluating mass retail and convenience store cigarette sales indicates that, from 2011–2015, 31.5 percent of the cigarette market was menthol (Ref. 93). Estimates of cigarette consumption from 2000 to 2018 in the United States show an overall decline of 46 percent in cigarette consumption (435.6 to 235.6 billion), but the decline was greater among non-menthol (52.9 percent; 322.8 billion to 152.0 billion cigarettes) than menthol cigarettes (26.1 percent; 112.8 billion to 83.3 billion cigarettes) (Ref. 94).

B. Menthol Smoking Is Widespread and Disproportionately Impacts Youth, Young Adults, and Other Vulnerable Populations in the United States

In 2019, there were more than 18.5 million current smokers of menthol cigarettes ages 12 and older in the United States (Ref. 44). Although menthol cigarette smoking is widespread in the United States, menthol cigarettes are used at a particularly high rate among youth, young adults, and other vulnerable populations such as African Americans and other racial and ethnic groups (Ref. 44).

In 2019, researchers estimated that approximately 1.15 million U.S. middle and high school students had smoked a cigarette in the prior month based on data from the NYTS, a nationally representative survey (Ref. 95). Of these youth smokers, 46.7 percent reported smoking a menthol cigarette in the prior month, representing an estimated 530,000 youths (Ref. 95). Additionally, data from the 2019 NSDUH estimates that nearly 5.7 million U.S. young adults aged 18–25 years were current smokers, of which 51 percent (2.96 million young adults) smoked menthol cigarettes (Refs. 96 and 44). Using the same 2019 NSDUH data, an additional 39.4 million older adults (aged 26 and older) were current cigarette smokers, of which, 39 percent were current menthol smokers (15.4 million older adults) (Refs. 96 and 44).

The disproportionate use of menthol cigarettes by youth and young adult smokers compared to older adults has been consistent over time and across multiple studies with nationally representative populations. A study that examined changes in menthol smoking prevalence among cigarette smokers using NSDUH data from 2004 to 2014 found that the prevalence of past-month menthol smoking between 2008–2010 and 2012–2014 was highest among youth smokers aged 12–17 years (52.5 percent to 53.9 percent), followed by young adult smokers aged 18–25 years (43.6 percent to 50 percent), adult smokers aged 26–34 (34.6 percent to 43.9 percent), adult smokers aged 35–49 (30.3 percent to 32.3 percent), and adult smokers aged 50 and older (30.6 percent to 32.9 percent) (Ref. 57). In 2019 NSDUH data, past-month menthol use among cigarette smokers was highest among young adults aged 18–25 years (51 percent), followed by youth aged 12–17 years (48.6 percent) and older adults aged 26 and older (39 percent) (Ref. 44). Results from a study of Wave 2 data from the PATH Study (2014–2015) support these data and indicate age-related differences in past-month menthol cigarette smoking, with a higher proportion of youth aged 12–17 years (46.6 percent) and young adult aged 18–24 years (50 percent) cigarette smokers being menthol smokers compared to older adults aged 25 and older (34.4 percent) (Ref. 97). While data on trends of cigarette smoking from NYTS show a decline in overall cigarette smoking and in menthol cigarette smoking among middle and high school student smokers from 2011 to 2018, nearly half reported smoking menthol cigarettes in 2018 (Ref. 56).

African American smokers, regardless of age, are disproportionately more likely to smoke menthol cigarettes than smokers of any other race (Refs. 55–56, 21–24, 57–59, 44), and are also more likely than other racial and ethnic groups to try a menthol cigarette as their first cigarette, regardless of age (Refs. 33, 25, and 31).

Findings from 2018 NYTS data show that, among middle and high school students who were current cigarette smokers, 51.4 percent of non-Hispanic Black youth and 50.6 percent of Hispanic youth reported smoking menthol cigarettes, compared to 42.8 percent of non-Hispanic White youth (Ref. 56). Statistically significant differences in this proportion by race and ethnicity have been observed in the NYTS over the 2011–2018 period. While declines in menthol cigarette use from 2011–2018 have been observed among non-Hispanic White youth, declines were not observed among non-Hispanic Black youth or Hispanic youth (Ref. 56). Similarly, among all adults, data from the National Health Interview Survey (NHIS) indicate that cigarette smoking decreased from 20.9 percent in 2005 to 15.1 percent in 2015 (Ref. 70). While there was a significant decrease in the prevalence of menthol cigarette smoking overall (5.3 percent in 2005 to 4.4 percent in 2015), the prevalence of menthol cigarette smoking did not decrease among male smokers, adult smokers aged 25–34, adult smokers aged 55 and older, non-Hispanic Asian smokers, Hispanic smokers, or smokers who had less than a high school education (Ref. 70). Additionally, this study highlights that while the prevalence of all cigarette smoking and menthol smoking, specifically, have decreased over time (2005–2015), the prevalence of menthol smoking in 2015 remained highest among specific groups, such as non-Hispanic Blacks (11.9 percent) (Ref. 70).

A systematic literature review of menthol smoking by gender found that female smokers are more likely to smoke menthol cigarettes compared to men

(Ref. 98). Additionally, in another study of trends in menthol smoking from 2004 to 2014, the NSDUH data showed that women are significantly more likely to smoke menthol cigarettes than men (Ref. 57). This is consistent with data from the 2019 NSDUH, which indicated that a higher proportion and number of female cigarette smokers smoked menthol (44.8 percent; 9.49 million) than male cigarette smokers (37.1 percent; 9.10 million) (Ref. 44). High levels of menthol cigarette smoking have also been reported in pregnant smokers. An analysis of 2006 to 2015 participant data from two racially and ethnically diverse cohorts of pregnant smokers with lower educational attainment and lower household income indicated high prevalence of menthol use in both cohorts (85 percent and 87 percent) (Ref. 71).

Study findings indicate that individuals who identify as lesbian, gay, or bisexual are more likely to report smoking menthol cigarettes compared to those who identify as heterosexual, as well as other disparities related to gender identity or sexual orientation.[9] [10] A study examining menthol use by LGBT status found a higher prevalence and a higher likelihood of smoking menthol cigarettes among LGBT smokers compared to heterosexual smokers, and that these differences in use were even greater among LGBT female respondents compared to heterosexual women (Ref. 69). In national data from the 2019 NSDUH, only 6.9 percent of those identifying as straight or heterosexual reported smoking menthol (15.95 million) compared to 14 percent of those identifying as lesbian, gay, or bisexual (2.04 million) (Ref. 44). An analysis of pooled data from the 2015–2019 NSDUH indicate that compared to heterosexual/straight respondents, respondents who identified as gay males, lesbian/gay females, or bisexual females reported higher prevalence of past 30-day smoking (Ref. 99). Additionally, compared to heterosexual/straight respondents, gay males, and bisexual males, findings indicated that lesbian/gay females and bisexual females had higher menthol preference (defined as past 30-day use of menthol cigarettes among those who smoked cigarettes in the past 30-days) (Ref. 99).

Study findings show social gradient effects (where higher levels of indicators such as household income are linked to better health outcomes and lower levels are linked to poorer health outcomes) for menthol cigarette use (Refs. 44, 57, and 59). In 2019 NSDUH data, the prevalence of menthol smoking was 13.5 percent among those with a total family income less than $20,000, 8.4 percent between $20,000 and $49,999, 6 percent between $50,000 and $74,999, and 3.6 percent above $75,000 (Ref. 44). In another study of 2012–2014 NSDUH data, among past 30-day smokers, 43.7 percent of smokers with household income less than $30,000 smoked menthol cigarettes compared to 32.1 percent of smokers with household incomes greater than $75,000 (Ref. 57). Additionally, a study using 2018 NSDUH data found that menthol preference among cigarette smokers was 46.8 percent among those living in poverty,[11] 42.3 percent among those with income up to two times above the Federal Poverty Threshold, and 35.8 percent among those with income more than two times above the Federal Poverty Threshold (Ref. 59).

Menthol cigarette use is also higher among adults with behavioral health conditions or illness (Refs. 44, 100, 68, 59, 101). In 2019 NSDUH data, 17.4 percent of adults age 18 and older who reported past-month serious psychological stress reported past-month menthol smoking compared to only 6.6 percent of those who did not report past month serious psychological distress (Ref. 44). An analysis of young adults (aged 18–30 years) with a serious mental illness who were receiving treatment for smoking cessation, more than half (58 percent) smoked menthol cigarettes (Ref. 101). In national data, a study utilizing 2008/2009 NSDUH data also found that cigarette smokers with mental health symptoms were significantly more likely to smoke menthol cigarettes than smokers who report mild or no mental health symptoms (Ref. 68). Another national study of women aged 18–34 years indicated that menthol smokers had higher odds of reporting anxiety or depression compared to non-menthol smokers (Ref. 100). Lastly, an analysis of young adults (aged 18–30 years) receiving treatment for smoking cessation also found that of those with severe mental illness, more than half (58 percent) smoked menthol cigarettes (Ref. 101).

C. Menthol in Cigarettes Increases Smoking Initiation, Increases Progression to Regular Use, and Contributes to Nicotine Dependence

1. Menthol's Flavor and Sensory Properties Make Cigarette Smoking Easier and the Initial Response to Cigarettes More Palatable

Menthol is a flavor compound that is added to cigarettes, which produces a minty taste and cooling sensation when inhaled (Ref. 2). As a result of its sensory properties, menthol can reduce irritation (Refs. 102 and 103), reduce coughing (Refs. 104 and 105), and relieve pain (Ref. 106). For this reason, compared to non-menthol cigarettes, menthol smokers perceive menthol cigarettes as easier to smoke, less irritating, smoother and more refreshing, and having a better taste (Refs. 4–5, 107–108). Such flavor and sensory effects of menthol reduce the harshness of cigarette smoking among new users, facilitating experimentation and regular use, particularly among younger smokers (Refs. 6, 7, and 5).

An individual initiates smoking upon first trying a cigarette, even if they take just one or two puffs (Ref. 32). The vast majority of smoking initiation occurs during adolescence (Ref. 32). Initiation can progress to repeated experimentation, where individuals continue to occasionally try cigarettes, but do not smoke every day, and then to smoking regularly (Ref. 32). When an individual first tries a menthol cigarette, the flavor and sensory effects of menthol make initial smoking experiences more palatable. This makes it easier for new users, particularly youth and young adults, to continue experimenting with smoking and progress to regular use. The 2019 NSDUH found that each day, approximately 1,500 youth (under the age of 18 years) and 2,600 young adults (aged 18–25 years) first smoke a cigarette (Ref. 96). Results from Waves 1–4 of the PATH Study (2013–2017) and the Truth Initiative Young Adult Cohort Study show that youth (aged 12–17

[9] Throughout the preamble of this proposed rule, FDA uses the terminology cited in the scientific studies.

[10] The relevant scientific studies cited herein do not provide data separated by sexual orientation and gender identity. Due to these study limitations, we discuss sexual orientation and gender identity in a combined manner, despite their important distinctions.

[11] ''Living in poverty'' was determined and recoded in the NSDUH public use file based on a person's family income relative to poverty thresholds. The full definition of this variable can be found in the 2019 NSDUH codebook at: *https://www.datafiles.samhsa.gov/sites/default/files/field-uploads-protected/studies/NSDUH-2019/NSDUH-2019-datasets/NSDUH-2019-DS0001/NSDUH-2019-DS0001-info/NSDUH-2019-DS0001-info-codebook.pdf.* The U.S. Census Bureau assigns a poverty threshold for each combination of family size and number of children in the household. To be at 100 percent of the poverty threshold is equivalent to having a family income that is the same as the poverty threshold. A poverty level less than 100 percent indicates having a family income less than the poverty threshold and therefore defined by the Federal Government as living in poverty. A poverty level greater than 100 percent indicates having a family income greater than the poverty threshold.

years) and young adults (aged 18–24 years) are more likely to try a menthol cigarette as their first cigarette than a non-menthol cigarette (Refs. 8, 31, and 33). A separate cross-sectional analysis of Wave 1 PATH Study data (2013–2014) also found that among ever cigarette smokers (*i.e.,* those who reported ever trying a cigarette, even one or two puffs), nearly 43 percent of youth (aged 12–17 years) and 45 percent of young adults (aged 18–24 years) reported that the first cigarette they smoked was mentholated, compared to 30 percent of adults (aged 25 years and older) (Ref. 109).

Consistent with the evidence that menthol makes cigarettes easier to use and reinforces tobacco use among new users, results from Wave 2 of the PATH Study (2014–2015) indicate that youth (aged 12–17 years) and young adults (aged 18–24 years) who initiate smoking with menthol cigarettes are more likely to report having a pleasant first smoking experience compared to smokers who initiate with non-menthol cigarettes (Ref. 110). Smokers in the study who reported a pleasant first smoking experience were more likely to smoke regularly (Ref. 110). In another study, young adult smokers (aged 18–24 years) reported that the taste of menthol (*e.g.,* ''minty'', ''cool'', ''refreshing'') made cigarettes ''less harsh'' and ''easier to inhale'' than non-menthol cigarettes, and these factors influenced their initial preference for menthol cigarettes (Ref. 5). A study evaluating the sensory experiences of first cigarette use among young adult and adult smokers (aged 18–34 years) also found that fewer menthol smokers reported experiencing nausea during their first smoking experience compared to non-menthol smokers (Ref. 33). Regular menthol smokers also cite the flavor and sensory factors as primary reasons for continuing to smoke menthol cigarettes (Refs. 4, 5, and 111).

Evidence from tobacco industry documents indicates that the industry has been adding menthol to cigarettes because of perceptions among new users that menthol cigarettes are less harsh and easier to smoke (Ref. 7). These documents indicate that menthol has traditionally been added to cigarettes as a design feature to attract new youth and young adult smokers (Refs. 7 and 6). For example, a 1987 document from one company states: ''Menthol brands have been said to be good starter products because new smokers appear to know that menthol covers up some of the tobacco taste and they already know what menthol tastes like, vis-à-vis candy'' (Ref. 112). Additionally, a 1978 document about a traditionally menthol-only cigarette brand states that the brand is ''being purchased by Black people (all ages), young adults (usually college age), but the base of our business is the high school student'' (Ref. 113). Menthol cigarettes continue to be used disproportionately by youth and new smokers (Ref. 44).

These findings support that menthol's flavor and sensory effects make cigarettes easier to smoke by masking the harshness and irritation of tobacco and reducing unpleasant smoking experiences that can deter new users from repeated experimentation.

2. Menthol Enhances Nicotine Addiction in the Brain

Menthol enhances the effects of nicotine in the brain by affecting mechanisms involved in nicotine addiction. Nicotine is the primary chemical in tobacco products that causes addiction through its psychoactive and reinforcing effects (Ref. 114). Nicotine addiction occurs as the result of repeated exposure to nicotine, which induces changes in the brain (Refs. 115, 9, and 116). Addiction to nicotine can lead to symptoms of nicotine dependence, which may include tolerance to the effects of nicotine, withdrawal symptoms upon cessation of use, and craving cigarettes (Refs. 9 and 1).

Upon inhaling smoke from a burning cigarette, nicotine is absorbed into the lungs and rapidly travels to the brain. Once in the brain, nicotine produces its initial effects by binding to nicotinic receptors, the primary targets for nicotine in the brain, and inducing release of the chemical dopamine (Refs. 115 and 9). Dopamine plays a major role in the pleasurable and reinforcing effects of smoking that promote continued use (Refs. 115 and 9). After repeated exposure to nicotine, nicotinic receptors become less responsive, prompting an increase in the number of brain nicotinic receptors; this process has been implicated in the development of nicotine addiction (Ref. 9).

A clinical study that analyzed brain images of adult non-smokers, menthol smokers, and non-menthol smokers found that menthol cigarette smokers have higher levels of brain nicotinic receptors than non-menthol smokers (Ref. 14). Studies in rodents have been used to provide insight into a mechanism for how menthol produces this effect in the brains of smokers. The nicotinic receptor composition, distribution, and function in the rodent brain is comparable to that of humans, and rodents can be trained to perform a variety of behavioral tasks (Refs. 117–119). Therefore, rodents serve as an appropriate model to examine the behavioral effects of nicotine and the effects of nicotine in the brain.

Studies demonstrate that menthol, like nicotine, binds to nicotinic receptors in the brain (Refs. 15 and 16), and menthol alone can increase the number of nicotinic receptors in the brain (Refs. 10 and 11). Consistent with clinical findings in menthol smokers (Ref. 14), animal studies also demonstrate that menthol in combination with nicotine increases the number of nicotinic receptors in the brain to a greater extent than nicotine alone (Refs. 10–12). This effect in the brain was accompanied by greater intensity of nicotine withdrawal signs in rodents treated with nicotine and menthol compared to those treated with nicotine alone (Ref. 10). Menthol also enhances nicotine's effects on dopamine in the rodent brain. Animal studies demonstrate that nicotine-induced dopamine release is greater in the presence of menthol (Ref. 13). Additionally, menthol enhances nicotine-induced increases in dopamine cell activity to a greater extent than nicotine alone; these changes were associated with differences in behavioral responses to the rewarding effects of nicotine, where menthol-treated rodents exhibited greater reward for nicotine than those treated with nicotine alone (Ref. 12). These findings demonstrate that menthol's effects on nicotine in the brain are associated with behaviors indicative of greater addiction to nicotine.

In combination with menthol's flavor and sensory effects, menthol's interaction with nicotine in the brain plays a role in making it easier to experiment, progress to regular smoking and dependence, and harder to quit smoking.

3. The Adolescent Brain Is Particularly Vulnerable to the Effects of Nicotine

Youth and young adults are particularly susceptible to becoming addicted to nicotine. Due to its ongoing development, the adolescent brain, which continues to develop until about age 25, is more vulnerable to nicotine's effects than the adult brain (Refs. 17–19). The 1994, 2012, 2014, and 2020 Surgeon General's Reports on smoking and health note that almost 90 percent of current adult regular smokers initiated smoking before age 18, and 99 percent initiated smoking before the age of 25, which is the approximate age at which the brain has completed development (Refs. 120, 32, 1, 245). Though age ranges for youth and young adults vary across studies, in general, ''youth'' or ''adolescent'' encompasses

those 11–17 years of age, while those who are 18–25 years old are considered ''young adults'' (even though, developmentally, the period between 18–20 years of age is often labeled late adolescence); those 26 years of age or older are considered ''adults'' (Ref. 32).

Studies in adolescent and adult rodents show that adolescents are more sensitive to the rewarding and reinforcing effects of nicotine than adults (Refs. 121–124). In particular, animal studies highlight that early adolescence is a critical period for vulnerability to nicotine addiction (Refs. 125–127). Studies have also found that nicotine exposure during adolescence induces changes in the brain that either do not occur in animals exposed to nicotine in adulthood or are observed to a lesser extent following adult nicotine exposure. For example, studies using adolescent and adult rodents show that nicotine exposure during adolescence induces changes in gene expression, changes in brain structure and activity, and greater, more widespread increases in brain nicotinic receptor expression compared to exposure in adulthood (Refs. 128–131). These effects of nicotine on the developing brain largely occur in brain regions involved in addiction, learning, and memory (Refs. 132–133, 129, 131). Rodent studies also support that many of these changes remain after nicotine exposure has ended, and persist into adulthood (Refs. 133, 132, 130, 17–18).

Studies among youth support the findings from animal studies and show that adolescence is a vulnerable period for nicotine addiction. Youth who initiate tobacco use at earlier ages are more likely than those initiating at older ages to report current daily smoking and symptoms of tobacco dependence (Refs. 134–136). Researchers in a 4-year study of sixth grade students found that the most susceptible youth lose autonomy (*i.e.,* independence in their actions) regarding tobacco within 1 or 2 days of first inhaling from a cigarette (Ref. 137). The study also found that ''[e]ach of the nicotine withdrawal symptoms appeared in some subjects *prior* to daily smoking'' (Ref. 137) (emphasis added). Ten percent of youth showed signs of dependence to tobacco use within 1 or 2 days of first inhaling from a cigarette, and half had done so by the time they were smoking seven cigarettes per month (Ref. 137). Another study that followed 12–13 year old adolescents over 6 years found that 19.4 percent of adolescents who smoked weekly were nicotine dependent (Ref. 138). In a study of nicotine dependence among recent onset adolescent smokers (9th and 10th grade students), individuals who smoked cigarettes only 1 to 3 days of the past 30 days experienced nicotine dependence symptoms such as loss of control over smoking and irritability after not smoking for a while (Ref. 139). Overall, these findings demonstrate that, due to ongoing brain development, youth and young adults who experiment with smoking are at greater risk of becoming addicted to nicotine and maintaining tobacco product use into adulthood (Refs. 17, 18, and 32). Therefore, due to the combined effects of nicotine and menthol in the developing brain, youth who smoke menthol cigarettes are particularly vulnerable to the effects of menthol on progression to regular use and dependence.

4. Menthol Facilitates Experimentation and Progression to Regular Cigarette Use Among Youth and Young Adults

Consistent with the impact of menthol in cigarettes on smoking ease and nicotine addiction, menthol cigarettes have been shown to facilitate progression to regular use in new smokers, particularly in youth and young adults. A longitudinal study that evaluated smoking behaviors in middle and high school students over the course of 3 years (2000–2003) found that youth who initiate smoking with menthol cigarettes are more likely to progress to regular cigarette smoking compared to youth who initiate smoking with non-menthol cigarettes (Ref. 25). These findings are supported by nationally representative data from the Evaluation of Public Education Campaign on Teen Tobacco longitudinal national youth survey, which examined youth over 3 years (2013–2016) (Ref. 30). Youth in the study who reported experimenting with menthol cigarettes in a prior year were more likely to report progressing to regular smoking than youth who smoked non-menthol cigarettes (Ref. 30). Additionally, data from the 2011 National Young Adult Health Survey (NYAHS) found that young adult (aged 18–34 years) current menthol smokers had double the odds of reporting an increase in cigarette smoking over the previous year compared to non-menthol smokers (Ref. 29).

Similarly, longitudinal data from Waves 1 and 2 of the PATH Study (2013–2015) were used to evaluate the association of flavored tobacco use with product initiation among youth (aged 12–17 years), young adults (aged 18–24 years), and older adults (aged 25 and older) over a 10–13 month timeframe (Ref. 31). The study found that among all age groups, those that first used a menthol cigarette were more likely to report any past 12-month or past 30-day smoking at followup compared to those who reported a non-menthol cigarette as the first cigarette smoked (Ref. 31). Further, among those in all age groups, those whose first cigarette was menthol were more likely to report smoking every day in the past 30 days at followup compared to smokers who initiated with non-menthol cigarettes (Ref. 31). Expanding on these findings, longitudinal data across Waves 1–4 of PATH data (2013–2017) showed that among young adults, those who smoked menthol as the first cigarette were more likely to report continued smoking over the past 12 months compared to smokers who initiated with non-menthol cigarettes (Ref. 8).

Overall, the evidence supports that menthol facilitates repeated experimentation and progression to regular smoking among youth and young adults. This finding is consistent across different populations and time periods, including in studies that assess large, nationally representative populations.

5. Menthol Contributes to Nicotine Dependence in Young People

Data from multiple studies across different populations and time periods demonstrate that menthol cigarettes contribute to greater nicotine dependence in youth (Refs. 20–28). One longitudinal study evaluated middle and high school students over 3 years (2000–2003) in 83 schools in 7 communities across 5 states. Data from the study show that youth who initiated smoking with menthol cigarettes scored higher on a scale of dependence than youth who initiated with non-menthol cigarettes (Ref. 25). Nationally representative data from the 2000 and 2002 NYTS found that youth who smoked menthol cigarettes on at least 1 day in the past month reported higher scores on a scale of nicotine dependence compared to non-menthol smokers (Ref. 21). In addition, studies using 2004 and 2006 NYTS data found that, compared to youth non-menthol smokers, youth menthol smokers report multiple indicators of nicotine dependence, including higher levels of craving for cigarettes, needing a cigarette within one hour after smoking, and increased feelings of restlessness and irritability without smoking (Refs. 22 and 24). Pooled NYTS analyses (2017–2020) also indicate that youth menthol smokers have greater odds of experiencing tobacco cravings and using tobacco within 30 minutes of waking than non-menthol smokers (Ref. 28). Similarly, results from Wave 2 PATH Study data (2014–2015) show that youth menthol

smokers report higher levels of craving, tolerance to the effects of nicotine, and affiliative attachment (feeling ''alone'' without cigarettes), indicating that youth menthol smokers are more physically dependent on nicotine and experience greater emotional attachment to cigarettes than youth non-menthol smokers (Ref. 26).

Studies also demonstrate that youth menthol smokers smoke more frequently than non-menthol smokers, indicating an increased risk of being more nicotine dependent than non-menthol smokers. Youth who smoke more frequently display greater symptoms of nicotine dependence (Ref. 138). Compared to smokers of ''other brands'' (at the time of the study ''other brands'' may have included non-menthol flavored and unflavored cigarettes), youth menthol smokers have reported greater levels of smoking, including having smoked more total cigarettes, smoking on more days and more cigarettes in a month, having smoked more recently, and having ever smoked daily (Ref. 23). Nationally representative data also indicate that higher proportions of youth menthol smokers report smoking more frequently compared to non-menthol smokers (Refs. 56, 27, and 28). In analyses of pooled 2016–2018 NYTS data, higher proportions of youth menthol smokers reported smoking on more days during the month, smoking more cigarettes per day, and smoking 100 or more cigarettes in their lifetime compared to non-menthol smokers (Ref. 56). These findings are supported by 2017–2020 NYTS data, which show that youth menthol smokers have greater odds of smoking 10–30 days out of the month compared to non-menthol smokers (Refs. 27 and 28). Furthermore, 2017 and 2018 NYTS data indicate that, compared to youth non-menthol smokers, youth menthol smokers are more likely to report intentions to continue smoking cigarettes in the following year (Ref. 27).

Some studies have not found a significant difference in dependence outcomes between youth menthol and non-menthol smokers. One study, using data from the Development and Assessment of Nicotine Dependence in Youths study, examined the relationship between the first smoking experience and the development of nicotine dependence symptoms in youth and did not find a difference in dependence level between menthol and non-menthol smokers (Ref. 140). A study that used PATH data to examine the association between first use of menthol cigarettes and nicotine dependence scores at a subsequent wave, also did not find a relationship between menthol cigarette use and dependence among youth (Ref. 8). Furthermore, a nationally representative study that evaluated associations between menthol use and dependence among youth (aged 15–19 years) in the 2003 and 2006–2007 Tobacco Use Supplement to the Current Population Survey (TUS–CPS) and youth (aged 12–19 years) in the 1999–2010 National Health and Nutrition Examination Survey (NHANES) did not find an association between menthol smoking and level of dependence (Ref. 141).

Studies that found no effect of menthol on dependence in youth constitute a smaller number of studies in the totality of evidence. The few studies (discussed in the previous paragraph) that did not find an effect of menthol in cigarettes on greater dependence in youth were either not nationally representative or had other limitations that reduced the generalizability or influenced the validity of the findings. These study limitations include small samples sizes, which may reduce ability to detect significant between-group differences; failure to report sample sizes for populations assessed; and survey data that included participants beyond the typical age range for youth studies (age 12–17 years), which reduces generalizability of the findings to youth.

Based on the number and strength of the studies that support the conclusion that menthol is associated with greater dependence among youth and the limitations of the evidence that did not find an effect of menthol on youth dependence, the totality of evidence supports that menthol in cigarettes contributes to greater dependence among youth. This conclusion is supported by multiple nationally representative studies that were designed to collect and evaluate survey data on tobacco use in youth populations.

D. Menthol in Cigarettes Makes Quitting Smoking More Difficult

1. Menthol Contributes to Reduced Cessation Success, Particularly Among Black Smokers

A number of nationally representative studies among young adult and adult smokers show that menthol in cigarettes contributes to reduced cessation success (Refs. 34–35, 42, 36–38, 40, 43). A study from the 2003 and 2006–2007 TUS–CPS examined quit attempts and quit rates in menthol and non-menthol smokers (Ref. 37). Overall, quit attempts were 8.8 percent higher among menthol smokers compared to non-menthol smokers, but menthol smokers had 3.5 percent lower rates of quitting within the past year and 6 percent lower rates of quitting within the past 5 years compared to non-menthol smokers (Ref. 37). Young adults (aged 18–24 years) who smoked menthol cigarettes made more quit attempts than menthol smokers of older adult age groups (aged 25 and older) and had higher rates of quitting for 3 months to 1 year than non-menthol smokers; however, when evaluating longer term quitting (*i.e.,* within the past 5 years) young adult menthol smokers were less likely to have successfully quit smoking than non-menthol smokers (Ref. 37). Taken together, these findings suggest that short-term quitting does not translate to long-term success in quitting among young adult menthol smokers. Other studies that used 2003 and 2006–2007 TUS–CPS data examined the role of menthol in cessation and found that, compared to non-menthol smokers, menthol smokers were less likely to have successfully quit smoking for at least 6 months (Ref. 42) and were less likely to report having quit smoking in the past 5 years (Ref. 36). Data from the 2010–2011 TUS–CPS also found that menthol smokers were less likely than non-menthol smokers to report having abstained from smoking for 1–3 years (Ref. 38).

Additionally, longitudinal studies demonstrate that menthol smokers have more difficulty quitting compared to non-menthol smokers. One PATH Study using data from Waves 1–4 (2013–2017) found that, after 12 months, quit rates were significantly lower among daily menthol smokers (4 percent) compared to daily non-menthol smokers (5.3 percent) after adjusting for age, sex, race and ethnicity, education, nicotine dependence, and past quit attempts (Ref. 40). Daily menthol smokers also had 24 percent lower odds of quitting smoking compared to non-menthol smokers (Ref. 40). Another PATH Study using data from Waves 1–4 (2013–2017) evaluated short-term (30-day) and long-term (12-month) smoking abstinence among menthol and non-menthol smokers who had attempted to quit smoking in the past 12 months (Ref. 43). Menthol smoking decreased the probability of 30-day smoking abstinence by 28 percent and the probability of 12 month smoking abstinence by 53 percent compared to smoking non-menthol cigarettes after adjusting for race, sex, age and frequency of smoking (Ref. 43). The Coronary Artery Risk Development in Young Adults (CARDIA) study, which evaluated smoking cessation behavior in young adult smokers (age 18–30 years)

across 15 years (1985–2000), also found that menthol smokers were more likely to report continued smoking at two consecutive followups and were almost twice as likely to have relapsed compared to non-menthol smokers (Ref. 142).

Short- and long-term clinical longitudinal studies of cessation also show that menthol smokers are less likely than non-menthol smokers to achieve cessation success (Refs. 143–147). A short-term cessation study found that menthol smokers were more likely than non-menthol smokers to relapse within 48 hours of quitting smoking (Ref. 147). A long-term cessation study evaluated the effectiveness of smoking cessation therapies and tested smokers for cessation success at several timepoints throughout the study (Ref. 146). Menthol smoking was associated with reduced likelihood of successful quitting at the 4-week, 8-week, and 26-week followup assessments (Ref. 146). These findings are supported by data from studies of smokers interested in quitting smoking, which show that menthol smokers are less likely to achieve cessation success than non-menthol smokers at study followups ranging from 3 weeks to 6 months (Refs. 148, 143–145).

Evidence from nationally representative studies show that the effect of menthol on reduced cessation success is particularly evident among Black smokers (Refs. 34–38, 40). Data from the 2005 NHIS Cancer Control Supplement were used to examine racial and ethnic differences in menthol cigarette smoking and found that African American menthol smokers had a significantly decreased likelihood of quitting smoking compared to African American and White non-menthol smokers (Ref. 35). Data from the 2005 and 2010 NHIS were also used to evaluate the association between menthol cigarette smoking and likelihood of being a former smoker (Ref. 38). Black menthol smokers were less likely than Black non-menthol smokers to report not having smoked in the past year (Ref. 38). Additional analyses of 2005 NHIS and 2003 and 2006–2007 TUS–CPS data found that, compared to Black non-menthol smokers, Black menthol smokers were less likely to report smoking ''not at all'' at the time of the survey and less likely to report having quit smoking in the past 5 years (Refs. 34 and 36).

Longitudinal studies using Waves 1–4 PATH data (2013–2017) and data from the CARDIA Study also demonstrate that African American menthol smokers have more difficulty quitting compared to African American non-menthol smokers. These studies evaluated the effect of menthol on cessation at multiple timepoints in the same population of smokers. A recent study using nationally representative PATH data found that, after 12 months, quit rates were significantly lower among African American daily menthol smokers (3 percent) compared to African American daily non-menthol smokers (6.2 percent) (Ref. 40). Among Black daily smokers, menthol smokers also had 53 percent lower odds of quitting smoking compared to non-menthol smokers after controlling for age, sex, education, nicotine dependence, and past quit attempts (Ref. 40). Additionally, the CARDIA study measured smoking cessation behaviors in young adult (aged 18–30 years) menthol and non-menthol smokers from four U.S. cities over 15 years (1985–2000) (Ref. 142). After adjusting for health insurance status and other factors, the study found that African American menthol smokers were less likely to report having sustained cessation at two consecutive followups than African American non-menthol smokers (Ref. 142). Among African Americans, menthol smokers were also more likely to have relapsed back to smoking (Ref. 142).

Clinical longitudinal studies have also evaluated short- and long-term cessation success in current smokers and smokers seeking treatment to quit. These studies show that among African Americans, menthol smokers are less likely than non-menthol smokers to remain abstinent from smoking (Refs. 149–152, 146). A cessation study in African American smokers determined that the smokers who had quit by the end of the 7-week study treatment were more likely to smoke non-menthol cigarettes, compared to menthol cigarettes (Ref. 152). Furthermore, a long-term cessation study found that, among African American smokers, menthol smokers were significantly less likely to have quit at the 6-month followup assessment (Ref. 151). Another clinical study in African American smokers found that menthol smokers were less likely to have quit smoking at the 6-month followup than non-menthol smokers (Ref. 150). Data from the 2003 and 2006–2007 TUS–CPS also found that African American menthol smokers made more quit attempts and had higher rates of quitting for 3 months to 1 year than smokers of other racial and ethnic groups; however, when evaluating quitting in the past 5 years, quit success was lower among African American menthol smokers compared to other racial/ethnic groups (Ref. 37).

Taken together, these findings suggest that short term quitting does not translate to long term success in quitting among African American menthol smokers. Furthermore, studies using 2006–2007 and 2010–2011 TUS–CPS data show that African American menthol smokers are more likely to make a quit attempt than African American non-menthol smokers, but these attempts do not necessarily translate into successful cessation (Refs. 153 and 154). Additionally, a community-based survey of African American adults in Minnesota aimed to understand African Americans' perceptions of menthol cigarettes and reasons for unsuccessful quit attempts among menthol smokers (Ref. 155). Menthol smokers in the study were more likely than non-menthol smokers to perceive menthol as harder to quit. Forty-five percent of menthol smokers who reported a failed quit attempt reported craving as the reason for the unsuccessful attempt (Ref. 155).

Some studies do not show that menthol smokers have more difficulty quitting than non-menthol smokers (Refs. 156–159, 67, 160, 64, 29, 161–163). For example, data from the 2003 and 2006–2007 TUS–CPS that evaluated smoking abstinence at 2 weeks did not find a difference in cessation success between menthol and non-menthol smokers (Ref. 64). Data from the nationally representative 2011 NYAHS study of young adults (aged 18–34 years) who self-reported past year smoking behaviors also did not find significant differences in the proportion of menthol and non-menthol smokers who reported quitting (Ref. 29). Among longitudinal studies, some studies have reported no difference in quit rates or odds of quitting between menthol and non-menthol smokers at 6-month, 7-month, 12-month, and 5-year followup assessments based on individual self-report (Refs. 159, 158, 156, 163). In another longitudinal study, researchers analyzed data from a randomized controlled trial of smoking cessation that tested breath carbon monoxide to confirm self-reported smoking status at an 8-week follow-up assessment (Ref. 161). The study found no difference in smoking abstinence rates between menthol and non-menthol smokers (Ref. 161).

Two meta-analyses of the literature that combined the results of multiple menthol and cessation studies, as well as one systemic literature review, all found statistically significant reductions in the likelihood of cessation among African American menthol smokers, and

two of the three found reductions for cessation in the general population (Refs. 39, 41, and 164). These studies highlight the large amount of variability across the different studies in this body of literature. For example, across menthol and cessation studies, populations varied by sociodemographic factors such as race or ethnicity, gender, and geographic region; studies ranged from large nationally representative samples to small clinical trials of cessation; studies varied by the followup timepoints at which they assessed cessation, ranging from 48 hours to 15 years; studies did not use the same methods or definitions to measure cessation; and studies did not control for the same factors that may influence cessation outcomes (*e.g.,* demographics, nicotine dependence, use behaviors). This variability may in part explain the inconsistencies across study findings related to menthol and cessation.

Of studies that evaluated menthol in populations of current and former smokers, studies which found that menthol smokers have more difficulty quitting were more likely to be longitudinal, allowing for assessments of cessation across multiple time points among the same individuals, and generally had longer followup periods than studies that found no effect of menthol on cessation success. Several studies which found that menthol reduces cessation success also confirmed whether menthol smokers had quit at followup assessments by testing for indicators of cigarette smoking in saliva and/or through breath carbon monoxide, in addition to individual self-report. An individual's self-report of quitting may not always be accurate (*e.g.,* individuals may not remember correctly or may not be truthful in responding); therefore, studies that also test for indicators of cigarette smoking through biochemical verification, such as levels of carbon monoxide in breath and/or nicotine metabolites in blood, urine, or saliva, provide strong evidence to validate individual responses (Ref. 165). Furthermore, the meta-analyses of the cessation literature only included studies published through 2017 (Refs. 39 and 41). Two recent studies using data from the nationally representative, longitudinal PATH Study, are thus not included in these meta-analyses; both PATH studies suggest that menthol smoking is associated with reduced smoking cessation across multiple years of data (Refs. 40 and 43). Therefore, despite some contrary findings, the studies that utilized designs that allowed for long-term assessments of menthol and cessation success and that used multiple methods to confirm smoking status at followups were more likely to find an effect of menthol on reduced cessation success in the general population.

2. Menthol's Interaction With Nicotine in the Brain Makes it Harder To Quit Smoking

Addiction to nicotine makes it difficult to quit smoking (Ref. 1). As discussed in section IV.C.2, repeated exposure to nicotine through smoking leads to an increase in nicotinic receptor levels in the brains of smokers; this process is associated with the development of nicotine addiction (Ref. 9). When an individual stops smoking, such as overnight or when attempting to quit, the nicotine levels in the brain decrease as the body clears nicotine, but the number of nicotinic receptors does not (Ref. 115). The combination of high levels of nicotinic receptors and low levels of nicotine in the brain produces the discomfort smokers feel when experiencing symptoms of nicotine withdrawal (Ref. 115). This is consistent with reports that smokers with greater brain nicotinic receptor levels have more difficulty quitting than smokers with lower brain nicotinic receptor levels (Ref. 166).

Clinical and animal studies show that menthol enhances brain nicotinic receptor levels to a greater extent than nicotine alone (Refs. 14, 10, and 11). These changes occur in brain regions involved in the development of nicotine addiction (Refs. 10–12). Therefore, menthol's ability to enhance the effects of nicotine in the brain contributes to why menthol smokers have greater difficulty quitting smoking compared to non-menthol smokers.

3. Conclusion

The totality of scientific evidence on menthol and cessation supports the conclusion that menthol cigarettes contribute to reduced cessation success, particularly among Black smokers. This effect of menthol among Black smokers is consistent across large nationally representative studies, smaller clinical studies of smokers, reviews of the menthol and cessation literature, and meta-analyses, which examined outcomes from multiple menthol and cessation studies. Findings among smokers in the general population produce more mixed results, which may be attributed in part to heterogeneity across study designs, methods, and populations; however, the evidence that supports an effect of menthol on reduced cessation success includes longitudinal studies that evaluated quitting outcomes in the same population of smokers for up to 15 years and studies of up to 6 months that tested for indicators of continued cigarette smoking to strengthen the validity of individual self-report.

When considering the evidence from nationally representative surveys, longitudinal studies that evaluated cessation outcomes over time, and menthol's effects on nicotinic receptors in the brain, the totality of evidence supports that menthol in cigarettes contributes to reduced cessation success, particularly among Black smokers.

E. Menthol Cigarettes Are Marketed Disproportionately in Underserved Communities and to Vulnerable Populations

Tobacco marketing activities (*e.g.,* advertising and promotions) are effective in promoting sales, increasing tobacco use, and engendering positive attitudes about tobacco products among youth, young adults, and other vulnerable populations (Refs. 167, 32, and 49). With regard to menthol cigarettes, decades of targeted marketing activities have helped to make menthol cigarettes more appealing and affordable and contributed to the pervasive and enduring nature of disparities in menthol cigarette smoking observed in vulnerable populations, particularly the Black community.

Tobacco industry research on menthol cigarettes illustrates that the industry ''carefully researched the menthol segment of the market'' and ''added [menthol] to cigarettes in part because it is known to be an attractive feature to inexperienced smokers'' (Ref. 7). In addition, evidence shows the tobacco industry employed a wide range of marketing activities, including branding, advertising and promotion, product placement, and pricing, to promote sales and increase menthol cigarette use by certain populations.

For example, research indicates that in the 1960s and 1970s, the tobacco industry's menthol cigarette advertising and promotion heavily targeted the African American community by use of darker-skinned models, tailored messaging and language, and reliance on media such as magazines with a high Black readership (Refs. 168, 90, and 92). Industry research identified the cultural values, geographic location, and taste preferences of Black smokers, which was then used to inform tobacco product branding (*e.g.,* ''Kool'' cigarettes), culturally-tailored imagery in advertisements, and locations to

reach and appeal to Black menthol smokers (Refs. 169, 168, 90–91).

Over many decades, tobacco companies continued to employ marketing strategies to promote menthol cigarette use among youth, young adults, and underserved communities, such as low-income Black communities. The strategies used to target underserved communities included discounts (Ref. 170), distribution of free samples (Refs. 168, 171, and 172), and advertising in nightclubs, bars, and special events (Ref. 171). The tobacco industry also marketed menthol cigarettes to low-income Black communities and youth, including Black teens as young as 16 years of age, by selling menthol cigarettes in smaller package quantities to encourage trial and initiation, and to provide a lower price point (Refs. 173 and 174).

Recent scientific evidence indicates that tobacco companies market menthol cigarettes in the retail environment to continually appeal to underserved communities. For example, menthol marketing is more prevalent in neighborhoods that have more Black and low-income residents (Refs. 170 and 175). Furthermore, tobacco retailers in predominantly Black neighborhoods are more likely to advertise discount promotions for menthol cigarettes, and sell menthol cigarettes at a lower price, as compared to tobacco retailers in predominantly White neighborhoods (Refs. 175, 170, and 176). Menthol marketing is also more visible in neighborhoods with predominately Black residents as compared to predominately White neighborhoods, as well as in urban neighborhoods (Ref. 175). A recent nationally representative study of tobacco retailers in the contiguous United States found that retail menthol advertising was more common in neighborhoods with more Black and low-income residents (Ref. 177). Furthermore, price promotions for Newport brand menthol cigarettes were more common in retailers in neighborhoods with more Black residents (Ref. 177).

Higher exposure to tobacco advertisements and retailing are associated with disparities in tobacco use susceptibility and tobacco use among youth. For example, youth who live or go to school in neighborhoods where tobacco retailers are disproportionately present are more susceptible to smoking (Refs. 178 and 179), are more likely to experiment with smoking (Refs. 180 and 179), and are more likely to smoke currently (Ref. 181).

Taken together, scientific evidence indicates that menthol cigarettes have historically and continue to be disproportionately marketed in underserved communities and contribute to the longstanding disparities in menthol cigarette smoking and health outcomes observed in vulnerable populations, particularly the Black community. While targeted marketing is only one factor in the development and perpetuation of menthol cigarette use and related harms, this background helps to explain and provide critical context for the outcomes and disparities that undermine public health and are of concern to FDA. Addressing how these products disproportionately affect vulnerable populations supports the Agency's mission of promoting public health.

V. Determination That the Standard Is Appropriate for the Protection of the Public Health

The Tobacco Control Act authorizes FDA to revise or adopt tobacco product standards by regulation if it finds that such tobacco product standards are appropriate for the protection of the public health (section 907(a)(2) and (a)(3)(A) of the FD&C Act). The notice of proposed rulemaking for such a product standard must set forth this finding with supporting justification, which FDA is doing here (section 907(c)(2)(A) of the FD&C Act).

In order to make this finding, FDA must consider scientific evidence concerning:

- The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;
- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- 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)

FDA has considered scientific evidence related to all three factors. Based on these considerations, as discussed below, we find that the proposed standard is appropriate for the protection of the public health because the prohibition of menthol as a characterizing flavor in cigarettes: Decreases the likelihood that nonsmokers would experiment with cigarettes, develop tobacco dependence symptoms, and progress to regular cigarette smoking and/or use of other tobacco products, while also decreasing the likelihood that current smokers would continue to smoke cigarettes. Cigarettes are the most toxic consumer product when used as intended and adding menthol as a characterizing flavor makes cigarettes more appealing and easier to smoke. The proposed standard is anticipated to decrease the likelihood of menthol cigarette experimentation and the subsequent progression to regular, established cigarette smoking and cigarette consumption. Further, the proposed standard is anticipated to improve the health of current smokers of menthol cigarettes by increasing the likelihood of cessation, which would lead to lower disease and death in the U.S. population due to diminished exposure to tobacco smoke for both users and nonusers of cigarettes. Prohibiting menthol as a characterizing flavor in cigarettes would reduce the death and disease caused by cigarette use.

A. The Likelihood That Nonusers Would Start Using Cigarettes

Menthol in cigarettes is a significant contributor to youth and young adult initiation of cigarette smoking. In this section, we summarize evidence from multiple study designs, incorporating findings from longitudinal studies, national surveys, policy evaluations, and qualitative research that illustrate the role menthol plays in facilitating initiation and experimentation of cigarettes. We also discuss how the proposed prohibition on menthol as a characterizing flavor in cigarettes would decrease experimentation and thus, reduce progression to regular cigarette smoking among current nonusers.

Menthol is a flavor compound that is added to cigarettes, which produces a minty taste and cooling sensation when inhaled (Ref. 2). These sensory properties are pleasing and drive smoker beliefs that menthol cigarettes have a better taste, are smoother and more refreshing, are easier to inhale, and are less irritating than non-menthol cigarettes (Refs. 3–5). These properties also mask the harshness of smoking for new smokers and facilitate repeated experimentation and progression to regular smoking of menthol cigarettes, particularly among youth and young adults (Refs. 6–7, 5, 8).

When an individual tries a menthol cigarette, the sensory effects associated with menthol make initial and continued smoking experiences more palatable. In a focus group study conducted with young adult (aged 18–24) menthol smokers, participants reported that the taste of menthol made cigarettes as ''minty'', ''cool'', and ''refreshing'', stating that these factors influenced their initial preference for menthol cigarettes (Ref. 5). Further, these young adults indicated that they

continued to smoke menthol cigarettes because they taste and smell better than non-menthol cigarettes (Ref. 5). In addition, a study evaluating the sensory experiences of first cigarette use among young adult smokers found that fewer menthol smokers reported experiencing nausea during their first smoking experience compared to non-menthol smokers (Ref. 33). Evidence from tobacco industry documents also support that menthol is added to cigarettes in part because it is known to be an attractive feature to new and younger inexperienced smokers who perceive menthol cigarettes as less harsh and easier to smoke than non-menthol cigarettes (Ref. 7).

The increased likelihood of initiation of menthol cigarettes is reflected in the high proportion of youth and young adults who report that their first cigarette was menthol as compared to older adult smokers and the high proportion of past 30-day menthol smoking among youth as compared to older adult smokers (Refs. 8, 31, 33, 65–66, 182–183, 55–57, 44, 95). National studies and data also show that younger smokers (aged approximately 12–25 years) are more likely to smoke menthol cigarettes than older adult smokers (aged 26 and older) (Refs. 65–66, 182–183, 57, 55, 44). Among middle and high school students, the prevalence of current past 30-day menthol cigarette smoking decreased from 2011 to 2018 in NYTS data (Ref. 56), however approximately 47 percent of youth who smoke cigarettes reported smoking menthol cigarettes in 2019 (Ref. 95). Baseline findings from PATH Study data indicate similar findings, with nearly 43 percent of youth (12 to 17 years of age) and 45 percent of young adult (18 to 24 years of age) ever cigarette smokers (*i.e.,* those young adults who have used a tobacco product even once or twice in their lifetimes) reported that the first cigarette they smoked was mentholated (Ref. 31). In a followup study examining Waves 1–4 (2013–2017) of PATH data, youth (aged 12–17 years) and young adult (aged 18–24 years) new smokers (smokers who reported trying a cigarette for the first time between any adjacent waves) were more likely to report smoking menthol cigarettes than adults aged 25 and older (Ref. 8). These findings are consistent across studies encompassing different populations and time periods, including studies that assess large, nationally representative populations (Refs. 65–66, 182–183, 55–57, 44, 95, 31, 8). Data indicating youth and young adults are more likely to smoke menthol cigarettes points to the importance of the proposed product standard in protecting these vulnerable populations.

Experimentation with cigarettes can lead to nicotine dependence, which in turn increases the likelihood that experimenters will progress to regular cigarette smoking. As discussed in section IV.C of this document, studies have long provided clear evidence that signs of nicotine dependence in youth can arise soon after they first start smoking cigarettes, even among intermittent users (Refs. 184, 137, and 135). Such results suggest that even infrequent experimentation can lead to early signs of dependence, which underscores the public health importance of decreasing the likelihood of cigarette experimentation among youth and young adults in the United States.

Menthol's flavor, sensory effects, and interaction with nicotine in the brain contribute to an even greater risk of nicotine dependence by facilitating repeated experimentation and progression to regular smoking. Youth who smoke menthol cigarettes have statistically significant higher scores for several indicators of nicotine dependence (*i.e.,* craving, affiliative attachment, and tolerance) compared to youth who smoke non-mentholated cigarettes (Ref. 26). Pooled data from 2017–2020 NYTS of past 30-day youth cigarette smokers also indicates menthol smokers have greater risk of smoking more frequently (20–30 days per month versus 1–5 days per month) and more cigarettes per day (11+ versus 1–5), and that they report higher levels of dependence (cravings for tobacco and wanting tobacco within 30 minutes of waking) and have lower intentions to quit smoking (Ref. 28).

The reported dependence on tobacco, even at low levels of use, puts adolescents at greater risk of continuing to use tobacco products into adulthood (Refs. 135 and 185). The adolescent brain, which continues to develop until about age 25, is particularly vulnerable to nicotine's addictive effects (Refs. 17, 18, and 32). Several studies among adolescent and young adult cigarette smokers have shown that early dependence symptoms are predictive of smoking continuation and progression or failed cessation attempts (Refs. 186 and 187). The addition of menthol as a characterizing flavor used in cigarettes enhances nicotine addiction, particularly for youth and young adults, through a combination of its flavor, sensory effects, and interaction with nicotine in the brain.

If this proposed rule is finalized, menthol as a characterizing flavor would not be available to mask the harshness of smoking cigarettes and make initial smoking experiences more appealing for new users. FDA anticipates that implementation of the proposed standard would result in fewer youth and young adults experimenting repeatedly with cigarettes, becoming nicotine dependent, and progressing to regular cigarette smoking. Through these impacts alone, the proposed standard is appropriate for the protection of the public health, as it would lead to a significant reduction in the number of new regular cigarette smokers and the well-documented health impacts associated with regular cigarette smoking.

If this proposed rule is finalized, FDA expects a significant reduction in youth initiation and progression to regular cigarette smoking, which would ultimately protect youth from a lifetime of addiction and disease, and premature death, attributable to cigarette smoking. To the extent that youth and young adults in the United States who would have initiated with menthol cigarettes do not initiate with non-menthol cigarettes or other tobacco products, the proposed standard would prevent future cigarette-related disease and death.

FDA's expectation of a significant reduction in youth initiation and progression to regular cigarette smoking is supported by real-world experience of youth tobacco use prevalence decreasing following implementation of policies restricting the sales of flavored tobacco products. Two nationally representative studies assessing the impact of the Special Rule for Cigarettes (section 907(a)(1)(A) of the FD&C Act), which banned non-menthol flavored cigarettes, both found that youth cigarette smoking rates decreased following implementation. In a study using 2002–2017 NSDUH quarterly data with older adults (aged 50 and older) as a comparison group, there was a temporary increase (''temporary'' was undefined in the study) in the odds of past 30-day cigarette smoking and past 30-day menthol cigarette smoking in youth and young adults immediately after the Special Rule went into effect (Ref. 188). Following the temporary increase, odds of past 30-day cigarette smoking and past 30-day menthol cigarette smoking in youth and young adults decreased through 2017 (Ref. 188). No increase in odds of past 30-day cigarette smoking and past 30-day menthol cigarette smoking was observed immediately after the Special Rule went into effect or following through 2017 among older adults (ages 50 and older). The study estimated the total effect of the Special Rule for Cigarettes and

found that the flavored cigarette ban overall was associated with a significant reduction in cigarette smoking for youth (ages 12–17), young adults (ages 18–25), and adults (ages 26–49), but not older adults (ages 50 and older). This includes reductions in menthol cigarette smoking among youth and youth adults likely due to the overall effect the Special Rule had on decreasing rates of smoking among these groups over time.

Another nationally representative study examining tobacco use among U.S. middle and high school students before and after the Special Rule for Cigarettes banning non-menthol flavored cigarettes, found an overall decrease in the prevalence of youth cigarette smoking, fewer number of cigarettes smoked per month, and an overall reduction in the probability of using any type of tobacco (Ref. 189). Adjusting for demographic variables, national-level tax inclusive price indices for cigarettes and non-cigarette tobacco products, youth unemployment rate, and time trends, there was a 17.1 percent reduction in the probability of middle and high school students being a cigarette smoker after the Special Rule for Cigarettes (Ref. 189). Additionally, middle and high school smokers reported smoking 59 percent fewer cigarettes per month after the Special Rule for Cigarettes (Ref. 189). While there were increases in the use of some types of tobacco products, including cigars (34.4 percent) and pipe tobacco (54.6 percent) that remained available in flavored varieties, the probability of using any type of tobacco overall was reduced by 6 percent (Ref. 189).

In recent years, several U.S. localities and some states have placed restrictions on the sale of menthol cigarettes in addition to restrictions on the sale of other flavored tobacco products. Results from evaluations of these policies provide evidence of decreases in use and sales of tobacco products after policy implementation (Refs. 190–193). In 2018, Minneapolis and St. Paul, Minnesota, expanded their sales restrictions on flavored tobacco products (including e-cigarettes) to include menthol, mint, and wintergreen tobacco products. An evaluation of this sales restriction found decreases in youth cigarette (3.8 percent to 2.3 percent), cigar (2.7 percent to 1.6 percent), smokeless tobacco (1.6 percent to 1.2 percent), and hookah (2.4 percent to 1.3 percent) product use after policy implementation in the Twin Cities metro area, which includes Minneapolis and St. Paul (Ref. 192). An increase in youth e-cigarette prevalence from 10.5 percent to 15.7 percent occurred after the policy in the Twin Cities, but this increase was lower than the rest of the State of Minnesota where e-cigarette prevalence increased from 10.0 percent to 18.8 percent (Ref. 192). Although prevalence of youth overall tobacco use increased after the policy in the Twin Cities from 12.2 percent to 16.5 percent and increased in the rest of the State from 13.9 percent to 20.1 percent, these increases were driven by youth e-cigarette use and align with national youth tobacco use trends (Ref. 192). Importantly, the increases in youth overall tobacco use after the policy were lower in the Twin Cities than in the rest of the State, suggesting that the policy mitigated increases in overall tobacco use.

In July 2018, San Francisco, California, implemented a sales restriction on all flavored tobacco products, including menthol cigarettes. The San Francisco Department of Public Health announced that enforcement would begin January 2019 and enforcement with routine retailer compliance inspections began April 2019 (Ref. 194). An evaluation of the impact of the San Francisco policy on tobacco product sales, a proxy for consumption, found that total tobacco sales decreased by a statistically significant 25 percent from before policy implementation (July 2015–July 2018) to a post-policy enforcement period (January–December 2019) (Ref. 190). This study also found a statistically significant decrease in the overall sales of flavored tobacco products (from 39,350 average weekly unit sales to 1,546 average weekly unit sales), including menthol cigarettes (from 21,463 average weekly unit sales to 860 average weekly unit sales), to low levels after policy enforcement (Ref. 190). Findings that total tobacco sales and flavored tobacco sales decreased post policy suggest that consumers did not completely substitute non-flavored tobacco products for flavored tobacco products, and that such a policy can be implemented effectively and reduce sales of products as intended.

Changes in sales of tobacco products in San Francisco after policy enforcement were also reflected in young adult tobacco use patterns. A retrospective study of a convenience sample of young adult ever tobacco users in San Francisco found a statistically significant lower prevalence of overall tobacco use among 18-to 24-year-olds (from 100 percent to 82.3 percent) and 25-to 34-year-olds (from 100 percent to 92.4 percent) about 11 months after policy enforcement (November 2019) (Ref. 191).

One study on San Francisco's flavored tobacco policy using Youth Risk Behavior Survey (YRBS) data reported that San Francisco's flavor restriction was associated with increased odds of cigarette smoking among high school students relative to other school districts (Ref. 195). However, another study reported a methodological mistake with these findings: Data collection for the 2019 YRBS in San Francisco occurred in Fall 2018, prior to when the San Francisco flavor restriction was enforced in April 2019 (Ref. 196). As previously noted, another study of the San Francisco policy observed an overall decline in tobacco product sales and total cigarette sales, suggesting that there was not complete substitution of tobacco or unflavored products for flavored products following the flavor restriction in San Francisco (Ref. 190).

In June 2020, Massachusetts implemented a statewide sales restriction on flavored tobacco products (including menthol cigarettes) (Ref. 193). An evaluation of retail sales data assessed State-level cigarette sales per 1000 people in Massachusetts and comparison states without statewide flavor sales restrictions (Ref. 193). After the flavor sales restriction, the adjusted sales of cigarettes in Massachusetts versus the comparison states decreased by 372.27 packs per 1000 people for menthol cigarettes and by 282.65 pack per 1000 people for all cigarettes (Ref. 193).

In addition to state and local menthol sales restrictions, in recent years many provinces in Canada have implemented menthol sales restrictions. An evaluation of provincial menthol sales restrictions in Canada on youth and adult cigarette use found that provincial menthol sales restrictions were associated with decreases in menthol cigarette smoking (Ref. 197). While this study found that provincial menthol sales restrictions were not associated with an overall change in youth and adult past 30-day cigarette use, this finding is inconsistent with the authors' supplemental analysis that found decreases in menthol cigarette sales and no effect on non-menthol cigarette sales post-implementation (Ref. 197). The study also found an increase in adult self-reported purchasing of cigarettes from First Nations reserves, which were exempt from the sales restriction (Ref. 197). This purchasing behavior was not assessed among youth. In the United States, however, the proposed menthol product standard would apply nationwide, including on Tribal lands, which likely would increase the effectiveness of a nationwide menthol standard as compared to Canada.

In addition to the studies discussed in this section, as of November 2021, at least 145 localities in the United States have passed restrictions on the sale of menthol cigarettes in addition to other flavored tobacco products (Ref. 198). FDA requests comments and data on the impact of these menthol cigarette sales restrictions on non-users and users of tobacco products.

Evaluations of local non-menthol flavored tobacco product sales restrictions also provide evidence of decreases in the use and sales of tobacco products after policy implementation (Refs. 199–203). In November 2010, New York City (NYC) began enforcing a sales restriction on all flavored tobacco products except for menthol-flavored, mint-flavored, and wintergreen-flavored tobacco products; all e-cigarettes were excluded from the sales restrictions. An evaluation of the impact of the policy on youth tobacco product use found that NYC youth (aged 13–17 years) had 37 percent lower odds of ever trying a flavored tobacco product in 2013 after the policy was enforced compared to youth in 2010. Similarly, youth in 2013 had 28 percent lower odds of ever using any tobacco products compared to youth before the policy was enforced (Ref. 199). Changes in youth flavored tobacco use patterns were also reflected in changes in overall sales of flavored tobacco products. Analyses of tobacco product sales found a statistically significant decline in sales of overall flavored tobacco products following policy implementation and enforcement (Refs. 199 and 200). Similar to findings in NYC, an evaluation of a policy restricting the sale of flavored tobacco products, including e-cigarettes and excluding menthol cigarettes, in Providence, Rhode Island, found a decrease in any tobacco product use among high school students after active enforcement of the policy began (Ref. 202). More specifically, this analysis found that youth current use of any tobacco product declined from 22.2 percent in 2016 to 12.1 percent in 2018 (Ref. 202).

In October 2016, Lowell, Massachusetts, a small locality, began enforcing a sales restriction on all flavored tobacco products, except for menthol; e-cigarettes were included in the sales restriction. An evaluation of the short-term (6-month) impact of the policy found that youth use of any flavored tobacco products and any non-flavored or menthol tobacco products decreased in Lowell from baseline to followup and increased in the comparison community; statistically significant decreases in both any flavored and any non-flavored or menthol tobacco use were observed when comparing changes from baseline to followup between the two communities (Ref. 201). More specifically, youth self-reported current use of any non-flavored tobacco products decreased 1.9 percent in Lowell while increasing in the comparison city by a statistically significant 4.3 percent for a statistically significant estimated difference of –6.2 percent between the communities (Ref. 201). These data suggest that overall, youth did not switch to non-flavored or menthol tobacco products and that the policy helped reduce use of tobacco products among youth (Ref. 201).

Additionally, a study of local level restrictions across Massachusetts from 2011–2017 found that counties with a greater proportion of county residents covered by local policies that limit the sale of flavored tobacco products (excluding menthol) were associated with a decrease in the number of days smoked in the past 30 days and a decrease in the likelihood of e-cigarette use among high school students (Ref. 203). Another study evaluated the impact of flavored tobacco sales restrictions (excluding menthol) in Attleboro and Salem, Massachusetts, on tobacco use among high school students (Ref. 204). While youth use of flavored tobacco products and nonflavored or menthol tobacco products increased from baseline to followup in Attleboro and Salem and in the comparison municipality, the increases were significantly smaller in Attleboro and Salem than the comparison municipality, suggesting that the policy mitigated increases in flavored and nonflavored or menthol tobacco use (Ref. 204). Furthermore, while no changes in youth overall tobacco use were observed after a sales restriction on flavored tobacco products (excluding menthol, mint, and wintergreen products) in Minneapolis and St. Paul, Minnesota (18.1 percent to 17.6 percent), significant increases in the prevalence of youth overall tobacco use were observed in the rest of the state (12.4 percent to 15.7 percent), suggesting that the policy may have prevented increases in overall tobacco use (Ref. 192). As discussed previously, after this sales restriction was expanded to include menthol, mint, and wintergreen tobacco products, increases in youth overall tobacco use were lower in the Twin Cities than in the rest of the State, suggesting that the expanded policy diminished increases in overall tobacco use (Ref. 192).

FDA acknowledges there may be limitations to relying on aggregate tobacco sales information as a proxy for consumption. In addition, overall sales data are more likely to be driven by adult than adolescent use, given the larger size of the adult population as well as the tendency for youth to acquire tobacco via social sources (Ref. 205). However, studies have shown that sales and consumption tend to be highly correlated (Refs. 206–208). Additionally, sales data provide information on purchases of tobacco products in a defined area (which could include neighboring jurisdictions) (Refs. 200 and 209) and can serve as a proxy for consumption of tobacco products after policy implementation.

Evaluations of local policies may underestimate the potential impact of a national policy. Depending on availability of tobacco products in jurisdictions neighboring those where local policies were passed, users and non-users may easily be able to access tobacco products from these locations. Even with these limitations, FDA finds sales and local policy evaluation data useful and supportive in informing our expectations about the impact of the proposed product standard on tobacco product use and potential product substitution. Overall, the evidence supports that sales and use of tobacco products decrease as a result of flavored tobacco product sales restrictions. FDA anticipates that a nationwide standard that prohibits the manufacture and sale of menthol cigarettes would likely have a greater impact in decreasing youth cigarette use compared to that observed from policies from limited jurisdictions, because a nationwide product standard would eliminate the manufacture of these products as well as the opportunity to easily travel to neighboring jurisdictions within the United States that do not have a menthol sales restriction or use online retailers to purchase menthol cigarettes.

Although there are limitations in attributing public health outcomes to the evaluations described in this section, such evaluations are useful to understand the anticipated effect of the proposed menthol product standard. Findings from these evaluations generally suggest that youth use of cigarettes would decrease following implementation of the proposed product standard. With reduced menthol cigarette smoking, we would see reduced smoking-related morbidity and mortality along with diminished exposure to secondhand smoke among non-smokers, decreased potential years of life lost, decreased disability, and improved quality of life for the current and future generations to come. For these reasons, FDA expects that prohibiting menthol as a characterizing

flavor in cigarettes would reduce the likelihood that youth and young adults would initiate with and progress to regular menthol cigarette smoking, thereby protecting many youth from a lifetime of addiction and disease, and premature death, attributable to cigarette smoking. From the expected impact on non-users alone, especially youth and young adults, this proposed product standard is appropriate for the protection of public health.

B. The Likelihood That Existing Menthol Cigarette Users Would Reduce Cigarette Consumption or Stop Cigarette Smoking

In addition to the long-term public health benefits that would accrue from the prevention or reduction of menthol cigarette smoking among youth and young adults, FDA anticipates that the proposed standard would increase the likelihood that many existing menthol cigarette smokers would stop smoking cigarettes altogether, yielding health benefits from smoking cessation. FDA expects that the proposed prohibition of menthol as a characterizing flavor in cigarettes would result in substantial changes in tobacco use patterns among current tobacco users. Current menthol smokers would either: (1) Quit smoking or tobacco use altogether; (2) transition to non-menthol cigarettes or other combusted tobacco products; or (3) switch to other tobacco products, including potentially less harmful products. Given the large proportion of menthol cigarette use among smokers, the role of menthol in reducing cessation success among cigarette smokers, and the empirical evidence published through 2021 from policies restricting the sales of flavored tobacco products in the United States and Canada, FDA expects that the proposed product standard would lead many menthol cigarette smokers to stop using cigarettes.

As discussed previously, menthol's flavor and sensory properties influence initiation and continued experimentation (see section IV.C of this document). Additionally, these sensory properties are a major factor for a smoker's continued use of menthol cigarettes. Smokers note that menthol in cigarettes impacts their sensory experience, including the perception of a better tasting, smoother, and more refreshing cigarette that is easier to inhale and produces a cooling effect in the mouth and throat; smokers report that these sensory effects from menthol contribute to their continued smoking (Refs. 3–5, 107–108). In a qualitative study, young adult menthol smokers (aged 18–24) reported that the taste of menthol made cigarettes ''minty'', ''cool'', and ''refreshing'', stating that these factors influenced their initial preference for menthol cigarettes (Ref. 5). They perceived menthol cigarettes as smoother, less harsh, and ''easier to inhale'' than non-menthol cigarettes, which were generally regarded as strong, harsh, and ''gross'' (Ref. 5). They also reported that menthol cigarettes deliver a ''fuller'' smoke and ''hit hard,'' and seemingly require fewer cigarettes to feel ''satisfied'' (Ref. 5). Among adult smokers aged 18 and older, another recent study found menthol cigarette smoking to be associated with self-reported subjective reward, satisfaction, and throat hit (Ref. 108). Similar findings have been noted in youth. In a PATH Study of Wave 1 data, youth cigarette smokers (aged 12–17), regardless of menthol use status, reported that menthol cigarettes are easier to smoke (Ref. 107). The menthol product standard, if finalized, would prohibit menthol as a characterizing flavor in cigarettes, eliminating menthol's sensory cue, thereby reducing the reinforcing appeal of cigarettes for current menthol smokers, and encouraging current menthol smokers to quit smoking.

The sensory effects of menthol serve to reinforce the effects of nicotine. While nicotine dependence is the driving factor for all tobacco use, including cigarettes, menthol's enhancement of nicotine dependence and the sensory properties of menthol contribute to continued use of menthol cigarettes, making it even more difficult to quit smoking (Refs. 1, 34–35, 42, 36–37). While there is some inconsistency in the literature regarding menthol's role on smoking cessation, when considering the evidence from systematic reviews, national surveys, longitudinal studies that evaluated cessation outcomes over time, and menthol's effects on nicotinic receptors in the brain, the totality of evidence supports that menthol in cigarettes contributes to reduced cessation success among smokers, particularly among Black smokers (Refs. 34–35, 42, 36–41).

Data from TUS–CPS found that in 2007, reporting a quit attempt in the past year was 8.8 percent higher among menthol smokers (41.4 percent) compared to non-menthol smokers (38.1 percent), but menthol smokers had 3.9 percent lower rates of quitting within the past year (menthol: 4.2 percent versus non-menthol: 4.4 percent) and 11.3 percent lower rates of quitting within the past 5 years (menthol: 18.8 percent versus non-menthol: 21.1 percent) compared to non-menthol smokers (Ref. 37). After adjusting for covariates, including nicotine dependence and race/ethnicity, the likelihood of quitting was 3.5 percent lower for quitting in the past year and 6 percent lower for quitting in the past 5 years in menthol compared with nonmenthol smokers (Ref. 37). Similar results have been noted in more recent data from Waves 1–4 of the PATH Study (2013–2018), which found that daily adult menthol smokers (ages 18 and older) had 24 percent lower odds of quitting smoking compared to daily non-menthol smokers (Ref. 40). Another PATH study evaluated short-term (30-day) and long-term (12-month) smoking abstinence among menthol and non-menthol smokers who had attempted to quit smoking in the past 12 months (Ref. 43). Menthol smoking decreased the probability of 30-day smoking abstinence by 28 percent and the probability of 12-month smoking abstinence by 53 percent compared to smoking non-menthol cigarettes (Ref. 43). The majority of cigarette smokers in the United States report wanting to quit smoking (2015 NHIS: 68.0 percent) (Ref. 210), and thus, in response to the proposed product standard, many menthol cigarette smokers may seek to quit tobacco altogether or switch to other, potentially less harmful products.

FDA expects that, if this proposed rule is finalized and menthol is prohibited as a characterizing flavor in cigarettes, many menthol cigarette smokers will either quit smoking or switch to a non-combusted tobacco product, such as ENDS. In an expert elicitation study estimating transitions in use under both menthol ban and status quo scenarios, the panel of experts estimated that an additional 20.1 percent of menthol smokers ages 35 to 54 would cease combustible tobacco use over 2 years under a menthol ban compared to the status quo, with about half (10.3 percent) switching to ENDS and about half (10 percent) quitting all tobacco use (Ref. 211). The expert panel also estimated that an additional 30.1 percent of menthol smokers ages 18 to 24 would cease combustible tobacco use over 2 years, with 15.6 percent switching to ENDS and 12.3 percent quitting all tobacco use (Ref. 211). Some menthol cigarette smokers may switch to non-menthol cigarettes. The expert elicitation study suggested that among menthol smokers age 35 to 54, 45.7 percent would become non-menthol cigarette smokers (compared to 4.6 percent under the status quo) while 3.7 percent would become non-menthol cigar smokers (compared to no change under the status quo) (Ref. 211). The expert elicitation study and the resulting population modeling study,

which utilized the expert elicitation, are discussed in further detail in section V.C.5 of this document.

Among Hispanic and Latino smokers, studies also suggest that menthol smokers have more difficulty quitting than non-menthol smokers (Refs. 34, 151, 42, 36). Data from cross-sectional surveys using nationally representative online cohorts of U.S. adults indicated that Hispanic, non-Hispanic African American, and non-Hispanic other (those who identified with more than two races) adults were more supportive of a menthol ban than non-Hispanic White adults (Ref. 212) and that, among menthol smokers, both African American and Hispanic adults were more supportive of a menthol ban than White adults (Ref. 213). African American adults and Hispanic adults are two of the three racial and ethnic groups that, in 2019, had the highest prevalence of menthol cigarette smoking.

Prohibiting menthol as a characterizing flavor in cigarettes would likely result in increased cigarette cessation among members of historically underserved communities, including Black smokers, due to increased quit attempts and lower likelihood of switching to non-menthol cigarettes. A recent review of the literature found that among smokers, African American menthol smokers had lower odds of smoking cessation compared to non-menthol smokers (Ref. 41). As discussed above, the totality of evidence supports that menthol in cigarettes contributes to reduced cessation success. Data from national surveys suggests that menthol likely plays a role in making quitting particularly difficult for African American cigarette smokers (Refs. 34–37, 40). A focus group study among Black smokers found that taste was the main reason for continuing to smoke a particular brand and was a reason for smoking menthol rather than non-menthol cigarettes (Ref. 4). Additionally, participants agreed that menthol cigarettes were ''refreshing'', ''soothing'', and ''smooth'' while non-menthol cigarettes were ''strong'' or ''harsh'' (Ref. 4). Participants' preference for menthol cigarettes in this study was so strong that non-menthol cigarettes were viewed as a cessation aid (Ref. 4). These findings support that prohibiting menthol as a characterizing flavor in cigarettes will reduce the appeal of cigarettes, lead to reduced initiation and experimentation, and reduce the likelihood of subsequent progression to regular, established smoking and smoking dependence among vulnerable populations.

While a menthol restriction is anticipated to benefit the general population, the benefits of a menthol restriction on smoking cessation are likely to be more pronounced among Black menthol smokers, as they are less likely to switch to non-menthol cigarettes. Older and more recent studies are consistent in their findings that there would be increased likelihood of quitting smoking altogether for many menthol smokers under a menthol ban. A 1993 study of adult cigarette smokers found that 56 percent of Black smokers, compared to 28 percent of White smokers, responded that they would not smoke non-menthol cigarettes if they could not smoke menthol cigarettes (Ref. 214). While all menthol smokers in a nationally representative study had lower odds of smoking cessation compared to non-menthol smokers, when stratified by race and ethnicity, African American menthol smokers had the lowest odds of smoking cessation of any group (Ref. 40). A 2011–2016 analysis of data from the Truth Initiative Young Adult Cohort showed that among past 30-day menthol smokers, African American smokers had greater odds of reporting that they would quit smoking if menthol cigarettes were unavailable compared to White smokers (Ref. 215). Another study evaluating the effect of a menthol sales restriction in seven Canadian provinces indicated that non-White cigarette smokers were more likely than White cigarette smokers to make a quit attempt (Ref. 216). Additionally, one experimental study recruited 29 current menthol adult smokers who were not currently using cessation treatments and were not trying to quit (Ref. 217). Participants were switched from smoking their usual brand menthol cigarettes to a matched-brand non-menthol cigarette and were monitored multiple times across 2 weeks to model a potential ban of menthol cigarettes (Ref. 217). After switching to non-menthol cigarettes, participants had significantly lower nicotine dependence scores and greater increases in quitting motivation and confidence (Ref. 217). Findings from this study indicated that Black smokers had greater reductions in cigarettes per day when compared to non-Black smokers (defined as Hispanic, White, or ''Other'' smokers) (Ref. 217). Taken together, these research findings suggest that the proposed menthol product standard could help to reduce tobacco-related health disparities as experienced by vulnerable populations.

Findings from surveys asking menthol cigarette smokers what they would do if menthol cigarettes were to be banned are consistent with the Agency's expectation that many menthol smokers would attempt to quit smoking following the implementation of the proposed menthol standard. A recent literature review examined such surveys and based on responses from U.S. menthol smokers, concluded that banning menthol cigarettes would increase quit attempts and switching to potentially less harmful tobacco products (Ref. 218). Across several surveys, menthol smokers have said that if menthol cigarettes were no longer available, they would consider quitting smoking altogether (Refs. 213, 219–223, 215). For example, a 2010 nationally representative survey found that approximately 39 percent of adult menthol cigarette smokers said they would ''try to stop smoking'' if menthol cigarettes were banned (Ref. 213). In a 2014 survey, adult menthol smokers in Minnesota were asked whether they would quit smoking if menthol cigarettes were no longer sold in U.S. stores (Ref. 221). Just under half (46.4 percent) of menthol smokers responded that they would quit smoking (Ref. 221). A longitudinal survey from 2011–2016 of young adult menthol smokers found that an average of 23.5 percent of menthol smokers reported that they would most likely quit smoking and not use any other tobacco product in response to a menthol ban (Ref. 215).

In another study of adolescent and adult cigarette smokers, more than 35 percent of menthol smokers indicated their intentions to try to quit smoking if a ban of menthol in cigarettes was enacted (Ref. 219). Two studies report higher proportions of non-Hispanic Black menthol smokers indicating their intentions to quit smoking than non-Hispanic White menthol smokers following a menthol cigarette flavor ban; however, these differences were not statistically significant in either study (Refs. 219 and 213). In a longitudinal study of young adults, non-Hispanic Black participants had significantly higher odds of reporting that they would most likely quit smoking if menthol cigarettes were no longer available compared to non-Hispanic White participants (Ref. 215). A study in Ontario, Canada, that compared individuals' behavioral intentions before a menthol sales restriction was implemented with actual responses 1 year after implementation found 38 percent of those with behavioral intentions to quit cigarettes in response to a menthol ban reported quitting 1 year after the menthol ban was implemented (Ref. 224). Fifteen percent of those who planned to switch to non-

menthol cigarettes, 34 percent of those who planned to switch to other flavored tobacco products, 19 percent of those who planned to switch to contraband, and 24 percent of those who were unsure of their response before the menthol ban also reported quitting cigarettes 1 year after the menthol ban (Ref. 224).

An additional study asked U.S. adult menthol smokers to complete a hypothetical shopping task in a virtual store under one of four experimental conditions that simulated various policy scenarios (1—no ban, 2—replacement of menthol cigarettes and ads with green replacement versions (*i.e.,* the term ''menthol cigarettes'' is replaced with the term ''green cigarettes''), 3—menthol cigarette ban, 4—all menthol tobacco product ban) and assessed tobacco purchases (Ref. 225). This study found that participants in scenarios with a menthol cigarette ban and all menthol tobacco product bans were less likely to purchase cigarettes than participants who were exposed to no ban (Ref. 225). This finding supports FDA's expectation that many menthol cigarette smokers would quit smoking altogether after implementation of a menthol product standard.

Real-world experience from Canada's laws prohibiting the sale of menthol tobacco products provides information on the potential behavioral impacts the menthol product standard could have on cigarette use in the United States. Studies evaluating the impact of these laws have found increased reports of quit attempts and quitting smoking following policy implementation (Refs. 226, 224, 227, 216). These findings are consistent with the Agency's expectation that, following implementation, the proposed menthol product standard would increase the number of menthol cigarette smokers who quit cigarette use. After menthol sales restrictions in Quebec, Ontario, Prince Edward Island, Newfoundland, and Labrador, and a nationwide restriction covering British Columbia, Saskatchewan, and Manitoba, smokers from these provinces reported high rates of quit attempts and quitting smoking (Refs. 226, 224, 227, 216). In a study of Ontario 1 year after policy implementation, 56 percent of study participants who were smokers before the sales restriction reported making a quit attempt and 19 percent reported quitting smoking (Ref. 224). In a study of smokers from the Canadian provinces previously mentioned, 21.5 percent of pre-ban menthol smokers reported quitting smoking (defined as those who had currently quit or cut down to smoking less than monthly) after policy implementation (Ref. 216). Another study of adult smokers from Canadian provinces that implemented menthol sales restrictions found a small non-significant increase in the likelihood of ever trying to quit following policy implementation (Ref. 197). While the percent of smokers who reported quitting post-policy in these studies varies based on the length of time after policy implementation, geographic location, and definition of quitting, the percent of quitting post-policy in these studies was higher than the percent of current smokers from Ontario who reported quitting smoking 30 days or longer pre-policy in 2014 (7.9 percent) (Ref. 228). This suggests the various Canadian menthol sales restrictions contributed to increases in the number of smokers who quit smoking. The high rates of quit attempts and quitting smoking in Canada after menthol sales restrictions support FDA's expectation that a ban on menthol cigarettes would increase the likelihood that existing menthol cigarette smokers will stop smoking cigarettes altogether. For reference, in 2018 in the United States, recent successful quitting (quit smoking for ≥6 months during the past year) was 7.5 percent among those who were either current smokers who smoked for ≥2 years or former smokers who quit during the past year (Ref. 229). Even if only a portion of the increase in cessation seen in Canada is experienced in the United States as a result of the proposed menthol standard, there would still be a significant net public health benefit.

Further supporting FDA's expectation that a prohibition on menthol cigarettes would increase quitting by menthol cigarette smokers is evidence from Canada that menthol smokers there report higher rates of quit attempts and quitting smoking than non-menthol smokers (Refs. 224, 227, and 216). Studies from Ontario 1 year and 2 years after policy implementation found a higher likelihood of quit attempts and quitting smoking among those who reported smoking menthol cigarettes daily before the sales restriction (baseline) when compared with smokers who reported smoking non-menthol cigarettes daily (Refs. 224 and 227). Similarly, in a study looking across seven Canadian provinces with menthol sales restrictions, menthol smokers were more likely than non-menthol smokers to make a quit attempt and remain quit (quit greater than 6 months at follow-up and were long-term quitters who stopped smoking before the nationwide ban and remained quit) (Ref. 216). In addition, there is evidence that previous menthol smoking is not associated with relapse (Refs. 227 and 216). This suggests that menthol sales restrictions help those who quit smoking menthol cigarettes to stay quit. Taken together, the results from these studies support FDA's expectation that menthol smokers will achieve quit rates similar to or higher than non-menthol smokers because of a menthol product standard.

Findings on cessation from Ontario are consistent with analyses of tobacco manufacturer wholesale sales data and retail scanner data (Refs. 230 and 231). These data are often used as a proxy for cigarette consumption. An analysis of wholesale cigarette sales data in 10 Canadian provinces found an overall decrease of 4.6 percent in total cigarette sales after menthol cigarette bans (Ref. 232). Another analysis of tobacco manufacturer wholesale sales data showed that total cigarette sales declined by 128 million units following the Ontario menthol sales restriction compared to British Columbia, a Canadian province demographically similar to Ontario that did not have a menthol sales restriction in place at the time of the study, in which no significant changes were observed (Ref. 230).

There are considerations in relying on: (1) Canadian-based data to inform U.S. policy and (2) tobacco manufacturer wholesale sales and retail sales data as a proxy for consumption. With regard to the Canadian-based data to inform U.S. policy, it is important to note that menthol cigarettes comprise a larger proportion of cigarettes sales in the United States (*e.g.,* 26 percent in the United States versus 4 percent in Canada in 2001) and that a larger proportion of Black cigarette smokers in the United States use menthol cigarette brands (*e.g.,* 78.4 percent of Black cigarette smokers in the United States versus 9.8 percent of Black cigarette smokers in Canada in 2002) (Ref. 88). Therefore, findings from Canada likely underestimate the impact of a menthol cigarette ban in the United States. Findings from Canada's menthol sales restrictions corroborate evidence from evaluations of flavored tobacco product sales restrictions in the United States (*e.g.,* Massachusetts; Providence, RI; New York City, NY; San Francisco, CA) that found that sales and use of tobacco products covered by the flavor restriction decreased after implementation (Refs. 193, 200, 199, 209, 190).

With regard to relying on tobacco manufacturer wholesale sales and retail sales data as a proxy for consumption, such data do not completely reflect individual-level tobacco use behaviors.

For example, smokers may have obtained cigarettes through channels not included in the Ontario sales data (*e.g.,* other provinces) or switched to non-restricted products, which may result in an overestimation of the impacts. The analysis of tobacco manufacturer wholesale data found a significant decline in the overall cigarette sales in Ontario in the month following Ontario's menthol sales restriction. This was followed by a statistically significant increase in the sales of overall cigarettes driven by an increase in non-menthol cigarettes in Ontario, suggesting a slight rebound effect; however, overall cigarette sales approximately 8 months following the menthol sales restriction were lower than study baseline (October 2012) (Ref. 230). Similarly, an analysis of retail sales data found a small increase (0.4 percent) in sales of non-menthol cigarettes in the 6 months following policy implementation (Ref. 231). In spite of this limitation, considering sales data with the self-report data suggests increased smoking cessation occurred as a result of the sales restriction.

As mentioned previously, several U.S. localities have placed restrictions on the sale of menthol cigarettes in addition to restrictions on the sale of flavored tobacco products. FDA is aware of two studies that report on the impact of the policy in San Francisco on cessation. The first, a retrospective study with a relatively small convenience sample of young adult ever tobacco users in San Francisco found of 20 exclusive menthol cigarette smokers before the policy, 5 percent (n=1) quit any tobacco use after the policy and, among 61 menthol cigarette and other tobacco users before the policy, 3.3 percent (n=2) quit after the policy (Ref. 191). A second study examining the impact of the same policy among clients enrolled in a San Francisco residential substance use disorder treatment facility found that participants surveyed about 5 months after the policy (n=102) were statistically significantly less likely to report menthol as the usual cigarette smoked compared to participants surveyed before the policy (Ref. 233). This study found no evidence that the policy was associated with decreased number of cigarettes per day or increased readiness to quit among current smokers (Ref. 233). The marginal effects observed in this study are not entirely unanticipated. Smoking prevalence rates are substantially higher among individuals with substance use disorder compared to those in the general population (Refs. 234–237), and these individuals report increased nicotine dependence levels (Ref. 238) and have less success at quitting smoking than individuals without substance use disorders (Refs. 239 and 240). Additionally, studies show that drugs of abuse may have unique pharmacological interactions with nicotine, increasing the reinforcing effects of both smoking and drug use among these populations (Refs. 241–244). This population with substance use disorder may have been less sensitive to the regional menthol ban compared to the general population due to their unique risk factors and pervasive patterns of tobacco use.

Taken together, these two San Francisco studies provide limited evidence of the impact of a menthol cigarette sales restriction on cessation in the United States (Refs. 191 and 233). Both studies rely on convenience samples and do not include a control group (Refs. 191 and 233) limiting their generalizability to people other than study participants. In addition, the retrospective study of a convenience sample of young adult ever tobacco users in San Francisco (Ref. 191), only collects data after the policy was implemented. Given this, FDA relies more on the evidence from Canada which includes multiple longitudinal cohort studies of the general population at different time points following policy implementation and in various locations that have implemented menthol sales restrictions to inform expectations on the impact of the proposed product standard on cessation.

As discussed previously, evaluations of local policies may underestimate the potential impact of a national policy. Depending on availability of tobacco products in jurisdictions neighboring those where local policies were passed, users and non-users may easily be able to access tobacco products from these locations. For example, in the study examining clients enrolled in San Francisco residential substance use disorder treatment facilities, 50 percent of menthol smokers reported purchasing menthol cigarettes in San Francisco after the menthol sales restriction (Ref. 233). Overall, the evidence supports that following a menthol sales restriction or ban, adult menthol cigarette smokers' quit attempts and quitting smoking increases. FDA anticipates that a nationwide standard that prohibits the manufacture and sale of menthol cigarettes would likely have a greater impact in increasing cigarette smokers' quit attempts and quitting smoking compared to that observed from policies from limited jurisdictions, because a nationwide product standard would eliminate the manufacture of these products as well as the opportunity to easily travel to neighboring jurisdictions within the United States that do not have a menthol sales restriction or use online retailers to purchase menthol cigarettes. While the 2020 Surgeon General's Report, ''Smoking Cessation'', concluded that ''the evidence is suggestive but not sufficient to infer that restricting the sale of certain types of tobacco products . . . increases smoking cessation . . . ,'' this assessment was based on empirical evidence published through 2019 (Ref. 245). Numerous studies have been published since the 2020 Surgeon General's Report and were considered in FDA's assessment of the impact of a proposed product standard on cessation. The recently published evaluation studies have examined the impact of menthol sales restrictions in multiple Canadian provinces (Refs. 216, 230, 227, 231–232, 197) and state and local jurisdictions in the United States (Refs. 190–191, 233, 193). When these studies are considered with the evaluation evidence published before 2020, FDA concludes that there is substantial evidence of increases in quit attempts and quitting by adult smokers after a menthol cigarette sales restriction (Refs. 77, 197, and 193). Further, recent longitudinal data from the PATH study and a systematic review of the literature all indicate that menthol cigarette smoking is associated with reduced cessation success compared to non-menthol smokers (Refs. 40, 43, and 41). Thus, by banning menthol cigarettes, FDA expects to increase smoking cessation across the population. This is further evidenced by expert elicitation and simulation studies, which assessed and modeled menthol restrictions in the United States, resulting in substantial estimated public health benefits (Refs. 46 and 211). These findings, all more recent than the 2020 Surgeon General's Report, suggest that a menthol ban is appropriate for the protection of the public health.

The sum of the available evidence, including the interaction of menthol and nicotine in the brain, the continued use of menthol cigarettes by millions of Americans, the difficulties of quitting smoking for menthol smokers, and the empirical evidence from policies restricting the sales of menthol cigarettes in Canada and flavored tobacco products in the United States, suggest that the proposed standard would lead many menthol cigarette smokers to stop using cigarettes, yielding considerable health benefits. There are currently more than 18.5 million menthol cigarette smokers ages

12 and older in the United States (Ref. 44). Thus, even small changes in initiation and cessation would result in a significant reduction in the burden of death and disease caused by smoking. Further, given the high concentration of menthol cigarette smoking among underserved communities, the effect of the standard on reducing cigarette smoking would be expected to be greater in these populations. From the expected public health impact on current adult menthol cigarette smokers alone, this proposed product standard is appropriate for the protection of the public health.

As discussed in section III.B.4 of this document, 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.

C. Benefits and Risks to the Population as a Whole

We expect that the proposed menthol product standard, if finalized, would reduce tobacco-related harms. As discussed in section IV of this document, the addition of menthol as a characterizing flavor to cigarettes makes it easier to start smoking, easier to continue smoking, and harder to quit smoking. By prohibiting the addition of menthol as a characterizing flavor to cigarettes sold in the United States, FDA anticipates that reductions in population harm would be realized through long-term health benefits resulting from prevention of cigarette uptake and progression to regular cigarette smoking among youth and young adults, as described in section V.A of this document, as well as shorter-term health benefits resulting from increased cessation of cigarette smoking among current menthol smokers, as described in section V.B of this document. Each of these impacts alone would result in significant health benefits to the U.S. population. In totality, they provide overwhelming evidence that the proposed standard would result in substantial health benefits over both the short- and long-term. In this section, we summarize the health benefits of never progressing to regular cigarette smoking, the health benefits of quitting smoking, the potential health benefits of switching from cigarettes to potentially less harmful tobacco products, and the health benefits of not being exposed to secondhand smoke. We also describe findings from population modeling studies that estimate the public health impact of the proposed standard. Finally, we describe potential risks of the product standard, including risks of countervailing effects of the tobacco standard such as increasing demand for contraband.

1. Given the Harmful Effects of Cigarette Smoking, Never Progressing to Regular Smoking Prevents Death and Disease

Never progressing to regular cigarette smoking prevents death and disease caused by smoking. Any effects of a menthol ban on preventing youth, young adult, and even adult never smokers from initiating/experimenting and progressing to regular cigarette smoking will have a population health benefit. According to the 2014 Surgeon General's Report, ''The Health Consequences of Smoking: 50 Years of Progress'', which summarizes thousands of peer-reviewed scientific studies and is itself peer-reviewed, smoking remains the leading preventable cause of death in the United States, and cigarettes have been shown to cause an ever-expanding number of diseases and health conditions (Ref. 1). As stated in the report, ''cigarette smoking has been causally linked to disease of nearly all organs of the body, to diminished health status, and to harm to the fetus'' and ''[t]he the burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products'' (Ref. 1 at 37).

The 2014 Surgeon General's Report estimates that 16 million people live with diseases caused by smoking cigarettes (Ref. 1). Comparing mortality to morbidity, for every person who dies from smoking, 30 more are living with a smoking-attributable disease (Ref. 1). Smoking is causally associated with a number of diseases affecting nearly all organs in the body, such as numerous types of cancer, heart disease, stroke, lung diseases such as chronic obstructive pulmonary disease, and diabetes, in addition to putting individuals at increased risk for tuberculosis, certain eye diseases, and immune system issues (Ref. 1). Furthermore, maternal smoking is causally associated with multiple adverse fetal outcomes, including fetal growth restriction and low birth weight, premature rupture of the membranes, placenta previa, placental abruption, preterm birth, preeclampsia, reduction of lung function in infants, and sudden infant death syndrome (SIDS) (Ref. 1).

A study using 2006–2012 data from the NHIS estimated that 6.9 million U.S. adults had a combined 10.9 million self-reported smoking-attributable medical conditions, highlighting that smoking cigarettes often causes co-morbid diseases (Ref. 246). The study noted that the morbidity estimates are likely underestimates due to underreporting of diseases in surveys and the lack of assessment of several major medical conditions (Ref. 246). Thus, it is likely that the true morbidity burden in the United States is substantially more than these estimates.

An analysis of the National Longitudinal Mortality Study, a longitudinal population-based, nationally representative health survey with mortality data from the National Death Index, found that exclusive regular cigarette smokers had substantially higher all-cause mortality risks than never tobacco users (Ref. 247). Another analysis, which examined NHIS data, found that life expectancy was shortened by more than 10 years among current cigarette smokers, compared with those who had never smoked (Ref. 248). Even non-daily smokers have higher mortality risk than never smokers. A recent study pooled data from the 1991, 1992, and 1995 NHIS and were linked to data from the National Death Index through 2011 (Ref. 249). The study indicated that lifelong non-daily smokers, who had smoked cigarettes on a median of 15 days and 50 cigarettes per month, had a 72 percent higher overall mortality risk resulting in about a 5-year shorter lifespan, than never smokers (Ref. 249). The study also found a gradient in number of cigarettes smoked among non-daily users, with higher mortality risks observed among lifelong non-daily smokers who reported 31–60 cigarettes per month and more than 60 cigarettes per month than never smokers, but no difference among those who smoked 11–30 cigarettes per month (Ref. 249). Daily smokers in the study had an even higher mortality risk and shorter survival (about 10 years less) than never smokers (Ref. 249).

As previously discussed, menthol cigarette smoking facilitates progression to regular cigarette smoking among youth and young adults. African American smokers are more likely than smokers from other racial and ethnic groups to try a menthol cigarette as their first cigarette, regardless of age (Refs. 33, 25, and 31). FDA anticipates that a menthol restriction will prevent a substantial number of youth, and especially Black youth, from initiating menthol cigarette smoking, thereby decreasing progression to regular cigarette smoking, resulting in reduced tobacco-related morbidity and mortality associated with menthol cigarette smoking.

2. Given the Harmful Effects of Cigarette Smoking, Quitting Smoking Reduces Death and Disease

Quitting cigarette smoking, including menthol cigarettes, substantially reduces the likelihood of tobacco-related death and disease. As stated in the 2004 Surgeon General's Report, ''[q]uitting smoking has immediate as well as long-term benefits, reducing risks for diseases caused by smoking and improving health in general'' (Ref. 250). The 2020 Surgeon General's Report also concluded, ''[s]moking cessation is beneficial at any age. Smoking cessation improves health status and enhances quality of life.'' (Ref. 245). As previously noted, FDA expects that, if this proposed rule is finalized, there will be a significant increase in smoking cessation in the U.S. population (see section V.B).

The benefits associated with smoking cessation happen quickly (Ref. 250). Within 2 to 12 weeks of quitting smoking, an individual's lung function and blood circulation improve (Ref. 250). During the first 1 to 9 months after cessation, coughing and shortness of breath decrease (Ref. 250). Within several months of quitting smoking, individuals can expect improvement in lung function (Ref. 250).

The benefits continue for those who remain smoke-free. Smoking cessation reduces the risk of cancers and other diseases (Ref. 245). For example, the risk of fatal lung cancer in adults over 55 is about 25 times higher among smokers relative to people who have never smoked (Ref. 251). After 10–15 years of abstinence from smoking, the risk of lung cancer is about 50 percent of the risk for individuals who continue to smoke (Ref. 245). The risk of cancer of the mouth, throat, esophagus, stomach, bladder, cervix, pancreas, liver, kidney, colon, rectum, and the risk of acute myeloid leukemia also decreases (Refs. 252 and 245). The evidence is also sufficient to infer that the risk of stroke decreases after smoking cessation, and approaches that of never smokers over time (Ref. 245). Furthermore, the evidence is sufficient to infer that the relative risk of coronary heart disease among former smokers compared with never smokers falls rapidly after cessation and then declines more slowly (Ref. 245).

Even smokers who quit smoking after the onset of life-threatening disease experience health benefits from cessation. Quitting smoking after a diagnosis reduces the chance of recurrences and future health problems. For example, people who quit smoking after having a heart attack can reduce their chances of having a second heart attack by 50 percent (Ref. 252). For those persons who have already developed cancer, quitting smoking reduces the risk of developing a second cancer (Refs. 253–256). Additionally, quitting smoking after a diagnosis of lung cancer reduces the risk of cancer progression and mortality (Ref. 257). Researchers also estimate that for current smokers diagnosed with coronary heart disease, quitting smoking reduces the risk of death overall, and reduces the risk of recurrent heart attacks and cardiovascular death by 30 to 40 percent (Refs. 245 and 256). The 2020 Surgeon General's Report concluded that quitting smoking reduces the risk of fatal stroke, and earlier reports have also said that it is reasonable to assume that quitting smoking would reduce the risk of recurrent strokes (Refs. 245 and 256). Quitting smoking also helps the body tolerate the surgery and treatments, such as chemotherapy and radiation, associated with certain smoking-related diseases (Refs. 250, 253, 256, 258) and reduces the risk of respiratory infections compared to continued smoking (Refs. 256 and 259).

Given the reduction in risk of smoking-related death and disease associated with cessation, those who successfully quit smoking increase their life expectancy. Using data from the Cancer Prevention Study II (CPS II), an ongoing study of 1.2 million adults, scientists have found that men who smoked at 35 years old and continued to smoke until death had a life expectancy of 69.3 years, compared with a life expectancy of 76.2 years for those who stopped smoking at age 35 (Ref. 260). After adjusting for the subsequent quit rate among current smokers at baseline (to account for the possibility that some current smokers at baseline quit smoking or some former smokers relapsed during followup and, thus, were incorrectly classified as continuing smokers in the unadjusted analysis), the life expectancy for male former smokers increased to 77.8 years (a life extension of 8.5 years) (Ref. 260). Women who smoked at 35 years old and continued to smoke until death had a life expectancy of 73.8 years, compared with a life expectancy of 79.7 years for those who stopped smoking at age 35 (Ref. 260). After adjustment for the subsequent quit rate among current smokers at baseline, the life expectancy for female former smokers increased to 81 years (a life extension of 7.7 years) (Ref. 260). Further, a man aged 60 to 64 who smokes 20 cigarettes (one pack) or more per day and then quits smoking reduces his risk of dying during the next 15 years by 10 percent (Ref. 256).

While cessation is beneficial for all ages, the health benefits are greatest for people who stop smoking at earlier ages (Refs. 256 and 250). Scientists in the United Kingdom found those who quit smoking at age 30 reduce their risk of dying prematurely from smoking-related diseases by more than 90 percent (Refs. 261 and 262). Those who quit at age 50 reduce their risk of dying prematurely by 50 percent compared to those who continue to smoke (Ref. 262). Using data from the NHIS, researchers also estimated that life expectancy in the United States would increase 4 years among smokers quitting cigarettes at 55 to 64 years of age, and 10 years among smokers quitting cigarettes at 25 to 34 years of age (Ref. 248). Scientists using the CPS II data (while accounting for the possibility that some current smokers at baseline quit smoking and some former smokers relapsed during followup) found that even smokers who quit at age 65 had an expected life increase of 2 years for men and 3.7 years for women (Ref. 260).

As discussed previously, there is a lower quit rate among smokers of menthol cigarettes than there is for non-menthol cigarettes. FDA anticipates that prohibiting menthol as a characterizing flavor in cigarettes would improve smoking cessation outcomes in adult smokers and result in longer life expectancies for more individuals. Additionally, FDA anticipates that this proposed product standard will benefit vulnerable populations by reducing tobacco-related morbidity and mortality by improving quitting and cessation among these populations. As previously discussed, the role of menthol in cigarettes in reducing cessation success among smokers is more pronounced among certain population groups, in particular, among Black smokers. Additionally, research has shown that cigarette smokers from underserved communities bear a disproportionate burden of tobacco-related morbidity and mortality. African Americans, and in particular African American men, experience the highest rates of incidence and mortality from tobacco-related cancers compared to people from other racial and ethnic groups (Refs. 263 and 264). Additionally, mortality due to tobacco-related disease such as heart disease, stroke, and hypertension is higher among African Americans compared to other racial and ethnic groups (Refs. 265–270, 50). Furthermore, as previously discussed, compared to White smokers, Black smokers report they may be more likely to quit smoking altogether if menthol

cigarettes were unavailable following a menthol restriction (Refs. 214, 215, and 217). Based on these collective findings, FDA anticipates that the proposed product standard will improve smoking cessation outcomes among vulnerable populations, in particular, Black smokers, leading to a reduction in adverse tobacco-related health effects in these populations.

3. Given the Harmful Effects of Cigarette Smoking, Switching to a Potentially Less Harmful Nicotine Delivery Product May Reduce Death and Disease

FDA recognizes that smokers who choose to switch completely to a potentially less harmful nicotine delivery product to maintain their nicotine dose also could, to the extent that those products result in less harm, significantly reduce their risk of tobacco-related death and disease (Ref. 271). The least harmful nicotine delivery products available to smokers are the pharmaceutical nicotine replacement therapies already approved by FDA as both safe and effective cessation tools, many of which are available in a variety of flavors, including mint, which could appeal to menthol smokers. However, smokers may also transition to tobacco products which utilize other forms of nicotine delivery in place of smoking combusted cigarettes. These include smokeless tobacco, dissolvable products, and ENDS products, among others.

In surveys, some menthol cigarette smokers and some dual users of menthol cigarettes and ENDS report intending to use ENDS if menthol cigarettes were no longer available (Refs. 221, 272, and 222). Experimental marketplace studies also suggest that, in addition to taking other actions, some menthol smokers may switch partially or fully to ENDS in the event of a menthol cigarette ban (Refs. 273 and 225). These empirical findings are consistent with the 2020 Surgeon General's Report, titled ''Smoking Cessation,'' and several systematic reviews, which suggest that some adult cigarette smokers report using ENDS to try to reduce or quit smoking (Refs. 245, 274–276). The literature also suggests that cigarette smokers who use ENDS more frequently (versus less frequently) have improved success in switching, however the long-term patterns of use remain unknown (Refs. 271, 277–279).

In an expert elicitation study estimating effects of a menthol ban on transitions in use, the panel of experts estimated that among menthol smokers aged 35 to 54 years, 55.1 percent would remain combustible tobacco users (a reduction of 20.1 percent from the status quo), with another 20 percent switching to a ''novel nicotine delivery product,'' defined in the study as ENDS or heated tobacco products (HTPs) (a 10.3 percent increase from the status quo), and about 22.5 percent quitting all tobacco use (a 10.0 percent increase from the status quo) (Ref. 211). Additionally, the experts estimated that among those aged 12 to 24 years who would have initiated as menthol cigarette smokers, under the menthol ban, 41.1 percent would still initiate combustible tobacco use (including non-menthol cigarettes, cigars, or illegal menthol cigarettes), while 17.6 percent would instead initiate with a ''novel nicotine delivery product,'' such as ENDS or HTPs; the result is a 58.9 percent reduction in combustible tobacco initiation from the status quo (Ref. 211). Additional details of the expert elicitation study and resulting population model study can be found in section V.C.5 of this document.

Data from the 2017 Ontario menthol sales restriction did not show increases in menthol smokers' self-reported use of e-cigarettes (Ref. 280) or increases in retail sales of e-cigarettes (Ref. 231) following policy implementation. To the extent that this may occur following implementation of this product standard, FDA recognizes that completely switching from combusted tobacco products to ENDS has the potential to reduce some tobacco-related disease risks among individual users (Ref. 271). However, cessation of all tobacco products leads to the greatest reduction in tobacco-related disease and death (Ref. 245).

4. Having Fewer People Smoke Cigarettes Will Reduce Smoking-Related Death and Disease Associated With Secondhand Smoke Exposure

Secondhand smoke exposure is harmful to the health of non-smokers. The 2006 Surgeon General's Report, ''The Health Consequences of Involuntary Exposure to Secondhand Smoke,'' concluded that ''secondhand smoke exposure causes premature death and disease in children and in adults who do not smoke'' (Ref. 281). Exposure to secondhand smoke is a cause of cancer and respiratory and cardiovascular disease (Ref. 1). According to the 2014 Surgeon General's Report, more than 437,000 premature deaths per year are caused by active cigarette smoking, and an additional 41,280 premature deaths among adults aged 35 years and older are due to secondhand smoke (Ref. 1). Specifically, the 2014 Surgeon General's Report estimated secondhand smoke causes approximately 7,330 deaths from lung cancer and 33,950 deaths from coronary heart diseases in non-smokers annually (Ref. 1).

Secondhand smoke is particularly harmful to children. The 2014 Surgeon General's Report estimated that secondhand smoke is associated with 150,000 to 300,000 lower respiratory tract infections in infants and children under 18 months of age, 790,000 doctor's office visits related to ear infections per year, and 202,000 asthma cases each year (Refs. 282 and 1). In 2014, the Surgeon General reported 400 SIDS deaths related to perinatal smoking or exposure to secondhand smoke; the ''Reproductive Outcomes'' section describes the impact of perinatal smoking (Ref. 1). Children of parents who smoke, when compared with children of nonsmoking parents, have an increased frequency of respiratory infections like pneumonia and bronchitis (Ref. 256). Children exposed to tobacco smoke in the home are also more likely to develop acute otitis media (middle ear infections) and persistent middle ear effusions (fluid behind the eardrum) (Ref. 256).

More recent data from the 2013–2014 NHANES estimates that approximately 58 million American non-smokers (1 in 4) were exposed to secondhand smoke, including 14 million children (Ref. 283). Approximately half of all U.S. children aged 3 to 18 years are exposed to cigarette smoke regularly at home or other locations that still permit smoking (Ref. 1). In 2019, approximately one-quarter of middle and high school students reported breathing in secondhand smoke in their homes or in a vehicle (Ref. 284).

The burden of secondhand smoke exposure is experienced disproportionately among members of some racial or ethnic groups and lower income groups. Among nonsmokers age 3 and older, findings from 2011–2018 NHANES data indicate that non-Hispanic Black persons and those living below the poverty level had the highest levels of secondhand smoke exposure compared to people of other races and those living above the poverty level, respectively; these disparities persisted across all years of the study analysis from 2011 to 2018 (Ref. 285). From 1999 to 2012, the percentage of the nonsmoking population age 3 and older exposed to secondhand smoke (defined in the study as levels 0.05–10 ng/mL) declined across all racial and ethnic groups (Ref. 286). However, a significantly higher proportion of non-Hispanic Black nonsmokers continued to have detectable serum cotinine levels, compared to Mexican American and non-Hispanic White nonsmokers. For example, in 2011–2012, nearly 50

percent of non-Hispanic Black nonsmokers had detectable serum cotinine levels, compared with 22 percent of non-Hispanic White and 24 percent of Mexican American nonsmokers (Ref. 286).

Disparities in the secondhand smoke exposure are found across various environmental settings. These disparities speak to the interrelated influences of individual factors (*e.g.,* age, race and ethnicity, income) and existing inequities in places where members from underserved communities are likely to reside, spend time, and work (Ref. 49). Findings drawn from the 2013–2016 NHANES data indicate that compared to non-Hispanic Whites, non-Hispanic Blacks had higher odds of secondhand smoke exposure in homes other than their own (Ref. 27). An analysis of NYTS data indicates that non-Hispanic Black and non-Hispanic White students both had higher prevalence of secondhand smoke exposure at home and in vehicles than Hispanic and non-Hispanic other students (Ref. 284). While secondhand smoke exposure in homes and vehicles significantly declined from 2011 to 2018, secondhand smoke exposure in homes among non-Hispanic Black students did not change (Ref. 284). Home smoking bans (or household rules that restrict or ban smoking inside the home) can reduce secondhand smoke exposure. A study using 1995–2007 data from the TUS–CPS found that among two parent households, higher levels of parental educational level, higher levels of annual household income, and both parents being Hispanic, non-Hispanic, Other race, or other combinations of parents of different race/ethnicities were associated with the higher reporting of a complete home ban as compared to lower levels of parental educational, lower levels of annual household income, and both parents being non-Hispanic White, respectively (Ref. 287). Such findings are consistent with a higher degree of autonomy over home environment for households with greater economic resources and housing flexibility, emphasizing the degree to which certain aspects of disadvantage (such as lower family income, lack of access to single-family housing, or lack of autonomy over the home environment) may compound tobacco-related health disparities. Workplace secondhand smoke exposure has also been shown to vary across population groups. Data from the 2010 and 2015 NHIS show that exposure to secondhand smoke in the workplace was disproportionately high among non-Hispanic Blacks, Hispanics, and workers with low education and low income (Ref. 288). Additionally, the study findings indicated that ''blue-collar workers'' (defined as those who performed manual labor such as manufacturing, mining, sanitation, and construction) experienced higher prevalence of secondhand smoke exposure as compared to ''white-collar workers'' (defined as those who primarily work in an office, with computer and desk setting, and perform professional, managerial, or administrative work) (Ref. 288). The proposed product standard is anticipated to reduce smoking-related morbidity and mortality for these vulnerable populations, especially youth.

FDA expects that the proposed menthol product standard would reduce the number of smokers and decrease non-smokers' exposures to secondhand smoke. As evidenced by evaluations of smoke-free policies, decreasing exposure to secondhand smoke will reduce exposure to tobacco smoke pollution and decrease smoking-related death and disease (Refs. 289 and 290).

5. Results From Simulation Models Are Consistent With the Findings That Prohibiting Menthol Cigarettes Would Benefit the Population's Health

The population health benefit of prohibiting menthol cigarettes has been examined in several simulation studies conducted in the past decade (Refs. 46, 211, 291, 45). A 2021 study by Levy et al. simulated the future benefit of a menthol cigarette ban on the U.S. population as a whole over the 2021–2060 period (Ref. 46). This model compared a *Status Quo Scenario,* in which no menthol ban was implemented, to a simulated *Menthol Ban Scenario* in which a complete ban on menthol cigarettes and cigars was implemented in 2021.[12] Additionally, as part of the model, it took into account the use of ENDS products (''nicotine vaping products'') by smokers and non-smokers over the study period (Refs. 46, 211, and 291).

The simulation used the Smoking and Vaping Model (SAVM), a model capable of simulating the population health effects of cigarette smoking and ENDS use for specific birth cohorts. For this study, the model was extended to evaluate non-menthol and menthol cigarettes separately, with the following use states captured in the model compartments: (1) Never users, (2) menthol smokers, (3) non-menthol smokers, (4) exclusive ENDS users, (5) former smokers using ENDS, (6) former smokers, and (7) former ENDS users.

The SAVM first utilized historical data from the NHIS (1965–2013) for estimates of smoking prevalence (specific model inputs can be found in the manuscript) (Refs. 46, 211, and 291). The model projected prevalence estimates of never, current, and former smoking by age and gender beginning in 2013. The model was then recalibrated using 2013–2018 NHIS data to improve model estimates of smoking prevalence after ENDS products became more widely available around 2013. Next, age- and gender-specific rates of smoking initiation (*i.e.,* any initiation of regular cigarette smoking by age 40) and cessation (*i.e.,* cessation of regular cigarette smoking for 2 years, including those who temporarily use ENDS but ultimately quit all tobacco use), cigarettes-to-ENDS switching (*i.e.,* cessation of regular cigarette smoking with initiation of regular ENDS smoking), and initiation of ENDS use (*i.e.,* initiation of regular ENDS use without regular cigarette smoking) were modeled using PATH Study data, with separate rates of initiation, cessation and switching for menthol and non-menthol smokers. To simplify the model, dual users of cigarettes and ENDS were not modeled separately from current smokers. Smokers who switched to ENDS before age 35 were treated the same as exclusive ENDS users, while smokers who switched to ENDS age 35 or later were considered separately as former smokers using ENDS. Additionally, the transitions modeled were unidirectional; relapse (*i.e.,* reinitiating regular cigarette smoking or ENDS use after entering any group containing former smokers/users) was not considered in the model. Although age- and gender-specific effects were modeled, other sources of population heterogeneity, such as race, ethnicity, socioeconomic status, and geographical location, were not simulated.

Based on PATH Study data and other publications, the ratio of menthol to non-menthol cessation was modeled as 0.8 and the ratio of menthol to non-

[12] The *Menthol Ban Scenario* models a ban of menthol in cigarettes and cigars, but includes only the benefits attributed to the menthol cigarette ban. Cigars are covered in the model because it is assumed that menthol cigarette smokers could simply switch to menthol cigars if a menthol cigarette ban was put in place and if menthol cigars were still available. FDA's expectation is that, even if menthol was not prohibited as a characterizing flavor in cigars, this rule would still reduce initiation and experimentation of cigarette smoking, decrease nicotine dependence and addiction, and increase cessation among current menthol cigarette smokers. However, since FDA is concurrently pursuing a proposed rule, published elsewhere in this issue of the **Federal Register**, that would prohibit characterizing flavors (other than tobacco) in cigars, the *Menthol Ban Scenario* is directly applicable.

menthol switching was modeled as 0.9, in effect modeling menthol cigarette smokers as 20 percent less likely to quit smoking and 10 percent less likely to switch to ENDS than non-menthol smokers (Refs. 46 and 211). Based on PATH Study data, all cigarettes-to-ENDS switching was assumed to decline 10 percent annually from 2018. The excess relative risk of mortality for ENDS products compared to cigarettes was set at 0.15, in effect modeling the mortality risk of ENDS use as 15 percent of the mortality risk of cigarette smoking over the same period.

To estimate the specific effects of a menthol ban on current and future tobacco use, an expert elicitation (EE) was conducted (Ref. 211). The EE used a systematic approach to identify eleven leading academic experts on topics related to the impacts of menthol flavor bans in tobacco products. Experts estimated a number of behaviors under a menthol ban, such as continued (illicit) menthol product use, menthol to non-flavored product switching, switching to other nicotine products (*e.g.,* ENDS, smokeless tobacco products), and tobacco cessation. These estimates were adapted to fit the simpler structure of the SAVM. For example, transitions from cigarettes to HTPs were treated as transitions to ENDS, while transitions from menthol cigarettes to non-menthol cigars were treated as a transition to non-menthol cigarettes. Transitions to smokeless tobacco products were also treated as transitions to non-menthol cigarettes. Experts estimated the effects of a menthol ban for youth and young adults ages 12–24 who would otherwise have initiated menthol smoking by age 24 (*i.e.,* counterfactual menthol smokers), which were used to calculate the ongoing initiation rates beginning with the simulated ban in 2021 in the *Menthol Ban Scenario.* Among menthol smokers in both the *Status Quo Scenario* and *Menthol Ban Scenario,* experts estimated transitions over a 2-year period for ages 18–24 and 35–54, which were modeled as mean net differences applied to menthol smokers up to age 30 and over age 30, respectively. The ban was assumed to have no effects on non-menthol smokers. In the expert elicitation study, it is likely that when the experts were answering survey questions around tobacco use behaviors under a future menthol ban, they considered the products available in the market at the time. The marketplace of products may change over time due to a variety of reasons, and it is possible that changes in the marketplace, if known, may impact experts' judgements about how menthol smokers and non-users at risk for initiation may act in response to a menthol ban.

The model estimated smoking-attributable deaths averted and life-years lost averted over the 2021–2060 period (Ref. 46). Compared to the *Status Quo Scenario,* in which no menthol ban was implemented, under the *Menthol Ban Scenario* the estimated overall smoking prevalence declined 14.7 percent by 2026 and 15.1 percent by 2060. This overall decrease was due to a sharp reduction in menthol smoking (down 92.5 percent by 2026, and 96.5 percent by 2060), coupled with a smaller increase in non-menthol smoking (up 47.4 percent by 2026, and 58.0 percent by 2060) over the same time period. The ban was also estimated to increase ENDS use 22.6 percent by 2026, up to a 26.5 percent relative increase by 2060. Totaling the effects, the model estimated 654,000 premature deaths and 11,300,000 life-years lost averted by 2060.

The study authors also conducted several sensitivity analyses to determine which model parameters had the greatest influence on outcome estimates (Ref. 46). Increasing the ratio of menthol to non-menthol cessation rate from 0.8 to 1.0, in effect making menthol cigarettes no harder to quit than non-menthol cigarettes, had the greatest impact on the model estimates, resulting in decreasing deaths averted by 29.5 percent (to 461,000) and life-years lost averted by 24.2 percent (to 8.58 million). Eliminating the 10 percent annual declines in cigarette-to-ENDS switching from the model, in effect increasing the appeal of complete switching for smokers in later years of the model, reduced deaths averted by 20.5 percent (to 520,000) and life-years lost averted by 21.9 percent (to 8.83 million). Other sensitivity analyses included 10 percent absolute increases and decreases in the excess relative risk of ENDS products to cigarettes, and 10 percent relative changes in smoking initiation, smoking cessation, time-independent cigarette-to-ENDS switching, ENDS initiation, and ENDS cessation. All of these sensitivity analyses resulted in modest (under 10 percent) changes to model-predicted deaths and life-years lost averted.

In addition to the SAVM study, a 2011 study by Levy et al. that simulated the future benefit of a menthol cigarette ban was also consistent with the findings of other studies. This study estimated potential impacts of a U.S. menthol ban on future smoking prevalence and smoking attributable mortality for the total population, and for African Americans specifically (Ref. 45). The model used data from the 2003 TUS–CPS to characterize current smoking status, initiation and cessation rates by cigarette type, various other sources to characterize smoking relapse rates, and CPS II to characterize mortality risks, which were treated as equivalent for menthol and non-menthol smokers. The analysis simulated the 2010–2050 period, with a menthol ban going into effect in 2011. The study compared three menthol ban scenarios against a status quo scenario with no menthol ban:

1. 10 percent of menthol smokers quit permanently and 10 percent who would have initiated as menthol smokers do not take up smoking,

2. 20 percent of menthol smokers quit permanently and 20 percent who would have initiated as menthol smokers do not take up smoking, and

3. 30 percent of menthol smokers quit permanently and 30 percent who would have initiated as menthol smokers do not take up smoking.

The study estimated that by 2050, under these menthol ban scenarios, 324,000 (scenario 1) to 634,000 (scenario 3) smoking attributable deaths would have been averted in the United States overall, while relative declines in smoking prevalence were expected to range from 4.8 percent to 9.7 percent, under scenarios 1 and 3, respectively. Among African Americans, by 2050, an estimated 92,000 to 238,000 smoking attributable deaths would have been prevented, while relative declines in smoking prevalence ranged from 9.1 percent to 24.8 percent (under scenarios 1 and 3, respectively) (Ref. 45).

In conclusion, population health models simulating menthol ban policies are consistent with a substantial public health benefit. The 2021 simulation by Levy et al., using the SAVM model, estimated approximately 650,000 premature deaths averted and 11.3 million life-years lost averted in the first 40 years of a menthol cigarette and cigar ban beginning in 2021 (Refs. 46, 211, and 291). The prevalence of smoking was also estimated to decline 15.1 percent in that period. Sensitivity analyses demonstrated that lower cessation among menthol smokers compared to non-menthol smokers was a notable driver of the public health impact of the simulated menthol ban. The overall findings were consistent with the 2011 simulation by Levy et al. that estimated 324,000–634,000 premature deaths averted under a similar ban and time period (Ref. 45).[13]

[13] The Further Consolidated Appropriations Act, 2020, made it unlawful for any retailer to sell a

Continued

6. Public Health Benefits Not Addressed in the Smoking and Vaping Model

While the SAVM projections of the potential impact from a menthol product standard suggest a significant public health benefit to the United States resulting from substantial reductions in smoking prevalence, these analyses do not address other additional benefits.

First, the SAVM simulation does not account for increased quality of life from decreased tobacco-related morbidity. The Surgeon General has reported that about 30 individuals will suffer from at least one smoking-related disease for every person that dies from smoking each year (Ref. 245). Researchers in one study estimated that individuals are living with 14 million major smoking-related conditions in the United States, including more than 7.4 million cases of chronic obstructive pulmonary disease, nearly 2.3 million heart attacks, 1.8 million cases of diabetes, nearly 1.2 million stroke events, more than 300,000 cases of lung cancer, and nearly 1 million cases of other smoking-attributable cancers (bladder, cervix, colon/rectum, kidney, larynx, mouth, tongue, lip, throat, pharynx, stomach) (Ref. 246). Another study, which examined disparities in tobacco-related cancer incidence and mortality, found that tobacco-related mortality decreased between 2004 and 2013, however tobacco-related cancer incidence and mortality rates remain highest among African Americans, accounting for more than 39,000 deaths annually between 2009 and 2013 (Ref. 293). Cigarette smoking, in addition to causing disease, can diminish overall health status, leading to higher risks for surgical complications, including wound healing and respiratory complications, increased absenteeism from work, and greater use of health care services (Ref. 1). Increased smoking cessation, reduced cigarette consumption, and lower progression to regular cigarette smoking would reduce not only the mortality from smoking, but it also would reduce the enormous burden of cigarette-attributable disease in the United States.

Second, the SAVM simulation does not account for the public health impacts of reduced secondhand smoke exposure. Exposure to secondhand smoke is a cause of cancer, respiratory, and cardiovascular disease (Ref. 1). Secondhand smoke exposure is currently estimated to be responsible for over 41,000 deaths annually in the United States (Ref. 1). Reducing secondhand smoke exposure through increased smoking cessation, reduced cigarette consumption, and lower progression to regular cigarette smoking would reduce the more than 7,300 lung cancer deaths and nearly 34,000 coronary heart disease deaths annually attributed to secondhand smoke (Ref. 1). Exposure to secondhand smoke can also cause adverse health effects in infants and children. Exposure to cigarette smoke among children and adolescents can trigger asthma attacks and lead to more frequent respiratory infections compared to those not exposed to smoke (Ref. 1). Prenatal tobacco exposure and postnatal secondhand smoke exposure increase the risks of fetal deaths, fetal growth restriction/low birth weight, respiratory conditions, and SIDS (Ref. 1).

Third, the SAVM simulation does not isolate differential effects as experienced by vulnerable populations. Menthol cigarette use, and the disease and death linked to such use, is disproportionately high among members of vulnerable populations such as African Americans and other racial and ethnic groups, those with lower household income, and those who identify as LGBTQ+ (Refs. 55–57, 21–24, 44). As a result, a menthol restriction is expected to confer larger benefits among these vulnerable populations by promoting improved public health outcomes. For example, studies have shown that after switching to non-menthol cigarettes, Black menthol smokers had greater reductions in cigarettes per day when compared to non-Black menthol smokers (Ref. 217). In comparison to White smokers, a higher prevalence of Black smokers report they would not smoke a non-mentholated cigarette if they could not smoke a mentholated cigarette (Ref. 214), a higher prevalence of Black menthol smokers reported intentions to quit following a menthol restriction (Refs. 219 and 215), and Black menthol smokers had lower odds of reporting that they would switch to a non-menthol brand (Ref. 213). Prior modeling has shown that by 2050, following a 2011 menthol ban, an estimated 92,000 to 238,000 smoking attributable deaths among African Americans would have been prevented, comprising almost one-third of the total deaths averted by the ban (Ref. 45). The relative reduction in African Americans' smoking prevalence in 2050 was also projected to range between 9.1 and 24.8 percent compared to the status quo of no menthol ban (Ref. 45).

Finally, the analysis does not account for reductions in harms caused by smoking-related fires. Lower prevalence of cigarette smoking, and reduced cigarette consumption are likely to decrease the occurrence of fires caused by smoking materials, including cigarettes and other lighted tobacco products. Even though all states have instituted laws requiring fire-safety-compliant cigarette paper (adoption began in 2003 with all states adopting these laws by 2012), smoking remained the second leading cause of residential fire deaths in the United States in 2018 (Ref. 294). In 2011, an estimated 90,000 fires in the United States were caused by smoking materials, of which 17,600 occurred in the home (Ref. 295). Between 2012 and 2016, there were an average of 18,100 home structure fires per year started by smoking material, accounting for around 1 in 20 of all home fires (5 percent) (Ref. 296). The fatality rate for smoking-related residential building fires is seven times greater than for nonsmoking related fires (Ref. 297). Moreover, smoking materials remain the leading cause of fatal home fires in the United States and smokers themselves are not the only victims (Refs. 295 and 296). One out of every four fatal victims of smoking-material fires were not the smoker whose cigarette initiated the fire (Ref. 298). Reductions in smoking as a result of the proposed standard are likely to have an impact on the 590 deaths and over 1,100 injuries from smoking-attributable structure fires (Ref. 296).

We note that, while the impact of a proposed rule prohibiting menthol as a characterizing flavor in cigarettes is likely to be sizable, there is uncertainty in precisely quantifying the effects. Although the exact magnitude of the effects of the proposed ban are uncertain, because of the sheer number of smokers currently using menthol cigarettes—an estimated 18.5 million persons ages 12 and older (Ref. 44)—even modest decreases in the percentage of the population initiating smoking and increases in the percentage of the population quitting smoking would save many lives.

tobacco product to any person younger than 21 years of age (Pub. L. 116–94, section 603 (2019)). The quantitative estimates of the impact of a menthol ban on premature mortality presented in these studies do not take into account the impact of T21. However, given the long lag period between smoking initiation and premature mortality from smoking, any impact of T21 on the mortality benefits described in this rule would not be observed for decades into the future. See section II.C.4.a of the Preliminary Regulatory Impact Analysis (PRIA) for a discussion of T21 impacts on premature smoking-attributable deaths averted (Ref. 292).

7. Potential Risks to the Population as a Whole of the Proposed Menthol Product Standard Would Not Outweigh the Potential Benefits of the Proposed Product Standard

There are possible countervailing effects that could occur from the proposed product standard, if finalized. Potential risks to the population, however, would generally only occur among individuals currently using tobacco or smoking cigarettes as FDA concludes there are little to no risks to nonusers of tobacco. These potential risks do not offset the anticipated benefits of the rule. The countervailing effects on current tobacco users could include continued combusted tobacco product smoking, smokers seeking to add menthol to their combusted tobacco product, and the possibility of illicit trade. As part of this rulemaking, FDA is required by the Tobacco Control Act to consider information submitted on such possible countervailing effects, including among vulnerable populations and other population subgroups.

With the removal of menthol cigarettes from the tobacco marketplace, some cigarette smokers may seek other sources of tobacco and/or nicotine. These could include nicotine replacement therapy products, non-menthol cigarettes, other combusted tobacco products, or other potentially less harmful tobacco products. Findings from evaluations of menthol sales restrictions in Canada suggest some users switch to non-menthol cigarettes and flavored combusted tobacco products following a menthol sales restriction (Refs. 226, 231, 230, 216, 193, 197).

FDA acknowledges that the availability of flavored cigars may impact the public health benefits of the proposed rule. FDA's expectation is that, even if menthol is not prohibited as a characterizing flavor in cigars, this rule would reduce initiation of and experimentation with cigarette smoking, decrease nicotine dependence and addiction to cigarettes, and increase the likelihood of cessation among current menthol cigarette smokers. It is also unlikely that all current or potential users of menthol cigarettes would switch to or initiate with menthol cigars. In studies assessing the potential impacts of banning menthol cigarettes, a minority of menthol smokers indicated that they might switch to flavored cigars (Refs. 219, 273, and 225). However, FDA is concurrently proposing a product standard to prohibit characterizing flavors (other than tobacco) in cigars, which would decrease the likelihood that menthol smokers would switch to cigars as a result of the proposed menthol cigarette standard. Working with others in HHS, FDA is currently exploring options to ensure that smokers who would like to quit cigarettes or would like to quit tobacco product use completely in response to the proposed standard will be aware of and have access to resources that provide cessation support.

FDA recognizes that, while some smokers may switch to non-menthol flavored cigarettes, the risks of this won't outweigh the benefits from smokers who quit smoking completely. FDA has no reason to believe that individuals switching from menthol cigarettes to other combusted tobacco products would be exposed to additional harm beyond their current exposure level. FDA requests comments regarding additional evidence on the extent and magnitude that menthol smokers will switch to other combusted tobacco products.

With the removal of menthol cigarettes from the tobacco marketplace, some users could seek out products that will add menthol to non-menthol cigarettes (*e.g.,* drops, capsules, filter tips for RYO tobacco, or cards that can be inserted into a cigarette pack or pouch of rolling tobacco) (Refs. 226, 299, and 300),[14] which would reduce the benefits of the proposed rule. A study of smokers from Ontario found that, before the menthol sales restriction, 4.4 percent of daily menthol smokers had previously tried flavored additives (including flavor cards, drops, oils, or other additives to add menthol to tobacco) (Ref. 299). One month after the menthol sales restriction in Ontario, 5.1 percent of daily menthol smokers had tried flavored additives, 1 year after 12.5 percent had, and 2 years after 9.5 percent had (Ref. 299). However, products used to alter or affect the cigarette's performance, composition, constituents, or characteristics are components and parts of the cigarette would also be subject to this rule. Thus, to the extent that flavor cards, drops, oils, or other additives that are components and parts of a cigarette contain menthol as a characterizing flavor, such products would be prohibited under proposed § 1162.3. Therefore, FDA does not anticipate a substantial number of individuals would utilize such products.

[14] While we recognize that some smokers could try to add menthol e-cigarette liquids (or e-liquids) to non-menthol cigarettes, we believe that the amount of e-liquid needed to impart a menthol characterizing flavor would make the cigarette unsmokeable.

Even if some people were to modify their non-menthol cigarettes in response to a menthol cigarette prohibition, FDA does not expect this behavior to result in significant additional harm beyond what menthol cigarette smokers are already being exposed to. Furthermore, with many other tobacco products available on the marketplace and the prohibition of products used to alter or affect the cigarette's performance, composition, constituents, FDA does not expect that many individuals would attempt to modify non-menthol cigarettes and thus, FDA does not expect that this potential countervailing effect would significantly reduce the impact of the rule (Ref. 299).

Finally, the removal of menthol cigarettes from the marketplace could result in some people seeking menthol cigarettes through the illicit trade market. FDA is considering whether illicit trade could occur as a result of a menthol product standard and potential implications.

Since the enactment of the Tobacco Control Act, FDA has been committed to studying and understanding the potential effects of a product standard on the illicit tobacco market. As part of FDA's consideration of possible regulations, the Agency asked the National Research Council (NRC) and Institute of Medicine (IOM) of the National Academy of Sciences to assess the international illicit tobacco market, including variations by country; the effects of various policy mechanisms on the market; and the applicability of international experiences to the United States (Ref. 301). In 2015, the NRC/IOM issued its final report titled ''Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences'' and concluded ''[o]verall, the limited evidence now available suggests that if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest.'' (Ref. 301 at 9). In addition, in March 2018, FDA issued a draft concept paper as an initial step in assessing the possible health effects of a tobacco product standard in the form of demand for contraband or nonconforming tobacco products (83 FR 11754). Among other things, the draft concept paper examined the factors that might support or hinder the establishment of a persistent illicit trade market related to a product standard but did not reach any conclusions regarding the potential demand that may develop due to a product standard (Ref. 79).

The recent implementation of local menthol restrictions in the United States and restrictions outside of the United

States provides real-world experience regarding the potential for illicit trade of menthol cigarettes. Evidence from Canada, England, and the United States suggest that the impact of the proposed rule on the illicit market would not be significant (Refs. 302, 226, 224, 216, 200, 209, 191, 303, 197). For example, a study evaluating a restriction on sales of menthol cigarettes in Nova Scotia, Canada found that the policy did not result in an increase in illicit cigarette seized (Ref. 302). The researchers noted that according to local Canadian authorities there were only a few small seizures of menthol cigarettes in the year following the policy (with the nature of the data analyzed indicating that seizures were from businesses only, not individual users, though the study is not clear on this point), and that there were no further seizures of menthol cigarettes after the first year (Ref. 302). Studies asking smokers about their responses to menthol sales restrictions in Canada find a small percentage that continue to use and purchase menthol cigarettes (Refs. 226, 224, and 216). When menthol smokers were asked where they purchased menthol cigarettes after menthol sales restrictions, a majority reported purchasing from First Nations Reserves (54.7 percent), which were generally exempted from the sales restrictions, followed by retail stores (31.0 percent); few reported purchasing menthol cigarettes online (7.5 percent) (Ref. 216). The study, however, was not able to determine the proportion of menthol cigarettes purchased by cigarette smokers post-policy that were contraband (Ref. 216). The authors also noted it is unclear how smokers were able to purchase menthol cigarettes at retail stores and hypothesized that smokers could be reporting the purchase of non-menthol cigarettes that were rebranded as menthol replacements with color on the pack or in the brand name to suggest menthol-like qualities (Ref. 216). Another study of a local Canadian menthol sales restriction found that one month following implementation of Ontario's menthol sales restriction, 14.1 percent of smokers reported using menthol cigarettes purchased from a First Nations reserve, other province, other country, or online (Ref. 226). A study of young adult ever tobacco users in San Francisco found that a small percentage reported purchasing flavored tobacco products illegally in San Francisco (5 percent) and purchasing flavored tobacco products online (15 percent) after the policy; however, this was a retrospective study with a relatively small convenience sample (Ref. 191).

These results are consistent with the expert elicitation study discussed previously (Ref. 211). In the expert elicitation study, 50.5 percent of menthol smokers were expected to remain combusted tobacco product users, with 40.3 percent becoming non-menthol cigarette smokers, and 3.7 percent becoming non-menthol cigar smokers; however, the experts also estimated that 6.5 percent would continue to use illicit menthol cigarettes (Ref. 211).

Taken together, these studies provide evidence that a major change to the availability of products covered by this proposed rule (see section VII.A) is not likely to lead to a surge in illicit menthol cigarette use. In reaching this conclusion, FDA has considered several factors that are likely to affect the potential for illicit trade. For example, FDA anticipates that a nationwide standard that prohibits the manufacture and sale of menthol cigarettes, coupled with FDA's authority to take enforcement actions and other steps regarding the sale and distribution of illicit tobacco products, would eliminate the manufacture and distribution of these products. FDA also expects that a nationwide product standard would eliminate the opportunity to easily travel to neighboring jurisdictions within the United States that do not have such menthol sales restrictions or use online retailers to purchase menthol cigarettes. FDA thus anticipates that the rule would result in much less illicit trade than observed in the case of a state or local requirement and that any such trade would be significantly outweighed by the benefits of the rule.

If an illicit market develops after this proposed menthol standard is finalized, FDA has the authority to take enforcement actions and other steps regarding the sale and distribution of illicit tobacco products, including those imported or purchased online (see section VII.C of this document for additional information about FDA's enforcement authorities). FDA conducts routine surveillance of sales, distribution, marketing, and advertising related to tobacco products and takes corrective actions when violations occur. After this proposed menthol standard is finalized and goes into effect, it would be illegal to import menthol cigarettes and such products would be subject to import examination and refusal of admission under the FD&C Act. Similarly, it would be illegal to sell or distribute menthol cigarettes, including those sold online, and doing so may result in FDA initiating enforcement or regulatory actions. We note that the Prevent All Cigarette Trafficking Act of 2009 (PACT Act) establishes restrictions that make cigarettes generally nonmailable through the U.S. Postal Service, subject to certain exceptions (18 U.S.C. 1716E). Outside of these exceptions, the U.S. Postal Service cannot accept or transmit any package that it knows, or has reasonable cause to believe, contains nonmailable cigarettes, smokeless tobacco, or ENDS.

As previously noted, FDA's enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. This regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumers for possession or use of menthol cigarettes. In addition, State and local law enforcement agencies do not independently enforce the FD&C Act. These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA's behalf. As noted previously, FDA recognizes concern about how State and local law enforcement agencies enforce their own laws in a manner that may impact equity and community safety and seeks comments on how FDA can best make clear the respective roles of FDA and State and local law enforcement.

Based on the available evidence, FDA finds that, while there may be potential countervailing effects that could diminish the expected population health benefits of the proposed standard, such effects would be significantly outweighed by the potential benefits of the proposed menthol product standard.

In this section, FDA has cited studies describing the potential countervailing effects of the proposed product standard. FDA requests additional information concerning the potential countervailing effects discussed in this section, as well as any other potential countervailing effects that could result from this rule, and how the potential countervailing effects could be minimized. FDA is particularly interested in receiving comments, including supporting data and research, regarding whether and to what extent this proposed rule would result in an increase in illicit trade in menthol cigarettes and how any such increase could impact the marketplace or public health.

D. Conclusion

FDA has considered scientific evidence related to the likely impact of the proposed rule prohibiting use of menthol as a characterizing flavor in cigarettes on current nonusers, current users, and the U.S. population as a whole. Based on these considerations, we find that the proposed tobacco product standard is appropriate for the protection of the public health because it would reduce the appeal and ease of smoking cigarettes, particularly for young people and new users, thereby decreasing the likelihood that nonusers of cigarettes who experiment with these tobacco products would progress to regular cigarette smoking. Additionally, the proposed tobacco product standard is anticipated to improve the health of current smokers of menthol cigarettes by decreasing cigarette consumption, increasing the likelihood of cessation among this population, and decreasing secondhand smoke exposure among current smokers and non-smokers. These positive public health impacts will also address the significant health disparities linked to menthol cigarettes.

Tobacco use is the leading preventable cause of disease and death in the United States (Ref. 1). As over 18.5 million Americans ages 12 and older smoke menthol cigarettes (Ref. 44), even modest reductions in the percentage of people initiating and modest increases in the percentage of people quitting smoking would lead to substantial reductions in the over 480,000 annual deaths and approximately 16 million cases of disease attributed to combustible tobacco products in the United States, as well as the economic and societal costs associated with such illness and death.

Each day in the United States, more than 1,500 youth under the age of 18 smoke their first cigarette (Ref. 96). Additionally, nearly 90 percent of adult current daily cigarette smokers in the United States report having smoked their first cigarette by the age of 18 (Ref. 1). Nicotine is a highly addictive substance, and multiple studies have shown that symptoms of nicotine dependence can arise early after youth start smoking cigarettes, even among infrequent users (Refs. 184, 137, and 135). Menthol in cigarettes enhances nicotine addiction through a combination of its flavor, sensory effects, and interaction with nicotine in the brain, facilitating repeated experimentation with cigarettes and progression to regular cigarette smoking, which repeatedly exposes the brain to nicotine (Refs. 6 and 9).

Evidence shows that adding menthol to cigarettes soothes irritation from nicotine and smoke inhalation, particularly among new smokers (Ref. 7). Data from the 2013–2014 PATH Study indicate that 43 percent of youth (aged 12–17 years), 45 percent of young adults (aged 18–24 years) and 30 percent of adults (aged 25 years and older) that have ever smoked a cigarette reported that their first tobacco product was mentholated (Ref. 31). Results from national studies also consistently show a preference for smoking menthol cigarettes among youth and young adult smokers, compared to older smokers, and existing research suggests that the likelihood of progressing to regular, established smoking is higher among youth who initiate with menthol smoking compared to those starting with non-menthol cigarettes (Refs. 25, 29–31, 8). The result is that nearly half of youth (48.6 percent) and young adults (51 percent) and two in five (39 percent) adult smokers report smoking menthol cigarettes (Ref. 44).

Prohibiting the use of menthol as a characterizing flavor in cigarettes would help to decrease future addiction, disease, and death among youth at risk of tobacco use. FDA anticipates that the proposed standard would produce substantial health benefits. Even small changes in initiation and cessation would result in a significant reduction in the burden of death and disease in the United States caused by smoking, including reductions in smoking-related morbidity and mortality, diminished exposure to secondhand smoke among non-smokers, decreased potential years of life lost, decreased disability, and improved quality of life for the current and future generations to come.

While preventing initiation to regular cigarette smoking by even modest amounts carries the greatest potential from this proposed standard to improve population health in the long term, FDA anticipates that the proposed standard would produce substantial short-term health benefits resulting from decreased cigarette consumption and increased cessation among current menthol cigarette smokers. In the United States, there are currently over 18.5 million smokers of menthol cigarettes ages 12 and older (Ref. 44). As previously described, the health benefits of smoking cessation are substantial. A published population modeling study estimated that as many as 654,000 smoking attributable deaths would be avoided by the year 2060 if menthol cigarettes were no longer available (Ref. 46). Beyond averted deaths, societal benefits would include reduced smoking-related morbidity and health disparities, diminished exposure to secondhand smoke among non-smokers, decreased potential years of life lost, decreased disability, and improved quality of life among former smokers.

FDA's expectation that the proposed product standard would be appropriate for the protection of the public health is reasonable and well-supported by scientific evidence. Cigarettes are the most toxic consumer product, when used as intended, and adding menthol as a characterizing flavor makes cigarettes more appealing and easier to smoke. Given the existing scientific evidence described in sections IV and V of this document, FDA expects that implementing the proposed menthol product standard would result in reduced smoking initiation and progression among youth and young adults, and increased smoking cessation among current cigarette smokers. Across the population, these changes in cigarette smoking behaviors would lead to lower disease and death in the United States in both the short term, and in the future, due to diminished exposure to tobacco smoke among both smokers and non-smokers.

FDA anticipates the proposed product standard also will improve health outcomes among vulnerable populations. As previously described, menthol cigarette use, and the disease and death linked to such use, is disproportionately high among members of vulnerable populations such as African Americans and other racial and ethnic groups, those with lower household income, and those who identify as LGBTQ+ (Refs. 55–57, 21–24, 44). For example, out of all non-Hispanic Black smokers, nearly 85 percent smoke menthol cigarettes, compared to 30 percent of non-Hispanic White smokers who smoke menthol cigarettes (Ref. 44). As a result, these population groups with the greatest menthol cigarette use would be expected to experience the greatest benefit from the proposed product standard through its impact on reducing youth initiation of and experimentation with cigarette smoking, decreasing the likelihood of nicotine dependence and addiction, and increasing the likelihood of cessation. Accordingly, the proposed product standard is anticipated to promote better public health outcomes across population groups.

VI. Additional Considerations and Requests for Comments

A. Section 907 of the FD&C Act

FDA is required by section 907 of the FD&C Act to consider the following

information submitted in connection with a proposed product standard:

- For a proposed product standard to require the reduction or elimination of an additive, constituent (including smoke constituent), or other component of a tobacco product because FDA has found that the additive, constituent (including a smoke constituent), or other component is or may be harmful, scientific evidence submitted by any party objecting to the proposed standard demonstrating that the proposed standard will not reduce or eliminate the risk of illness or injury (section 907(a)(3)(B)(ii) of the FD&C Act).
- Information submitted regarding the technical achievability of compliance with the standard, including with regard to any differences related to the technical achievability of compliance with such standard for products in the same class containing nicotine not made or derived from tobacco and products containing nicotine made or derived from tobacco (section 907(b)(1) of the FD&C Act).
- All other information submitted, including information concerning the countervailing effects of the 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 chapter IX of the FD&C Act and the significance of such demand (section 907(b)(2) of the FD&C Act).

As required by section 907(c)(2) of the FD&C Act, FDA invites interested persons to submit a draft or proposed tobacco product standard for the Agency's consideration (section 907(c)(2)(B)) and information regarding structuring the standard so as not to advantage foreign-grown tobacco over domestically grown tobacco (section 907(c)(2)(C)). In addition, FDA invites the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard (section 907(c)(2)(D) of the FD&C Act).

FDA is requesting all relevant documents and information described in this section with this proposed rule. Such documents and information may be submitted in accordance with the ''Instructions'' included in the preliminary information section of this document.

Section 907(d)(5) of the FD&C Act allows the Agency to refer a proposed regulation for the establishment of a tobacco product standard to TPSAC at the Agency's own initiative or in response to a request that demonstrates good cause for a referral and is made before the expiration of the comment period. If FDA opts to refer this proposed regulation to TPSAC, the Agency will publish a notice in the **Federal Register** announcing the TPSAC meeting to discuss this proposal.

B. Request for Comments on the Potential Racial and Social Justice Implications of the Proposed Product Standard

FDA is aware of concerns raised by some that this proposed rule could lead to illicit trade in menthol cigarettes, increased policing, and criminal penalties in underserved communities, including Black communities, which tend to have higher rates of menthol cigarette use and experience greater tobacco-related morbidity and mortality. We reiterate that this regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumer possession or use of menthol cigarettes. FDA's enforcement of this proposed rule will only address manufacturers, distributors, wholesalers, importers, and retailers. State and local law enforcement agencies do not independently enforce the FD&C Act. These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA's behalf.

Recognizing concerns related to how State and local law enforcement agencies enforce their own laws in a manner that may impact equity and community safety, FDA requests comments, including supporting data and research, on any potential for this proposed rule to result, directly or indirectly, in disparate impacts within particular underserved communities or vulnerable populations. With respect to any potential disparate impacts, FDA requests comments and data on whether and how specific aspects of the rule, if finalized, might increase the likelihood of such outcomes beyond what would be expected to occur in the absence of the rule, and potential strategies for avoiding or addressing such impacts of the rule within the bounds of FDA's authorities. FDA also requests comments and data related to the existence, nature and degree of any change in police activity or community encounters with State or local law enforcement within a State, locality or other jurisdiction following implementation of a prohibition of menthol cigarettes. Finally, FDA requests comment on any other policy considerations related to potential racial and social justice implications of the rule.

VII. Description of the Proposed Regulation

We are proposing to establish a new 21 CFR part 1162 (part 1162) that would prohibit menthol as a characterizing flavor in cigarettes. Part 1162 would describe the scope of the proposed regulation, applicable definitions, and the prohibition on use of menthol as a characterizing flavor in cigarettes.

A. Scope (Proposed § 1162.1)

Proposed § 1162.1(a) would provide that this part sets out a tobacco product standard under the FD&C Act regarding the use of menthol as a characterizing flavor in cigarettes. We are proposing that this product standard would cover all products meeting the definition of ''cigarette'' in section 900(3) of the FD&C Act (21 U.S.C. 387(3)) (proposed § 1162.3 includes a definition of cigarette). This includes all types, sizes, nicotine strengths and formulations of cigarettes, cigarette tobacco and RYO tobacco, as well as HTPs that meet the definition of a cigarette in the FD&C Act (cigarettes that are HTPs).

In general, as discussed in this document, menthol as a characterizing flavor in tobacco products enhances product appeal, usability, and addictiveness and has played a role in creating and perpetuating tobacco-related health disparities. While these effects raise concerns in the context of any tobacco product—none of which is without risk—FDA recognizes that certain products that meet the definition of cigarette in the FD&C Act may present different considerations with respect to this proposed product standard. For example, certain cigarettes may produce significantly fewer or lower levels of toxicants or have significantly reduced potential for creating or sustaining addiction. Recognizing that tobacco products exist on a continuum of risk, with combusted cigarettes being the deadliest, FDA recognizes that certain, specific products meeting the definition of a cigarette (*e.g.,* some that are not combusted or are minimally addictive) may pose less risk to individual users or to population health than other products meeting the definition of a cigarette. FDA also notes that there is wide variability even within certain types of cigarettes, such as variability in toxicants or youth appeal among HTPs or minimally addictive cigarettes.[15]

[15] For additional information about the variability of tobacco products, see the Premarket Tobacco Product Applications and Recordkeeping

Accordingly, FDA is considering options that would allow certain products that present different considerations to seek exemptions from the product standard on a case-by-case basis.

Section 910 of the FD&C Act provides that those seeking to market new tobacco products via a premarket tobacco application may justify a deviation from a product standard to which it does not conform. However, no similar provision exists for pre-existing products or products that already are authorized under, or that seek authorization under, other pathways, *i.e.,* the substantial equivalence pathway or exemption from substantial equivalence. FDA is considering whether a final product standard rule should include a provision for requesting an exemption from the standard for certain products within particular categories, on a case-by-case basis, consistent with the potential for differential public health impacts among products meetings the definition of ''cigarette'', as discussed above.

Accordingly, we are requesting comments on exemptions, including: (1) Whether the final rule should include a provision that allows for firms to request an exemption from the standard for specific products of certain types (*e.g.,* noncombusted, reduced nicotine), on a case-by-case basis; (2) for what types of products should firms be eligible to request an exemption; (3) for an exemption provision, how should the Agency evaluate exemption requests, and what data and information should firms be required to submit for this; and (4) if an exemption provision should apply to products currently on the market at the time of the final rule's effective date, how the exemption process should work (*e.g.,* require that any exemption request be received within 180 days of publication so the Agency has time to make a determination before the effective date). As part of this, comments could address or account for impact on industry, impact on the Agency's use of resources and the Agency's ability to protect public health, as well as situations where the commenter believes an exemption would or would not be appropriate.

Proposed § 1162.1(b) would prohibit the manufacture, distribution, sale, or offering for distribution or sale, in the United States of a cigarette or any of its components or parts that is not in compliance with the tobacco product standard. This provision is not intended to restrict the manufacture of cigarettes with menthol as a characterizing flavor intended for export. Consistent with section 801(e)(1) of the FD&C Act (21 U.S.C. 381(e)(1)), a tobacco product intended for export shall not be deemed to be in violation of section 907 of the FD&C Act or this product standard, if it meets the criteria enumerated in section 801(e)(1), including not being sold or offered for sale in domestic commerce.

B. Definitions (Proposed § 1162.3)

Proposed § 1162.3 provides the definitions for the terms used in the proposed rule. Several of these definitions are included in the FD&C Act or are used in other regulations.

- *Accessory:* FDA defined ''accessory'' in the deeming final rule (81 FR 28974, May 10, 2016; codified at § 1100.3 (21 CFR 1100.3)). We are proposing to use that definition here as it applies to cigarettes to provide further understanding as to the scope of the proposed standard. Therefore, FDA proposes to define ''accessory'' in the context of part 1162 to mean any product that is intended or reasonably expected to be used with or for the human consumption of a cigarette; does not contain tobacco or nicotine from any source, and is not made or derived from tobacco; and meets either of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a cigarette; or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a cigarette but (i) solely controls moisture and/or temperature of a stored cigarette; or (ii) solely provides an external heat source to initiate but not maintain combustion of a cigarette. An example of a cigarette ''accessory'' is an ashtray.
- *Cigarette:* As defined in section 900(3) of the FD&C Act, the term ''cigarette'': (1) Means a product that: (i) Is a tobacco product and (ii) meets the definition of the term ''cigarette'' in section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)) and (2) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as RYO tobacco.
- *Cigarette tobacco:* As defined in section 900(4) of the FD&C Act, the term ''cigarette tobacco'' means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under 21 CFR chapter I also apply to cigarette tobacco.
- *Component or part:* FDA defined ''component or part'' in the deeming final rule (§ 1100.3). We are proposing to use that definition here as it applies to cigarettes. Therefore, FDA proposes to define ''component or part'' in the context of part 1162 to mean any software or assembly of materials intended or reasonably expected: (1) To alter or affect the cigarette's performance, composition, constituents or characteristics or (2) to be used with or for the human consumption of a cigarette. The term excludes anything that is an accessory of a cigarette. Examples of cigarette components or parts that would be subject to this proposed product standard include cigarette paper, filters, and flavor additives. With respect to these definitions, FDA notes that ''component'' and ''part'' are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this rule, FDA is using the terms ''component'' and ''part'' interchangeably and without emphasizing a distinction between the terms. FDA may clarify the distinctions between ''component'' and ''part'' in the future.
- *Person:* As defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)), the term ''person'' includes an individual, partnership, corporation, and association.
- *Roll-your-own tobacco:* As defined in section 900(15) of the FD&C Act, the term ''roll-your-own tobacco'' means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.
- *Tobacco product:* As defined in section 201(rr) of the FD&C Act, the term ''tobacco product'' is defined as any product that is made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that is: A drug under section 201(g)(1); a device under section 201(h); a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)); or a food under section 201(f) if such article contains no

Requirements (PMTA) final rule (86 FR 55300, October 5, 2021) available at *https://www.federalregister.gov/documents/2021/10/05/2021-21011/premarket-tobacco-product-applications-and-recordkeeping-requirements.*

nicotine, or no more than trace amounts of naturally occurring nicotine.

• *United States:* As defined in section 900(22) of the FD&C Act, the term ''United States'' means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midways Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

C. Prohibition on Use of Menthol as a Characterizing Flavor in Cigarettes (Proposed § 1162.5)

Proposed § 1162.5 would establish a tobacco product standard prohibiting the use of menthol as a characterizing flavor in cigarettes. Specifically, proposed § 1162.5 would state that a cigarette or any of its components or parts (including the tobacco, filter, wrapper, or paper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, menthol that is a characterizing flavor of the tobacco product or tobacco smoke.[16] This proposal takes into consideration, among other information, the comments received by FDA on the ANPRMs and citizen petition, including comments urging FDA to ban menthol as a characterizing flavor in cigarettes, comments arguing for a total ban on menthol in cigarettes, comments recommending that any product standard for menthol also cover additives and components which convey menthol flavoring, and comments opposing any product standard for menthol in cigarettes. As discussed in section V of this document, FDA finds that this proposed product standard, which would prohibit menthol as a characterizing flavor in cigarettes, would be appropriate for the protection of the public health.

FDA would enforce the requirements of this proposed product standard under various sections of the FD&C Act, including sections 301, 303, 902, and 903. Section 907(a)(4)(B)(v) of the FD&C Act states that product standards must, where appropriate for the protection of the public health, include provisions requiring that the sale and distribution of the tobacco products be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under section 906(d). Similar to section 907(a)(4)(B)(v), section 906(d) of the FD&C Act gives FDA authority to require restrictions on the sale and distribution of tobacco products by regulation if the Agency determines that such regulation would be appropriate for the protection of the public health. Because this sale and distribution restriction of menthol cigarettes would also assist FDA in enforcing the standard and would ensure that manufacturers, distributors, and retailers are selling product that complies with the standard, the Agency has found the restriction to be appropriate for the protection of the public health consistent with sections 907(a)(4)(B)(v) and 906(d) of the FD&C Act.

Failure to comply with any requirements prescribed by this product standard may result in FDA initiating enforcement or regulatory actions, including, but not limited to, warning letters, civil money penalties, no-tobacco-sale orders, criminal prosecution, seizure, and/or injunction. In addition, adulterated or misbranded tobacco products offered for import into the United States are subject to detention and refusal of admission. As previously discussed, FDA's enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. FDA cannot and will not enforce against individual consumer possession or use of menthol cigarettes.

Among the factors that FDA believes are relevant in determining whether a cigarette has a characterizing flavor are:

• The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;

• The multisensory experience (*i.e.,* taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts;

• Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of tobacco products;[17] and

• Any other means that impart flavor or represent that the tobacco product has a characterizing flavor.

FDA expects that the approach proposed in this rule—relying on specific, flexible factors to make a case-by-case determination as to a characterizing flavor of menthol—would provide important clarity for FDA, regulated industry, and other stakeholders while also ensuring critical flexibility and enforceability to achieve the public health goals of this rule. FDA requests comments regarding these factors and other potential factors that the Agency might consider in determining whether a cigarette has menthol as a characterizing flavor.

FDA also requests comments, including supporting data and research, regarding any alternatives to prohibiting menthol as a characterizing flavor (*e.g.,* prohibiting all menthol flavor additives, compounds, constituents, or ingredients).

We note that this prohibition also would cover menthol flavoring that is separate from the cigarette. For example, menthol can be added to non-menthol cigarettes via drops, capsules, filter tips for RYO tobacco, or cards that can be inserted into a cigarette pack or pouch of rolling tobacco (Refs. 299 and 300). Such menthol flavorings would be considered components or parts of cigarettes under proposed § 1162.3, as they could be intended or reasonably expected to: (1) Alter or affect the cigarette's performance, composition, constituents, or characteristics or (2) be used with or for the human consumption of a cigarette, and they would not be accessories of cigarettes. Therefore, the manufacture, distribution, sale, or offer for distribution or sale of such products would be prohibited should this proposed rule be finalized.

VIII. Proposed Effective Date

In accordance with section 907(d)(2) of the FD&C Act,[18] FDA proposes that any final rule that may issue based on this proposal become effective 1 year after the date of publication of the final rule. Therefore, after the effective date, no person may manufacture, sell, or offer for sale or distribution within the United States a cigarette or any of its components or parts that is not in compliance with part 1162. This

[16] We note that the language in section 907(a)(1)(A) of the FD&C Act states that the Special Rule for Cigarettes applies to cigarettes or ''any of its component parts.'' For purposes of this standard, we have used the phrase ''any of its components or parts'' and have defined ''component or part'' for clarity and consistency with the deeming final rule (81 FR 28974 at 28975).

[17] If a cigarette has a characterizing flavor (other than tobacco), but its labeling or advertising represents that it does not, then the product may be, among other things, misbranded under section 903 of the FD&C Act because its labeling or advertising is false or misleading. Similarly, if a product does not have a characterizing flavor, but its labeling or advertising represents that it does, then the product may be misbranded under section 903 of the FD&C Act because its labeling or advertising is false or misleading.

[18] Section 907(d)(2) of the FD&C Act states that a regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health.

regulation does not include a prohibition on individual consumer possession or use.

FDA finds this proposed standard appropriate for the protection of the public health because it would reduce the ease of smoking cigarettes, particularly for young people and new users, thereby decreasing the likelihood that nonusers who experiment with these products would progress to regular smoking. In addition, the proposed tobacco product standard would improve the health of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation. Additional delay, past 1 year, would only increase the numbers of youth and young adults who experiment with menthol cigarettes and become regular smokers, delay cessation by current smokers, and exacerbate tobacco-related health disparities.

FDA also finds that a 1-year effective date will ''minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade'' pursuant to section 907(d)(2) of the FD&C Act. As discussed in the preliminary economic analysis (Ref. 292), FDA believes that most currently marketed menthol cigarettes are available for purchase in currently marketed non-menthol versions. Therefore, FDA does not expect that this rule, if finalized, would result in many new tobacco product applications. For these reasons, FDA believes that the availability of currently marketed non-menthol versions of currently marketed menthol cigarettes would minimize the economic loss to, and disruption of, domestic and international trade.

We also note that the Tobacco Control Act banned characterizing flavors in cigarettes with a 90-day effective date (section 907(a)(1)(A) of the FD&C Act). FDA is proposing a longer effective date here in accordance with section 907(d)(2) of the FD&C Act. FDA requests comments as to whether a shorter effective date, such as 90 days, would be necessary for the protection of the public health. In setting the effective date, FDA will consider information submitted in connection with this proposal by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the proposed 1-year timeframe.

FDA is aware of retailers' concerns regarding unsold inventory when any final rule goes into effect. FDA requests comments, including supportive data and research, regarding a sell-off period (*e.g.,* 30 days after the effective date of a final rule) for retailers to sell through their current inventory of menthol cigarettes.

IX. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order (E.O.) 12866, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is an economically significant regulatory action as defined by E.O. 12866. As such, it has been reviewed by the Office of Information and Regulatory Affairs.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because a portion of business revenues may revert back to consumers who currently purchase menthol cigarettes, we find that the rule may have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule, if finalized, would result in expenditures that meet or exceed this amount.

B. Summary of Costs and Benefits

The summary of benefits and costs is presented in Table 1. The proposed rule, if finalized, would establish a tobacco product standard prohibiting the use of menthol as a characterizing flavor in cigarettes. The quantified benefits of this proposed rule come from lower smoking-attributable mortality in the U.S. population due to diminished exposure to tobacco smoke for both users and nonusers of cigarettes. Qualitative benefits include: decreased illness and associated reductions in medical costs (both publicly and privately funded), decreased productivity loss, and improved health-related quality of life for menthol smokers and non-smokers; reductions in smoking-related fires; and reductions in cigarette butt litter and associated harms to the environment. We estimate that the present value of the monetized benefits over a 40-year time horizon ranges between $2,529 billion and $8,253 billion (primary estimate of $5,428 billion) at a 3 percent discount rate, and range between $1,369 billion and $4,470 billion (primary estimate of $2,941 billion) at a 7 percent discount rate. The primary annualized benefits equal $232 billion at a 3 percent discount rate and $220 billion at a 7 percent discount rate. Unquantified benefits are expected to provide additional benefits beyond those amounts and additional health and related benefits are expected to occur outside the time horizon used in this analysis.

The proposed rule, if finalized, would also create costs for firms, consumers and the Federal Government. Firms face one-time costs to read and review the rule (undiscounted primary estimate of $186.6 million with a range of $56.0 million to $349.9 million), and may face one-time costs for reallocation, friction, and adjustment in the cigarette product market (undiscounted primary estimate of $235.9 million with a range of $0.2 million to $471.9 million). Firms may also face costs due to producer surplus loss over the 40 year time horizon (undiscounted primary estimate of $10,628 million with a range of $0 to $21,256). Consumers may face one-time search costs of $359.3 million (undiscounted, range of $179.7 million to $539.0 million) to find substitute tobacco products as a replacement for menthol cigarettes. The FDA may face annual costs associated with enforcement of the proposed product standard (undiscounted range from $0 to $1.3 million, primary estimate $0.7 million per year). Qualitative costs may include changes in consumer surplus for some menthol cigarette product users, including potential utility changes for smokers of menthol cigarette products who switch from menthol to non-menthol cigarette products. We estimate that the present value of monetized costs over a 40-year time horizon ranges between $223.0 million and $13,421.6 million (primary

estimate of $6,805.9 million) for a 3 percent discount rate, and between $208.0 million and $8,051.3 million (primary estimate of $4,113.2 million) at a 7 percent discount rate. The primary estimates for the annualized cost are $291 million at a 3 percent discount rate and $307 million at a 7 percent discount rate. In addition to benefits and costs, this rule, if finalized, will create significant transfers from State governments, Federal Government, and firms to consumers in the form of reduced revenue and tax revenue. The primary estimates for annualized transfers related to Federal taxes are $2.0 billion at a 3 percent discount rate and $2.0 billion at a 7 percent discount rate. The primary estimates for the annualized transfers related to State taxes are $3.7 billion at a 3 percent discount rate and $3.7 billion at a 7 percent discount rate. The primary estimates for the annualized transfers between cigarette product manufacturers and consumers are $13.3 billion at a 3 percent discount rate and $13.0 billion at a 7 percent discount rate. Benefits, costs, and transfers are summarized in Table 1.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

[$ Millions of 2020 dollars over a 40 year time horizon]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized ($m/year)	$220,000	$102,000	$334,000	2020	7	40	
	232,000	108,000	353,000	2020	3	40	
Annualized Quantified							
Qualitative	*Qualitative benefits include:* Decreased illness and associated reductions in medical costs (both publicly and privately funded), decreased productivity loss, and improved health-related quality of life for menthol smokers and non-smokers; reductions in smoking-related fires; and reductions in cigarette butt litter and associated harms to the environment.						
Costs:							
Annualized Monetized ($m/year)	307	16	601	2020	7	40	
	291	9	573	2020	3	40	
Annualized Quantified							
Qualitative	Changes in consumer surplus may occur for some menthol smokers.						
Transfers:							
Federal Annualized Monetized ($m/year)	2,000	1,000	2,000	2020	7	40	
	2,000	1,000	2,000	2020	3	40	
	From: Federal Government			To: Consumers			
State Annualized Monetized ($m/year)	4,000	3,000	4,000	2020	7	40	
	4,000	3,000	4,000	2020	3	40	
	From: State Government			To: Consumers			
Other Annualized Monetized ($m/year)	13,000	9,000	15,000	2020	7	40	
	13,000	9,000	15,000	2020	3	40	
	From: Cigarette Product Manufacturers			To: Consumers and Manufacturers of Other Tobacco Products			

Effects:

State, Local, or Tribal Government: See transfers for estimated State excise tax impacts. See distributional effects for discussions of impacts to tribally-affiliated manufacturers and/or manufacturers operating on tribal lands.

Small Business: Small menthol cigarette manufacturers are expected to face one-time costs for reading and understanding the rule and for planning and implementing reallocation procedures for menthol cigarette production lines. Small menthol cigarette manufacturers would also face revenue transfers as consumers cease purchasing menthol cigarette products.

Wages: No effect.

Growth: No effect.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (see Ref. 292) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

X. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding is available in the docket for this proposed rule (see Refs. 304 and 305) and may be seen in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* Under FDA's regulations implementing the National Environmental Policy Act (21 CFR part 25), an action of this type would require an environmental assessment under 21 CFR 25.20.

XI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required.

XII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. Section 4(a) of the Executive order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' We have determined that the proposed rule, if finalized, would not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

This rule is being issued under section 907 of the FD&C Act, which enables FDA to prescribe regulations relating to tobacco product standards, and the sale and distribution restriction in this rule is also being issued under section 906(d) of the FD&C Act, which enables FDA to prescribe regulations restricting the sale and distribution of a tobacco product. If this proposed rule is made final, the final rule would create requirements whose preemptive effect would be governed by section 916 of the FD&C Act, entitled ''Preservation of State and Local Authority.''

Section 916 broadly preserves the authority of states and localities to protect the public against the harms of tobacco use. Specifically, section 916(a)(1) establishes a general presumption that FDA requirements do not preempt or otherwise limit the authority of States, localities, or tribes to, among other things, enact and enforce laws regarding tobacco products that relate to certain activities (*e.g.,* sale, distribution) and that are in addition to or more stringent than requirements established under chapter IX of the FD&C Act.

Section 916(a)(2)(A) of the FD&C Act is an express preemption provision that establishes an exception to the preservation of State and local governmental authority over tobacco products established in section 916(a)(1). Specifically, section 916(a)(2)(A) of the FD&C Act provides that ''[n]o State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards . . . .''

However, section 916(a)(2)(B) of the FD&C Act limits the applicability of section 916(a)(2)(A), narrowing the scope of state and local requirements that are subject to express preemption. In particular, paragraph (a)(2)(B) provides that preemption under paragraph (a)(2)(A) does not apply to State or local ''requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.''

If this proposed rule is finalized as proposed, the final rule would create requirements that fall within the scope of section 916(a)(2)(A) because they are ''requirements under the provisions of the chapter relating to tobacco product standards.'' Accordingly, the preemptive effect of those requirements on any state or local requirement would be determined by the nature of the state or local requirement at issue—specifically, whether the state or local requirement is preserved under section 916(a)(1), and/or excepted under section 916(a)(2)(B) (such as if it relates to the ''sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products''). State and local prohibitions on the sale and distribution of flavored tobacco products, such as menthol cigarettes, would not be preempted by this rule, if finalized, because such prohibitions would be preserved by FD&C Act section 916(a)(1) or, as applicable, excepted from express preemption by FD&C Act section 916(a)(2)(B). FDA invites comments on how State or local laws may be implicated if this proposed rule is finalized.

XIII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XIV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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List of Subjects in 21 CFR Part 1162

Labeling, Smoke, Smoking, Tobacco, Tobacco products.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended by adding part 1162 to subchapter K to read as follows:

PART 1162—PRODUCT STANDARD: MENTHOL IN CIGARETTES

Subpart A—General Provisions

Subpart B—Product Standard for Menthol in Cigarettes

Authority: 21 U.S.C. 331, 333, 371(a), 387b, 387c, 387f(d), 387g.

Subpart A—General Provisions

§ 1162.1 Scope.

(a) This part sets out a tobacco product standard under the Federal Food, Drug, and Cosmetic Act regarding the use of menthol as a characterizing flavor in cigarettes.

(b) No person may manufacture, distribute, sell, or offer for distribution or sale, within the United States a cigarette or any of its components or parts that is not in compliance with this part.

§ 1162.3 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a cigarette; does not contain tobacco or nicotine from any source, and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a cigarette; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a cigarette; but

(i) Solely controls moisture and/or temperature of a stored cigarette; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a cigarette.

Cigarette, as used in this part:

(1) Means a product that:

(i) Is a tobacco product; and

(ii) Meets the definition of the term ''cigarette'' in section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)); and

(2) Includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

Cigarette tobacco means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the cigarette's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a cigarette. The term excludes anything that is an accessory of a cigarette.

Person includes an individual, partnership, corporation, or association.

Roll-your-own tobacco means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

Tobacco product means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the Federal Food, Drug, and Cosmetic Act is: A drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food under section 201(f) if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

United States means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

Subpart B—Product Standard for Menthol in Cigarettes

§ 1162.5 Prohibition on use of menthol as a characterizing flavor in cigarettes.

A cigarette or any of its components or parts (including the tobacco, filter, wrapper, or paper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, menthol that is a characterizing flavor of the tobacco product or tobacco smoke.

Dated: April 22, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–08994 Filed 4–28–22; 11:15 am]

BILLING CODE 4164–01–P