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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1166

[Docket No. FDA-2021-N-1309]

RIN 0910-AI28

Tobacco Product Standard for Characterizing Flavors in Cigars

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

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars and their components and parts. Characterizing flavors in cigars, such as strawberry, grape, cocoa, and fruit punch, increase appeal and make the cigars easier to use, particularly among youth and young adults. Over a half million youth in the United States use flavored cigars. This proposed product standard would reduce the appeal of cigars, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, development of nicotine dependence, and progression to regular use. FDA is taking this action to reduce the tobacco-related death and disease associated with cigar 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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-1309 for "Tobacco Product Standard for Characterizing Flavors in Cigars." 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: Courtney Smith or Nathan Mease, 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:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

B. Summary of the Major Provisions of the Proposed Rule

C. Legal Authority

D. Costs and Benefits

II. Table of Abbreviations/Commonly Used Acronyms

III. Background

A. Need for the Regulation

B. Relevant Regulatory History

C. Legal Authority

D. FDA's Consideration of Health Equity

IV. Characterizing Flavors Impact Cigar Use, Particularly Among Youth and Young Adults

A. Recent Market Trends of Flavored Cigars in the United States

B. Over Half a Million Youth, and Even More Young Adults, in the United States Use Flavored Cigars

C. Adult Use of Flavored Cigars in the United States

D. Characterizing Flavors Increase Appeal and Make Tobacco Products, Including Cigars, Easier to Use

E. Characterizing Flavors Increase Youth and Young Adult Experimentation with Tobacco Products, Including Cigars, and Make Progression to Regular Tobacco Use More Likely

F. Real-World Experiences Demonstrate that Restricting Characterizing Flavors in Tobacco Products, Including Cigars, Decreases Tobacco Use

G. Flavored Cigars Are Marketed Disproportionately in Underserved Communities and to Vulnerable Populations

V. Cigar Use Is Common, Addictive, and Harmful

A. Prevalence of Cigar Use Among Youth, Young Adults, and Older Adults in the United States

B. Flavored Cigar Use Exposes Users to Additional Toxicants

C. Cigar Use Is Addictive

D. Research Clearly Demonstrates a Causal Relationship Between Cigar Smoking and Death and Disease

E. Secondhand Tobacco Smoke, Including Cigar Smoke, Increases the Risks of Lung Cancer, Heart Disease, and Other Adverse Health Effects in Nonsmokers

F. Disparities in Tobacco Use, Including Cigar Use, Lead to Disparities in Tobacco-Related Morbidity and Mortality

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

A. The Likelihood That Nonusers Would Start Using Cigars

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

C. Benefits and Risks to the Population as a Whole

D. Conclusion

VII. Additional Considerations and Requests for Comments

A. Section 907 of the FD&C Act

B. Pathways to Market

C. Considerations and Request for Comments on Scope of Products

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

VIII. Description of the Proposed Rule

A. Scope (Proposed § 1166.1)

B. Definitions (Proposed § 1166.3)

C. Prohibition on Use of Characterizing Flavors in Cigars (Proposed § 1166.5)

IX. Proposed Effective Date

X. Preliminary Economic Analysis of Impacts

A. Introduction

B. Summary of Costs and Benefits

XI. Analysis of Environmental Impact

XII. Paperwork Reduction Act of 1995

XIII. Federalism

XIV. Consultation and Coordination with Indian Tribal Governments

XV. References

I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in cigars manufactured or sold in the United States. In developing this proposed rule, FDA carefully considered the scientific evidence and complex policy issues related to characterizing flavors in cigars.

Each year, an estimated 9,000 premature deaths are attributed to regular cigar smoking, defined as smoking cigars on 15 or more of the past 30 days; approximately 5,200 of these premature deaths occur in regular cigar smokers who did not also smoke cigarettes. In 2019, not excluding use of other tobacco products, more young adults tried a cigar for the first time each

day than tried a cigarette for the first time (3,163 cigar vs. 2,640 cigarette initiates per day). According to the 2020 National Youth Tobacco Survey (NYTS), an estimated 3.5 percent (960,000) of middle and high school students, including 5 percent (770,000) of high school students (grades 9-12) and 1.5 percent (180,000) of middle school students (grades 6-8), had smoked a cigar (cigar, cigarillo, or little cigar) in the preceding 30 days. Of particular concern is the number of youth smoking cigars with characterizing flavors. More than half (58.3 percent) of youth cigar smokers, or approximately 550,000 youth, reported using a flavored cigar during the past 30 days.

Researchers have found that characterizing flavors in cigars and other tobacco products play a key role in how users and nonusers, particularly youth, initiate, progress, and continue using tobacco products. Characterizing flavors in tobacco products increase the appeal of those tobacco products to youth and promote youth initiation, resulting in an increased likelihood that youth and young adults experimenting with flavored cigars will progress to regular cigar smoking. This proposed product standard is expected to reduce the appeal of cigars, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, development of nicotine dependence, progression to regular use, and the resulting tobacco-related disease and death. The proposed standard also is anticipated to improve public health by increasing the likelihood of cessation among existing cigar smokers. And it will improve health outcomes within groups that experience disproportionate levels of tobacco use, including certain vulnerable populations, thus advancing health equity. 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.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would prohibit characterizing flavors (other than tobacco) in cigars and cigar components and parts. Under the proposed rule, no person may manufacture, distribute, sell, or offer for distribution or sale, within the United States a cigar or any of its

components or parts that is not in compliance with the product standard. We also are proposing an effective date of 1 year after the date of publication of the final rule. We seek comment on all parts of this proposed rule.

Characterizing Flavor Prohibition--This proposed rule would prohibit the use of characterizing flavors in all cigars. FDA proposes to define "cigar" as a tobacco product that: (1) is not a cigarette and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco. This rule would provide that a cigar or any of its components or parts (including the tobacco, filter, or wrapper, as applicable) must not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including, but not limited to, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, mint, or menthol, that is a characterizing flavor of the tobacco product or tobacco smoke. Among the factors that FDA believes are relevant in determining whether a cigar 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 a tobacco product; and
- Any other means that impart flavor or represent that a tobacco product has a characterizing flavor.

However, cigars with tobacco as their characterizing flavor would not be subject to this proposed product standard's prohibition. For those who experiment with cigars, especially youth

and young adults, tobacco-flavored[1] cigars do not currently appear as attractive as cigars with other characterizing flavors. FDA is committed to monitoring the use of cigars with tobacco as their characterizing flavor through surveillance of national representative data sources and other data to determine whether to take additional action in the future consistent with FDA's authority.

Proposed Effective Date--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, distribute, sell, or offer for distribution or sale within the United States a cigar or any of its components or parts that is not in compliance with part 1166 (21 CFR part 1166). 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 flavored cigars. 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

This proposed rule is being issued upon FDA's authority to establish a tobacco product standard under section 907 of the FD&C Act (21 U.S.C. 387g), including its authority thereunder to require the reduction or elimination of a constituent (including a smoke constituent), or harmful component of tobacco products, and respecting the construction, components, ingredients, additives, constituents (including smoke constituents), and properties of the tobacco

[1] Throughout this document, FDA uses the terms "tobacco-flavored," "non-flavored," and "unflavored." FDA relies on the specific term used by researchers when citing to individual studies; however, FDA generally considers a cigar that does not have a characterizing flavor other than tobacco to be "tobacco-flavored."

product (section 907(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 under sections 907(a)(4)(B)(v) and 906(d) (21 U.S.C. 387f); FDA's authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387b and 387c); FDA's authorities related to prohibited acts and penalties under sections 301 and 303 (21 U.S.C. 331 and 333); and FDA's rulemaking authority under section 701 of the FD&C Act (21 U.S.C. 371).

D. Costs and Benefits

The quantified benefits of this proposed rule, if finalized, come from reduced smoking-attributable mortality that are the result of cigar use among adult cigar smokers and reduced mortality from secondhand smoke among non-users. 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, the 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 $7,024 million at a 7 percent discount rate, with a low estimate of $3,962 million and a high estimate of $10,140 million, and $8,575 million at a 3 percent discount rate, with a low estimate of $4,837 million and a high estimate of $12,378 million.

Over a 40-year time horizon, we estimate that the annualized costs will equal $112 million at a 7 percent discount rate, with a low estimate of $9 million and a high estimate of $216 million, and $102 million at a 3 percent discount rate, with a low estimate of $5 million and a high estimate of $200 million.

II. Table of Abbreviations/Commonly Used Acronyms

Abbreviation/Acronym	What It Means
AI/ANs	American Indians or Alaskan Natives
ANPRM	Advance notice of proposed rulemaking
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CO	Carbon monoxide

COPD	Chronic obstructive pulmonary disease
CPS I	Cancer Prevention Study I
CPS II	Cancer Prevention Study II
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
HHS	U.S. Department of Health and Human Services
IARC	International Agency for Research on Cancer
IOM	Institute of Medicine
LCCs	Little cigars and cigarillos
LGBTQ+	Lesbian, Gay, Bisexual, Transgender, or Queer
MI	Myocardial Infarction
MSS	Minnesota Student Survey
MYTS	Minnesota Youth Tobacco Survey
NATS	National Adult Tobacco Survey
NCI	National Cancer Institute
NHANES	National Health and Nutrition Examination Survey
NHIS	National Health Interview Survey
NHIS-LMF	National Health Interview Survey-Linked Mortality Files
NRC	National Research Council
NSDUH	National Survey on Drug Use and Health
NYC	New York City
NYTS	National Youth Tobacco Survey
OMB	Office of Management and Budget
PAH	Polycyclic aromatic hydrocarbon
PATH	Population Assessment of Tobacco and Health
RYO	Roll-your-own
SE	Substantial equivalence
TPSAC	Tobacco Products Scientific Advisory Committee
TUS-CPS	Tobacco Use Supplement to the Current Population Survey
WHO	World Health Organization
YPLL	Years of potential life lost
YRBS	Youth Risk Behavior Survey

III. Background

A. Need for the Regulation

FDA is proposing to prohibit characterizing flavors[2] (other than tobacco) in cigars. Specifically, FDA is proposing a product standard that would prohibit a cigar or any of its components or parts (including the tobacco, filter, or wrapper, as applicable) from containing, as

[2] For the purposes of this proposed rule, we are using the terms "flavoring" in a tobacco product, a tobacco product with "flavors," or a "flavored tobacco product" to refer to a tobacco product with characterizing flavors, which is the subject of this proposed rule.

a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including, but not limited to, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, mint, or menthol that is a characterizing flavor of the tobacco product or tobacco smoke.

Use of cigars[3] overall has increased in recent years. Since 2000, sales of cigars have doubled from approximately 6.2 billion cigars in 2000 to more than 14 billion cigars in 2019 (Refs. 1 and 2). Each year, an estimated 9,000 premature deaths are attributed to regular cigar smoking (defined in the study as smoking cigars on 15 or more of the past 30 days); approximately 5,200 of these premature deaths occur in regular cigar smokers who do not also smoke cigarettes (Ref. 3). It is estimated that cigar-attributable annual healthcare expenditures amount to $1.8 billion per year (Ref. 4). Analysis of 2014-2015 data from the Tobacco Use Supplement to the Current Population Survey (TUS-CPS) found that adult flavored-cigar smokers had greater odds of daily cigar smoking and smoking within 30 minutes of waking than non-flavored cigar smokers, after adjusting for age, sex, race/ethnicity, and multiple tobacco product use (Ref. 5).

As discussed in section IV.B of this document, youth consumption of cigars is substantial, and nicotine dependence in cigar smokers could result from even a limited exposure to nicotine during adolescence (Ref. 6). According to the 2020 NYTS, an estimated 960,000 middle and high school students, including 5 percent (an estimated 770,000) of high school students (grades 9-12) and 1.5 percent (an estimated 180,000) of middle school students (grades 6-8), had smoked a cigar (cigar, cigarillo, or little cigar) on at least 1 day during the past 30 days (Ref. 7). Overall, the prevalence of cigar smoking among middle and high school students is comparable to the prevalence of cigarette smoking, with 4.6 percent (an estimated 710,000) of high school students and 1.6 percent (an estimated 190,000) of middle school students having

[3] Throughout this document, FDA uses the terms “traditional,” “conventional,” “regular,” “large,” “little,” “filtered,” and “cigarillo” when discussing different types of cigars. FDA relies on the specific term used by researchers when citing a specific study. FDA uses the term “cigar” when not citing a specific study.

smoked cigarettes on at least 1 day during the past 30 days (Ref. 7). For non-Hispanic Black[4] students, cigar smoking prevalence (6.5 percent) is considerably greater than cigarette smoking (2.5 percent) (Ref. 7). Of particular concern is the number of youth smoking cigars with characterizing flavors. According to 2020 NYTS data analyzing flavored cigar use among youth, 58.3 percent of youth cigar smokers, or approximately 550,000 youth, reported using a flavored cigar during the past 30 days (Ref. 8).

Characterizing flavors in cigars and other tobacco products reduce the harshness, bitterness, and astringency of tobacco during inhalation and soothe irritation during use (Refs. 9-11). Characterizing flavors thus increase the youth[5] appeal of those tobacco products and promote youth initiation, resulting in an increased likelihood that youth and young adults experimenting with flavored cigars will become addicted and progress to regular smoking (see sections IV.D and IV.E of this document). Recent evidence from an analysis of data from Wave 5 of the Population Assessment of Tobacco and Health (PATH) Study[6] (2018-19) demonstrates that over half of youth (aged 12-17 years) who used cigars in the past 30 days identified flavors as a reason for use (Ref. 12). In addition, research has shown that characterizing flavors in tobacco products can trigger reward pathways in the brain that are responsible for reward-related learning, which may increase the attractiveness of flavored products to consumers and the probability of repeated use (Refs. 13-15).

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[4] Throughout this document, 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.

[5] 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. 17).

[6] The PATH Study is a collaboration between the Center for Tobacco Products, FDA and the National Institute on Drug Abuse, National Institutes of Health. It was launched in 2011 to inform FDA's regulatory activities under the Tobacco Control Act. The PATH Study is an ongoing longitudinal cohort study on tobacco use behavior, attitudes and beliefs, and tobacco-related health outcomes. More information can be found at: https://www.icpsr.umich.edu/web/NAHDAP/series/606.

FDA's experience with manufacturers' historical practices as well as the prohibition of characterizing flavors, other than menthol, in cigarettes (section 907(a)(1)(A) of the FD&C Act; 21 U.S.C. 387g(a)(1)(A)) is instructive for purposes of evaluating cigars' characterizing flavors and this proposed product standard. Reflective of the appeal that flavored tobacco products have for youth and young adults, internal tobacco industry documents attest to cigar manufacturers' historical practices of adding characterizing flavors to diminish the harshness of tobacco products' taste with specific intent to appeal to young consumers (Refs. 16 and 17). Tobacco industry practices reflect the fact that non-tobacco flavors appear to enhance youth appeal (Refs. 9-11). Researchers have concluded that tobacco companies have engaged in a "calculated effort to blur the line between LCCs [little cigars and cigarillos] to increase appeal to cigarette smokers, and the use of flavours facilitated these efforts" (Ref. 16).

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act; Pub. L. 111-31) prohibited, among other things, cigarettes with characterizing flavors other than tobacco or menthol. In 2009, when the Act was passed, national cross-sectional data suggested that the use of flavored cigarettes was most prevalent among younger smokers (Ref. 18), which caused concern that the availability of flavored cigarettes was contributing to youth tobacco use (Ref. 19). Additional evidence available at that time showed that younger tobacco users and nonusers had greater positive expectancies (e.g., beliefs that smoking will enhance positive affect and control weight) for flavored cigarettes compared to non-flavored cigarettes (Ref. 20), a finding that was consistent with evidence from internal industry documents showing that tobacco product manufacturers targeted flavored cigarettes toward young populations (Refs. 9, 10, and 21). Moreover, the Surgeon General has concluded that most smokers try, and become addicted to, cigarettes before adulthood (Ref. 17) and that smoking causes severe disease, disability, and death (Refs. 22 and 23).

As with cigarettes, first cigar use often occurs during youth or young adulthood (Refs. 24 and 25). In a cross-sectional analysis of data collected between 2011 and 2017 as part of a

longitudinal study, among almost 10,000 young adult college students who had ever used cigars, the mean age of first cigar use was 13.6 years (Ref. 24). A longitudinal analysis of Waves 1-4 (2013-2017) of PATH Study data found the proportion of youth who initiate cigar use increases considerably between ages 15 and 20 years (Ref. 25). Whereas only 1.5 percent of 15-year-olds in the PATH Study (2013-2017) had ever used any cigar (i.e., cigarillo, filtered cigar, or traditional cigar), by age 20, 31 percent had ever used any cigar, with the greatest increase in first use between 17 and 18 years of age (Ref. 25). Similarly, an analysis of harmonized data from five large national surveys found a consistent peak in cigar initiation among individuals aged 17-19 years (Ref. 26). The consistency of this age of initiation across all five studies increases the confidence in this finding and suggests cigar initiation extends into young adulthood (Ref. 26). A longitudinal study of Waves 1-3 (2013-2016) of PATH Study data found that 9.0 percent of youth (aged 12-17 years) and 12.0 percent of young adults (aged 18-24 years) started using cigars for the first time between Wave 1 (2013-2014) and Wave 3 (2015-2016) (Ref. 27). In comparison, 3.3 percent of adults over 25 years old initiated cigar use in the same time period (Ref. 27). Study findings also indicate racial and ethnic disparities in cigar product use. Non-Hispanic Black youth were 47 percent more likely to initiate past 30-day cigarillo or filtered cigar use at earlier ages compared to non-Hispanic White youth (Ref. 25).

We also know that a majority of youth and young adults initiate with a flavored cigar compared to older adults based on data from Wave 5 (2018-2019) of the PATH Study (Ref. 12) and that first use of flavored cigars is associated with continued use of these products (Refs. 28 and 29). In a longitudinal analysis of Waves 1-4 (2013-2017) PATH Study data, youth whose first cigar was either a mint or menthol cigar or an “other” flavored cigar (e.g., fruit, alcohol, chocolate, candy, and other flavor) were more likely to be a past-30-day cigar user at a subsequent wave (approximately 1 year later) compared to those who first used a non-flavored cigar. Similarly, young adults (aged 18-24 years) who first used a mint or menthol cigar or other

flavored cigar were more likely to be a past-30-day cigar user at a subsequent wave compared to those first using a non-flavored cigar (Ref. 29).

Similar to cigarettes with characterizing flavors, cigars with characterizing flavors expose users to the highly addictive chemical nicotine and other toxic and carcinogenic chemicals found in combusted tobacco products. Little cigars, in particular, deliver similar (and sometimes higher) levels of nicotine, as well as similar (and sometimes higher) levels of carcinogens, compared to cigarettes (Refs. 30 and 31). People who smoke cigars regularly are at increased risk for many of the same diseases as cigarette smokers, including oral, esophageal, laryngeal, and lung cancer; cardiovascular diseases; and chronic obstructive pulmonary disease (COPD) (Ref. 32).

In particular, youth and young adult exposure to the nicotine in cigars can result in negative health effects. Exposure to nicotine can disrupt brain development, which continues through approximately age 25, and may lead to long-term adverse consequences for cognitive function into adulthood (Ref. 33). Nicotine exposure in adolescence may have lasting implications and can result in decreased attention, increased impulsivity, and various lasting mental health conditions (Ref. 34). Nicotine is highly addictive. Using nicotine in adolescence may increase risk for future addiction to other drugs (Ref. 33).

FDA finds that this product standard is appropriate for the protection of the public health because it would reduce the appeal of cigars, particularly to youth and young adults, by eliminating flavorings that increase appeal, reduce the harshness and bitterness of cigars, and make them easier to smoke, thereby decreasing the likelihood that both nonusers would experiment with cigars and that current experimenters would continue to use cigars, as further discussed in sections IV.D and IV.E of this document. Furthermore, FDA finds that this product standard would decrease the likelihood that both nonusers and current experimenters would be exposed to the toxic and carcinogenic chemicals in cigars, develop nicotine dependence, and progress to regular tobacco use, as further discussed in sections IV.E and V.B of this document.

Additionally, as discussed in section VI.B of this document, the proposed product standard could improve the health of current flavored cigar smokers by increasing their likelihood of smoking cessation or reduction. The population health benefits of the proposed product standard are discussed in detail in section VI of this document. Thus, based on the information discussed in the following sections of this document, FDA finds that the proposed tobacco product standard would be appropriate for the protection of the public health.

Reducing the appeal and use of cigars by eliminating characterizing flavors (other than tobacco) also is expected to substantially decrease tobacco-related health disparities and to equitably promote health 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 capacity and infrastructure (e.g., political systems, educational institutions), access to resources (e.g., access to health services and programs), and environmental secondhand smoke exposure (Refs. 35-37). Tobacco-related health disparities affect those who have systematically experienced greater obstacles to health based on group membership due in part to the inequitable distribution of social, political, economic, and environmental resources (Refs. 37-39). Health equity is the attainment of the highest level of health for all people (Ref. 39). 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. 39-41). The advancement of health equity is integral to the reduction and elimination of tobacco-related health disparities, which affect those who have been denied opportunity and access to economic, political, and social participation. Members of underserved communities[7] experience a disproportionate burden

[7] As defined by Executive Order (E.O.) 13895, "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.

of cigar use in initiation, prevalence of use, current use, and frequency of use (see section V.A of this document), leading to observed tobacco-related health disparities within those communities. Such disparities in cigar use contribute to higher rates of observed tobacco-related morbidity and mortality among underserved communities and vulnerable populations,[8,9] such as youth and young adults, some racial and ethnic populations, those with lower household income and educational attainment, and individuals who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ+),[10] as further discussed in section V.F of this document. This proposed product standard is anticipated to promote better public health outcomes across population groups.

B. Relevant Regulatory History

In its implementation of the Tobacco Control Act over the past several years, FDA has engaged in close study and careful consideration of the scientific evidence and complex policy issues related to flavored tobacco products. FDA has issued an advance notice of proposed rulemaking (ANPRM) to solicit data and information about the roles of flavors in tobacco products, sponsored research on a variety of cigar- and flavors-related topics through contracts and interagency agreements with Federal partners, including the National Institutes of Health (NIH),[11] and undertaken its own scientific review related to the impact of characterizing flavors in cigar products. Among other things, FDA has considered the comments and information received in response to the ANPRM and scientific review in developing this proposed rule.

1. ANPRM

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[8] Throughout this document, 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.

[9] Underserved communities are overrepresented in vulnerable populations.

[10] Throughout this document, FDA uses the term "LGBTQ+" broadly when referring to lesbian, gay, bisexual, transgender, and queer (and other) communities. When we describe findings from the published literature, we refer specifically to the groups that are studied. For example, some authors examine tobacco-related outcomes for members who identify as lesbian, gay, bisexual, or transgender (LGBT) only; as such, the data are limited to those who identify as LGBT, and authors interpret the findings for those specific groups.

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

In July 2017, FDA announced a comprehensive approach to tobacco and nicotine regulation to protect youth and reduce tobacco-related disease and death (Ref. 42). 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, entitled "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. 43).

The Flavors ANPRM requested data and information about the role that flavors play in tobacco products (83 FR 12294). Specifically, the Flavors ANPRM requested comments, data, research results, or other information about, among other things, how flavors attract youth to initiate tobacco product use. While the Flavors ANPRM discussed potential product standards and a range of product types, it also specifically requested public input on the role of flavors in cigars. FDA received over 525,000 comments on the Flavors ANPRM, a large proportion of which were form letters related to 61 different organized campaigns. Five of these campaigns, which included a combined total of approximately 329,668 comments, were identified as being automatically generated "bot" comments. Some of the issues raised in the comments to the ANPRM are highlighted below.

Comments generally in support of the regulation of flavors in tobacco products stated that a product standard prohibiting the use of flavors in tobacco products would be appropriate for the protection of the public health. In particular, many comments argued that such a tobacco product standard would be appropriate for the following reasons: (1) to protect youth and young adults from becoming tobacco product users; (2) to prevent widened appeal of tobacco product use; and (3) to discourage addiction to tobacco products. FDA received many comments expressing

concern about the use of flavors to capture new users, particularly children, into lifelong nicotine addiction by making tobacco products more appealing and/or palatable. Citing internal tobacco industry documents that have since been made public, many commenters, including several public health advocacy groups, some professional associations, and multiple State attorneys general, pointed out that the industry has a long and well-established history of deliberately targeting children through the development and/or marketing of flavored tobacco products.

FDA received many comments in support of the regulation of flavors in cigar products, specifically. These comments often noted that flavors are frequently added to cigars for the express purpose of making harsh products more palatable to new users. Citing national survey data trends and various recent studies, these commenters often noted that youth and young adults report flavors as a key reason for their use of cigars, including little cigars and cigarillos (LCCs), and that a substantial percentage of youth cigar smokers exclusively use flavored cigars.

FDA also received comments from individuals and representatives from the tobacco industry generally opposing the regulation of flavored tobacco products. These comments generally stated that such regulation was not likely to decrease the appeal of such tobacco products to youth nor have positive effects for society at large. Some comments opposed to a tobacco product standard addressing flavors in cigars, specifically, stated that FDA had not presented the scientific basis for such a product standard, noting what they characterized as gaps in the scientific literature regarding usage patterns and consumer perceptions of flavored cigars, particularly among youth. Other comments from tobacco industry representatives conclude that any tobacco product standard for flavors in cigars should exclude premium cigars.

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 tobacco product standard. FDA also received comments in support of regulation suggesting that FDA define "characterizing flavor" in a way

that makes the prohibition clear to manufacturers and retailers, protects public health, and prevents manufacturers from evading the intent of the product standard.

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

2. Scientific Review

As the body of evidence continues to grow, FDA recently undertook a review of the scientific evidence regarding the role characterizing flavors play in increasing the appeal and use of tobacco products, particularly cigars, among youth, young adults, and adults in the United States. This review, entitled "Scientific Assessment of the Impact of Flavors in Cigar Products," summarizes findings from the peer-reviewed, publicly available scientific literature organized around three research questions: (1) how does the addition of characterizing flavors to tobacco products, including cigars, impact product appeal and product use; (2) how do characterizing flavors impact youth and young adult experimentation with tobacco products, including cigars, and do they make progression to regular tobacco use more likely; and (3) what impact do local and national policies restricting the sale of flavored cigars and other flavored tobacco products have on cigar sales and use? The "Scientific Assessment of the Impact of Flavors in Cigar Products" has been peer reviewed by independent external experts. Taking into consideration comments from this peer review (Ref. 44), FDA revised the scientific assessment, and the final peer-reviewed scientific assessment is available in the docket for this proposed rule (Ref. 45). This scientific assessment informed the development of this proposed product standard.

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. 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 tobacco (RYO), and smokeless tobacco to protect the public health and to reduce tobacco use by youth. The Tobacco Control Act also gave the Agency authority to conduct rulemaking to "deem" any other tobacco products subject to chapter IX of the FD&C Act. In 2016, FDA issued a final rule deeming products meeting the statutory definition of "tobacco product" (including cigars), except accessories of the newly deemed products, to be subject to chapter IX of the FD&C Act, as amended by the Tobacco Control Act (81 FR 28974) (deeming final rule).

Among the tobacco product authorities provided to FDA is the authority to adopt tobacco product standards where FDA determines that such standard is appropriate for the protection of the public health (section 907(a)(3) of the FD&C Act). 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 Characterizing Flavors in Cigars

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.

Pursuant to section 907(a)(3) and (c) of the FD&C Act, FDA is proposing this product standard that would require the elimination of characterizing flavors (other than tobacco) from cigars, because it would reduce the disease, disability, and death caused by tobacco 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) of the FD&C Act. In addition, this proposed rule would prohibit the distribution, sale, and offer for distribution or sale of cigars with characterizing flavors (other than tobacco). Because this sale and distribution restriction would assist FDA in enforcing the standard and would ensure that manufacturers and retailers are selling product that complies with the standard, 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 VI of this document.

FDA is proposing this product standard under the authorities discussed previously, along with section 701 of the FD&C Act, which provides FDA with the authority to "promulgate regulations for the efficient enforcement of this Act."

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 flavored cigars 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. Characterizing Flavors Impact Cigar Use, Particularly Among Youth and Young Adults

A. Recent Market Trends of Flavored Cigars in the United States

Congress passed the Tobacco Control Act in 2009 to address the premature death, disease, and other serious health conditions caused by tobacco use. The Tobacco Control Act gave FDA a mandate to reduce tobacco product dependence and use, particularly among youth (see section 3(2) and (9) of the Tobacco Control Act). Of particular importance for this proposed product standard, the Tobacco Control Act established a ban on characterizing flavors (other than tobacco or menthol) in cigarettes (section 907(a)(1)(A) of the FD&C Act). The legislative history of the Tobacco Control Act reflects that the goal of the Act's cigarette characterizing flavor ban was to eliminate one emerging group of tobacco products that was particularly appealing to youth (Ref. 46 at 37-38). Congress determined that banning cigarettes with characterizing flavors would benefit youth because flavored cigarettes were typically used by individuals experimenting with tobacco products, such as youth, and noted that such products were not typically used by regular adult smokers (Ref. 46 at 37-38). In 2009, FDA issued guidance on the statutory provision (see General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2), available at https://www.fda.gov/regulatory-

information/search-fda-guidance-documents/general-questions-and-answers-ban-cigarettes-contain-certain-characterizing-flavors-edition-2), noting that "flavored products make it easier for new smokers to start smoking by masking the unpleasant flavor of tobacco" and that "[r]emoving these flavored products from the market is important because it removes an avenue that young people can use to begin regular tobacco use." Research and data concerning the impact of Congress's decision to ban flavored cigarettes are instructive for purposes of evaluating cigars' characterizing flavors and this proposed product standard.

After the ban on characterizing flavors in cigarettes became effective, researchers noted that certain products previously marketed as cigarettes likely were modified or rebranded as "cigars" so that they could remain on the market in flavored varieties (e.g., Ref. 47). Little cigars are often indistinguishable from cigarettes given their shape, size, filters, and packaging (Refs. 48 and 49). An analysis of NYTS data from middle and high school students between 1999 and 2013 found that cigar use rose 34.4 percent following the ban on characterizing flavors in cigarettes (Ref. 50). The analysis found an overall decrease of 17 percent in the prevalence of youth cigarette smoking, fewer cigarettes smoked per month, and, despite the rise in cigar use, an overall reduction of 6 percent in the probability of using any type of tobacco (Ref. 50). A review of publicly available internal documents from a clove cigarette company found that the company started to develop a clove cigar product in 2007 in anticipation of the Tobacco Control Act and its ban on cigarettes with characterizing flavors, including clove-flavored cigarettes (Ref. 47). According to these documents, the goal was to be prepared for a product transition to allow for continual marketing of a clove-flavored combusted tobacco product (Ref. 47). Immediately following the prohibition on cigarette characterizing flavors, sales of clove cigars increased more than 1,400 percent between 2009 and 2012 (Ref. 47), strongly suggesting that users of clove cigarettes switched to clove cigars on the basis of flavor availability.

A similar trend in modifying or rebranding of products has been seen in several U.S. jurisdictions[12] where laws have been enacted to further restrict the sale of flavored tobacco products, including cigars. Subsequent to these restrictions on the sale of flavored tobacco products, researchers have noted the emergence of "concept" flavored named products that include ambiguous names that imply flavor but do not explicitly indicate any particular flavor on the products labeling or packaging (e.g., purple, tropical sunset) (Refs. 51 and 52). Sales of concept flavors (e.g., sweet, jazz) increased from 2.2 percent of U.S. flavored cigar sales in 2009 to 21.4 percent of U.S. flavored cigar sales in 2020, a 33 percent average annual percentage change (Ref. 53).

Flavored cigars continue to maintain a substantial share of the cigar market. Researchers analyzing Nielsen data trends found that cigar dollar and unit sales in convenience stores increased by 23 percent and 50 percent, respectively, between 2008 and 2015, and that flavored cigar dollar sales--including, for example, those with characterizing flavors such as chocolate, mint, or rum--increased by 46.5 percent (Refs. 54 and 55). A more recent study also found that flavored cigar sales increased substantially between 2009 and 2020, while non-flavored cigar sales did not change (Ref. 53). Another study analyzing trends in cigars using Nielsen data found that during January 2016 to June 2020, monthly cigarillo unit sales, which represented 94.2 percent of total cigar unit sales during the study period, increased from about 131 million to 190 million (Ref. 56). Additionally, proprietary data gathered by Euromonitor International in March 2021 reveals that, in 2020, flavored cigars, including flavored cigarillos, accounted for approximately 19.1 percent of all cigar U.S. dollar sales and 41.9 percent of all cigar unit sales, suggesting that the average price of a single unit of flavored cigar was lower than that of a single unit of tobacco-flavored cigar in 2020.

[12] For more information on U.S. localities and the implementation of flavored tobacco product restrictions, see section IV.F of this document.

Data suggest that due to both Congress's prohibition on cigarettes with characterizing flavors and the pressure placed on price-sensitive smokers (i.e., those smokers whose smoking behaviors change based on the cost of tobacco products) by increased taxation of cigarettes resulting from the 2009 Children's Health Insurance Program Reauthorization Act (Pub. L. 111-3), some price-sensitive cigarette smokers smoke cigars as a flavored, less expensive alternative to cigarettes (Ref. 57). In addition, the popularity of cigar products among young adults may be due to their lower price relative to cigarettes, lack of minimum pack size requirements, and exclusion from the advertising restrictions of the Tobacco Master Settlement Agreement (Ref. 54). Findings from a survey study indicated that affordability and flavors were the most commonly cited reasons for little cigar and cigarillo use among White and Black young adult ever users and past 30-day users (Ref. 58).

Given the current market share of flavored cigar products, research demonstrating how sales of flavored cigars increased in the years following the removal of flavored cigarettes, and how industry contributed to these shifts by marketing clove-flavored cigars nationally and introducing concept flavors, FDA is proposing to prohibit characterizing flavors (other than tobacco) in cigars to prevent youth and young adults from entering the market and progressing from experimentation to regular use of these products, and to promote cessation among existing users of these products.

B. Over Half a Million Youth, and Even More Young Adults, in the United States Use Flavored Cigars

Widespread use of flavored cigars by youth supports FDA's determination that this proposed rule would have a considerable positive impact on public health. Using NYTS 2020[13] data, researchers estimated that approximately 960,000 U.S. middle and high school students had smoked a cigar in the prior month (Ref. 7). Overall, the prevalence of cigar smoking among

[13] The 2020 NYTS is a survey that was conducted after the Federal law went into effect prohibiting sales of tobacco products to those under the age of 21 (Further Consolidated Appropriations Act, 2020, Pub. L. 116-94, section 906(d) of the FD&C Act), thus potentially capturing some of the impacts of the new law.

middle and high school students is comparable to cigarette smoking, and for non-Hispanic Black students, cigar smoking prevalence (6.5 percent) is considerably greater than cigarette smoking (2.5 percent) (Ref. 7). In 2019, not excluding use of other tobacco products, more young adults tried a cigar for the first time each day than tried a cigarette for the first time (3,163 cigar vs. 2,640 cigarette) (Ref. 59 at Table A.3A). As discussed throughout this proposed rule, evidence is well documented of broad youth and young adult use of cigars and the reasons cited for their use. In addition, local policy evaluation studies of restrictions on the sale of flavored tobacco products, including cigars, found a decrease in overall tobacco use by youth (Refs. 51 and 60-62), further supporting the conclusion that prohibiting the use of characterizing flavors (other than tobacco) in cigars is likely to result in less cigar use and less tobacco product use overall, especially among youth and young adults.

Studies indicate that a substantial percentage of youth cigar users smoke flavored cigars. Data from Wave 5 (2018-2019) of the PATH Study indicate that among youth (aged 12-17 years) 44.0 percent of past 30-day cigar smokers reported using flavored cigars (i.e., 33.9 percent of youth traditional cigar smokers, 46 percent of youth cigarillo users, and 50.2 percent of youth filtered cigar users reported past 30-day use of a flavored cigar) (Ref. 63). Data from the 2020 NYTS indicate that 58.3 percent of middle and high school students who smoke cigars (or approximately 550,000 youth), reported using a flavored cigar during the past 30 days (Ref. 8). The majority of youth cigar smokers identify the availability of cigar flavors as a leading reason for their cigar use (Refs. 64 and 65).

The data indicate a similar preference for flavors among young adults. According to Wave 5 (2018-2019) data from the PATH Study, approximately 630,000 young adults aged 18 to 24 years reported past month flavored cigar smoking (Ref. 63). An analysis of Wave 5 (2018-2019) PATH Study data indicated that among young adults (aged 18-24 years) who used cigars some or every day, 54.1 percent of traditional cigar users, 66.5 percent of cigarillo users, and 65.1 percent of filtered cigar users reported flavoring as a reason for cigar use (Ref. 12). Among

young adult past 30-day cigar smokers 18-24 years old, 38.3 percent reported that the cigar product they smoked in the past 30 days was flavored (i.e., 17.7 percent of young adult traditional cigar smokers, 46 percent of young adult cigarillo users, and 41 percent of young adult filtered cigar users reported past 30 day use of a flavored cigar) (Ref. 63). Since the brain continues development into an individual's mid-twenties, cigar use in both youth and young adulthood can harm the developing brain (Ref. 33). As discussed in section V.C of this document, nicotine can disrupt brain development and have long term consequences.

Studies illustrate some disparities in young adult flavored cigar use across population groups. Among a sample of college students aged 18-29 who used cigars in the past 30 days (n=523), Black, Asian, and Hispanic young adults were all significantly more likely to have used flavored cigars than White young adults (Ref. 66). Participants aged 18-24 years also had greater odds of using flavored cigars compared to participants aged 25-29 years (Ref. 66). Lastly, young adults who identified as lesbian, gay, or bisexual had higher odds of reporting past 30-day flavored large cigar and LCC use compared to respondents who identified as straight/heterosexual (Ref. 67).

The data also show that a substantial percentage of youth and young adult cigar users initiate with flavored cigars. Data from Wave 5 (2018-2019) of the PATH Study revealed that 60.4 percent of the youth participants (aged 12-17 years) and 63.2 percent of young adults (aged 18-24 years) who reported ever using cigars said that the first cigar they used was flavored, statistically significantly higher than the 41.9 percent of adults (aged 25 years and older) who have ever used cigars (Ref. 12).

C. Adult Use of Flavored Cigars in the United States

While the evidence is clear that youth and young adults use flavored cigars, it is important to note that older adults also use them. According to Wave 5 data (2018-2019) from the PATH Study, 36.0 percent of adult cigar smokers (adults aged 25 years and older who used cigars in the past 30 days), or over 3 million adults, reported use of a flavored cigar in one or

more of the past 30 days (Ref. 63). When considering the type of cigar, reported use of a flavored cigar in the past 30 days occurred less frequently for adult traditional cigar smokers (19.7 percent) compared with adult smokers of all other cigar types (46.5 percent for cigarillos and 48.7 percent for filtered cigars) (Refs. 63).

Many adult cigar consumers also identify the availability of characterizing flavors as a reason for their cigar use. Among adults over 25 years old who used cigars every or some days, 54.8 percent of traditional cigar users, 69.6 percent of cigarillo users, and 71.4 percent of filtered cigar users reported flavoring as a reason for cigar use (Ref. 12). Among adults, studies suggest males are more likely than females to use cigars, with some differences across cigar types (Refs. 63, 66, 68, and 69). However, among cigar users, females are more likely to use flavored cigars. For example, a study of college students aged 18-29 years who had used cigars in the past 30 days found that 60.5 percent of cigar users were male, but, among cigar users, males were statistically significantly less likely to have used flavored cigars than females (Ref. 66). Likewise, in every wave of the PATH Study, adult males were more likely to use any cigar in the past 30 days, but among past-30-day cigar users, females were statistically significantly more likely to have used flavored cigar products (Ref. 63).

Furthermore, there are differences in adult use of flavored cigars across population groups. Among adults who were past-30-day users of any cigar type, non-Hispanic Black adults were statistically significantly more likely to have used a flavored cigar in the past 30 days compared to non-Hispanic White adults at every survey wave of the PATH Study (2013-2019) (Ref. 63). Likewise, at every wave of the PATH Study, among adults aged 25 years and older who had smoked cigars in the past 30 days, individuals with a college degree were statistically significantly less likely to use a flavored cigar (20.0 percent) than individuals categorized as having less than a high school diploma (44.9 percent), a high school diploma (37.4 percent), or some college (42.9 percent) (Ref. 63). Using 2009-2010 National Adult Tobacco Survey (NATS)

data, adults who identified as lesbian, gay, bisexual, or transgender were also more likely to use flavored cigars (8.2 percent) compared to the national prevalence (2.8 percent) (Ref. 70).

This proposed rule, if finalized, could lead adult flavored cigar smokers to cease tobacco use, reduce tobacco use, or encourage them to switch to other, potentially less harmful tobacco products.

D. Characterizing Flavors Increase Appeal and Make Tobacco Products, Including Cigars, Easier to Use

Characterizing flavors increase the appeal of cigars and make them easier to use. Characterizing flavors are added to tobacco products, including cigars, for numerous reasons that relate to product appeal, such as to ensure pleasant flavor and taste; to reduce the harshness, bitterness, and astringency of tobacco during inhalation; and to soothe irritation during product use (Refs. 9-11). As documented by the Surgeon General, tobacco product manufacturers have historically added characterizing flavors to products with lower levels of free-nicotine content (i.e., those products that have lower amounts of nicotine easily absorbed by the user) intended for use as "starter products" for new tobacco users (Ref. 17).

In particular, the addition of menthol as a characterizing flavor in combusted tobacco products, including cigars, can soothe irritation and increase appeal. Menthol is a flavor compound that when added to combusted tobacco products produces a minty taste and cooling sensation when inhaled (Ref. 71). Smokers report that mentholated products have a better taste, are smoother and more refreshing (Refs. 72-74). Menthol's flavor and sensory effects reduce the harshness of smoking among new users and facilitates product use, particularly among youth and young adults (Refs. 29 and 74-76).

While much of the evidence on the role of flavors in increasing appeal focuses on cigarettes and tobacco products overall, internal industry documents also specifically discuss the role of flavors in cigars (Ref. 16). Internal tobacco industry documents illustrate cigar manufacturers' historical practices of adding characterizing flavors to diminish the harshness of

tobacco products' taste with specific intent to appeal to young consumers (Refs. 16 and 17). A review of the Truth Tobacco Industry Documents, an archive of tobacco industry documents, showed that some flavors in cigars (e.g., vanilla bean, peach, apricot, licorice, cocoa) may mask the bitterness of tobacco leaves, throat burn, and heavy taste, thereby facilitating inhalation, making smoking more tolerable for current users, and increasing palatability for new users. These documents illustrate that the effect of characterizing flavors in the appeal of other tobacco products is applicable to the effect of characterizing flavors in the appeal of cigar products. These documents also illustrate that the tobacco industry added flavors and changed some design characteristics of little cigars and cigarillos to facilitate inhalation and make smoking more tolerable for current smokers, as well as more palatable for new users, including youth (Refs. 16 and 77-79).

Flavors play an important role in attracting youth to tobacco products, including cigars (Refs. 55, 80, and 81). In survey and qualitative research, youth report that flavors in cigars are a leading reason for use. In 2018-2019 PATH Study data, 50.4 percent of youth participants (aged 12-17 years) who reported past 30-day cigar smoking identified flavors as a reason for use (Ref. 12). Results from qualitative research indicate that youth themselves acknowledge that flavorings impact their cigar use (Ref. 82). Similarly, some young adult participants mentioned that the flavors of little flavored cigars and cigarillos were particularly appealing, with one stating: "They taste basically like a strawberry. And I like the Tropical Fusion cause it's like a coconut." In a qualitative study involving focus groups of youth and young adults who used cigars (Ref. 83), the most appealing component of cigar packaging were aspects that indicated the flavor (e.g., a flavor name or image), which was identified by nearly half of all participants, and participants indicated that the words describing the flavor (e.g., "sweet") were a reason to buy the product. In a qualitative study of adolescents (aged 15-18 years) (Ref. 84), both users of tobacco products (including users of cigars/cigarillos) and nonusers indicated flavors make tobacco products appealing and are a reason to use tobacco products. Participants indicated that both the taste and

smell of flavored products were appealing (specifically mentioning minty, sweet, and fruit flavors) and noted that the smell of flavors could obscure the smell of tobacco.

Both younger and older adults similarly report flavors as a leading reason for cigar use. Among young adults (aged 18-24 years) in the PATH Study (2018-2019) who used cigars regularly and currently used cigars every or someday, 54.1 percent of current traditional cigar users, 66.5 percent of current cigarillo users, and 65.1 percent of current filtered cigar users reported flavoring as a reason for cigar use (Ref. 12). Likewise, adults aged 25 years and older report flavors as a leading reason for cigar use. Among adults aged 25 years and older in the PATH Study, 54.8 percent of current traditional cigar smokers, 69.6 percent of current cigarillo smokers, and 71.4 percent of current filtered cigar smokers reported flavoring as a reason for cigar use. There was not a statistically significant difference by age group in reporting flavors as a reason for use (Ref. 12).

Characterizing flavors increase susceptibility to use (a measure of how much individuals report being open or willing to use a tobacco product) in nonsmoking young adults, as documented in a 2020 study that tested cigarillo pack images containing the most popular characterizing flavors. Susceptibility to cigarillo use was statistically significantly greater among participants exposed to the packs with characterizing flavors (Ref. 85). Results from focus groups and semistructured interviews with 90 young adult past 30-day LCC-only, cigarette-only, and dual cigarette and LCC smokers provide insight about the appeal of characterizing flavors in certain cigars to youth and young adults (Ref. 82). Among study participants, the average age of initiation of LCC was 16.1 years, and nearly two-thirds of the participants reported first using an LCC that was flavored (Ref. 82). Participants frequently reported that smoking flavored LCCs relieved stress and that flavored LCC use sometimes depended on mood and was associated with boosted mood and gratification (Ref. 82). Participants frequently mentioned that flavored tobacco made smoking LCCs more palatable than smoking unflavored (or regular flavor) cigars (Ref. 82). For many participants, seeing or hearing the phrase “little cigars or cigarillos” evoked

thoughts about their favorite flavors (Ref. 82). In addition, for many participants, peers played an important role in continued experimentation because friends would often suggest flavors to one another (Ref. 82). Moreover, many participants stated that the appeal of the variety of available flavored LCCs on the market influenced their decision to try LCCs (Ref. 82). These studies indicate that flavors are an important factor in initiation and use of cigars among young adults.

Four systematic reviews of the scientific literature concluded that flavored tobacco products attract youth to the tobacco product (Refs. 86-89). Two of the systematic reviews included cigars and assessed studies on use and attitudes related to non-menthol flavored tobacco products (Refs. 88 and 89). The two reviews concluded that characterizing flavors were an appealing feature of tobacco products and that flavors influence perceptions, initiation, and progression to use of tobacco products, particularly among youth (Refs. 88 and 89).

The appeal of flavors in tobacco products, including cigars, is not only consistent across the literature on tobacco products, but is also consistent with the food literature. Physiologically, scientists have described how youth have a heightened preference for sweet food tastes and greater rejection of bitter food tastes; these preferences diminish with age (Refs. 90-93).

An FDA-funded scientific review of 474 articles published between 1931 and 2015 conducted to understand how youth and adults differ with respect to their preferences for characterizing flavors, primarily in food, concluded that preference for sweetness and saltiness is generally higher for children than it is for adults; and the level of sugar selected as most preferred in clinical experiments decreased between adolescence and adulthood (Ref. 94). The researchers hypothesized that the higher caloric needs of youth to sustain growth likely account for the more pronounced preference for sweetness in youth (Ref. 94).

Laboratory research has confirmed that the chemical-specific flavor sensory cues associated with fruit flavors in tobacco products are often the same as those found in popular candies (Refs. 95 and 96). While inhaling flavored chemicals is in many ways very different than ingesting flavored foods, researchers reviewed the levels of flavor chemicals in several brands of

candy and Kool-Aid drink mix and concluded that the chemical amounts and combinations largely overlapped with similarly labeled "cherry," "grape," "apple," "peach," and "berry" cigar and other tobacco products (Refs. 95 and 96).

Overall, FDA finds that evidence regarding the role of flavors in increasing appeal of cigars to youth and young adults, promoting progression to regular use, and increasing the addiction potential indicates that removing flavors from cigars would reduce initiation and use of such products, especially among youth and young adults. As a majority of adult regular tobacco users become dependent on or addicted to nicotine as youth and young adults, reducing initiation and use of cigar products in youth would reduce the likelihood that youth progress to nicotine dependence and regular use, as well as subsequent tobacco-related illness and death. Therefore, FDA anticipates that removing flavors from cigars would substantially reduce tobacco-related disease and death as a result of averted youth initiation.

E. Characterizing Flavors Increase Youth and Young Adult Experimentation with Tobacco Products, Including Cigars, and Make Progression to Regular Tobacco Use More Likely

Cigars are more commonly used among youth and young adults relative to other combusted tobacco products, including cigarettes. An analysis of PATH Study data found that new cigar use (i.e., initiation since a prior wave of data collection) at Waves 2, 3, or 4 (2014-2017) was more common (14.5 percent youth, 19.7 percent young adults, 6.3 percent adults aged 25 and older) relative to new cigarette use (i.e., initiation since a prior wave) (14.0 percent youth, 7.1 percent young adults, 1.1 percent adults aged 25 and older) (Ref. 29). Data from the 2019 National Survey on Drug Use and Health (NSDUH) found that each day 1,210 youth 12-17 years and 3,163 young adults aged 18 to 25 years tried a cigar for the first time (Ref. 59 at Table A.3A). In 2019, prevalence of past 30-day cigar use surpassed that of past 30-day cigarette use among U.S. high school students for the first time (Ref. 97). Flavors make tobacco products, including cigars, easier to use and reinforce tobacco use among youth and young adults. FDA

finds that eliminating characterizing flavors (other than tobacco) in cigars would decrease the number of first-time users of cigars who progress to regular use.

The process of becoming a regular cigar smoker includes stages of experimentation, development of nicotine dependence, and progression to regular use (Refs. 98 and 99). FDA finds that eliminating flavored cigar varieties would decrease the number of youth experimenting and the likelihood that youth will progress to regular, sustained use of tobacco products, and, thus, would reduce the risk of tobacco-related death and disease.

Experimentation with cigars can lead to nicotine dependence and regular use in less than one year. Longitudinal data from the nationally representative Truth Longitudinal Cohort (2014-2019) were used to examine the progression from cigar initiation to regular use among youth and young adults aged 15 to 25 years (Ref. 100). Nearly half (44.7 percent) of participants who initiated cigar use reported current (i.e., past-30-day) cigar use 6 months after initiation (Ref. 100). Compared to participants who did not become past-30-day users 6 months after initiation, those who were past-30-day users engaged in a higher frequency of cigar use during the initial 6-month period, were younger, non-Hispanic African American, and were more likely to use other tobacco products. For example, non-Hispanic African American participants (relative to non-Hispanic White participants) had over twice the odds of past-30-day cigar use and had a higher average frequency of use (2.21 days/month vs. 1.34 days/month, respectively) 6 months after initiation of cigar use (Ref. 100).

Experimentation with flavored cigar use is associated with subsequent use. Another study used longitudinal data from Waves 1 (2013-2014) and 2 (2014-2015) of the PATH Study to assess whether there is a prospective association between first flavored use of a tobacco product and subsequent use of that specific product (Ref. 28). This analysis found that first use of any flavored cigar or first use of flavored cigarillos and filtered cigars (including menthol) at Wave 1 (2013-2014) of the nationally representative PATH Study was subsequently associated with

daily or nondaily use of these products in young adults (aged 18-24 years) and adults (aged 25 years and older) 1 year later (2014-2015) compared with first non-flavored use (Ref. 28).

Studies have shown that menthol's flavor and sensory effects reduce the harshness of smoking among new users and facilitate experimentation and progression to regular smoking of menthol products, particularly among youth and young adults (Refs. 29 and 74-76). A subsequent analysis using Waves 1-4 (2013-2017) of PATH Study data assessed the relationship between new use of a menthol/mint-flavored or other flavored (e.g., fruit, alcohol, chocolate, candy, and other flavor) cigar at Wave 2 or 3 with cigar use at a subsequent wave (Wave 3 or 4) compared to first use of a non-flavored cigar (Ref. 29). The analysis found that among youth (aged 12-17 years) and young adults (aged 18-24 years), first use of any menthol/mint-flavored or other flavored cigar (e.g., fruit, alcohol, chocolate, candy, and other flavor) was associated with greater odds of past 30-day use of these products at the subsequent wave compared with first use of a non-flavored (i.e., tobacco) cigar, even after controlling for sociodemographic variables (Ref. 29). Youth who first used a menthol/mint-flavored cigar or other flavored cigar were 72 percent (menthol/mint) and 47 percent (other flavor) more likely to be past-30-day cigar users at a subsequent wave (1 or more years later) compared to those first using a non-flavored cigar. Similarly, young adults (aged 18-24 years) who first used a menthol/mint-flavored cigar or other flavored cigar were 71 percent and 52 percent more likely to be past-30-day cigar users at a subsequent wave compared to those first using a non-flavored cigar (Ref. 29). For both youth and young adults, the association between the first flavor used and subsequent cigar use was not statistically significantly different for menthol/mint-flavored compared to other flavored cigars. Among adults (25 years and older), first use of an "other" flavored cigar (e.g., fruit, alcohol, chocolate, candy, and other flavor) was also associated with higher likelihood of subsequent past 30-day cigar use (Ref. 29). Overall, this study extends findings from the Wave 1 (2013-2014) to Wave 2 (2014-2015) PATH Study analysis (Ref. 28) finding that among youth and young adults newly using cigars, first use of any menthol/mint-flavored cigar or other flavored cigar is

associated with greater continued use of these products at the subsequent wave compared with first use of non-flavored cigars (Ref. 29).

Several studies examining nicotine dependence found that smoking cigars fosters addiction by reducing cravings and the urge to smoke to a similar magnitude as cigarettes (Refs. 101-103). Cigars, like cigarettes, have also been shown to decrease acute nicotine withdrawal symptoms (e.g., craving, anxiousness) (Ref. 104). Available scientific data on nicotine's addictiveness demonstrate that the adolescent brain is more vulnerable to developing nicotine dependence than the adult brain (Ref. 17). Exposure to substances such as nicotine can disrupt brain development and may lead to long-term consequences for cognitive function (Refs. 105 and 106). Exposure to nicotine from cigarette smoking in adolescence is associated with changes in the brain that could increase the likelihood for addiction and dependence as adults (Ref. 34). Furthermore, nicotine exposure in adolescence may have lasting effects; it has been associated with decreased attention, increased impulsivity, and various lasting mental health conditions in adult smokers (Ref. 34). While research is not yet able to fully disentangle whether the association of nicotine with changes in attention and impulsivity are primarily a result of nicotine exposure or partially due to pre-existing vulnerability to changes in attention and impulsivity (Ref. 34), considerable research shows that exposure to nicotine in adolescence causes long-term changes in the brain, with implications for nicotine dependence, attention, and impulsivity, as well as other areas of cognitive function and substance use (Refs. 17 and 34). Researchers analyzing data from the 2017-2018 NYTS found that 43.1 percent of middle and high school students using cigars in the past 30 days reported nicotine dependence, including feeling a strong craving to use a tobacco product or using a tobacco product within 30 minutes of waking (Ref. 107). An analysis of Waves 1-4 (2013-2017) PATH data did not find a longitudinal association between first use of a menthol- or mint-flavored cigar and nicotine dependence scores (Ref. 29). Similarly, a cross-sectional analysis of 2017-2018 NYTS data found that exclusive use of cigars was associated with lower odds of reporting dependence compared to exclusive use of another

product (Ref. 107). However, frequent cigar use (use on 20 or more days in the past 30 days) as well as current cigar use including both exclusive and polyuse of cigars was associated with increased odds of youth reporting nicotine dependence (Ref. 107). In this analysis, use of cigars in combination with other tobacco products was common: 76.1 percent of youth past 30-day cigar users used cigars in combination with one or two additional tobacco products (Ref. 107). Given the role of frequent use and polyuse in the relationship between cigar use among youth and dependence, the authors noted "the importance of examining behaviors related to use, as they can affect and/or exacerbate the risk of nicotine dependence" (Ref. 107).

Given that nicotine is highly addictive and present in all cigars, as youth experimenters continue to use these products, there is a risk of nicotine dependence and progression to regular use, resulting in an increased risk of developing the many negative health consequences associated with regular cigar use. Based on the totality of the evidence, prohibiting characterizing flavors (other than tobacco) in cigars would reduce the appeal and ease of use of such products and is an important step toward reducing the likelihood of nicotine dependence, experimentation, and progression to regular use.

F. Real-World Experiences Demonstrate that Restricting Characterizing Flavors in Tobacco Products, Including Cigars, Decreases Tobacco Use

As previously discussed in section IV.A of this document, Congress passed the Tobacco Control Act in 2009 to address the premature death, disease, and other serious health conditions caused by tobacco use. To address the appeal and use of flavored combusted tobacco products among the Nation's youth, in 2009, the Tobacco Control Act prohibited cigarettes with characterizing flavors other than tobacco or menthol. Researchers analyzed repeated cross-sectional data from the NYTS and concluded that the ban was associated with a 17 percent reduction in the probability of being a cigarette smoker and a 6 percent reduction in the probability of any tobacco use (i.e., cigarette, cigars, smokeless tobacco, or pipe tobacco) in the past 30 days among U.S. middle and high school students (Ref. 50). While cigarette smoking

decreased among the Nation's youth following implementation of the Tobacco Control Act, researchers noted that youth use of cigars and pipe tobacco, which remained available in flavored varieties, rose after implementation of the ban on characterizing flavors in cigarettes (Ref. 50).

While the prior analysis (Ref. 50) was limited in its ability to attribute changes in tobacco use, particularly flavored use, directly to the Federal restriction (as the NYTS was not designed to evaluate such a policy), recent evaluation studies implementing pre-post study designs with geographic comparisons provide real-world examples of how tobacco product use changes as a result of a sales restriction on characterizing flavors in tobacco products, including cigars. Such recent evaluations of restrictions on the sale of tobacco products with characterizing flavors in U.S. localities include studies of New York, NY (NYC); Providence, RI; Lowell, MA; Attleboro and Salem, MA; San Francisco, CA; Minneapolis and St. Paul, MN (Twin Cities); as well as Canada (See table 1, below, summarizing the evaluation studies). Taken in totality, the real-world experience of state and local jurisdictions implementing sales restrictions on flavored tobacco products provide insight into the likely responses of youth and young adults as well as current cigar smokers to a proposed product standard restricting characterizing flavors (other than tobacco) in cigar products, including decreases in youth cigar use and cigar consumption among current cigar smokers.

Table 1.--Summary of Evaluation Studies on Sales Restrictions including Flavored Cigars

Jurisd-iction	Policy[1]	Effective or Enforcement Year	Retailer Exemptions	Study Design & Reference	Sample Size	Key Outcome Measures[2] and Findings
NYC, NY	Restriction includes all flavored products except menthol-, mint-, and wintergreen-flavored products. In 2020, restriction was expanded to include flavored Electronic Nicotine Delivery Systems (ENDS) products, including menthol-, mint-, and wintergreen-flavored ENDS products.	2010	Tobacco bars with ≥10% gross income from tobacco sales	Pre/Post Design (Ref. 51)	Youth Tobacco Use: n=1708 (2010); n=8814 (2013)	*Sales*: Flavored cigars dollar sales declined. Cigar dollar sales of non-flavored cigars increased. *Youth (aged 13-17 years) Tobacco Use*: Youth had lower odds of ever trying a flavored tobacco product and of ever using tobacco products.
				Pre/Post Design with	N/A	*Sales*: Overall cigar unit sales declined. Flavored cigar unit

Jurisd-iction	Policy[1]	Effective or Enforcement Year	Retailer Exemptions	Study Design & Reference	Sample Size	Key Outcome Measures[2] and Findings
				Comparison (Ref. 108)		sales declined. Flavored cigar unit sales increased in comparison counties.
Providence, RI	Restriction includes all flavored products except menthol, mint, and wintergreen flavors.	2013	All smoking bars	Pre/Post Design with Comparison (Ref. 109)	N/A	*Sales*: Decrease in flavored cigar unit sales. Decreases in overall cigar unit sales. Flavored cigar unit sales increased in the rest of the State.
				Post-only Design (Ref. 60)	n=2,150 (2012); n=2,062 (2016); n=2,223 (2018)	*Youth (10th and 12th grade students) Tobacco Use*: Youth current use of any tobacco product declined. *Youth (10th and 12th grade students) Cigar Use*: Youth current use of cigars/cigarillos declined.
Lowell, MA	Restriction includes all flavored products (except menthol, mint, or wintergreen).	2016	Adult-only (21+ years old) retail tobacco stores with ≥90% of sales from tobacco products	Post-only Design with Comparison (Ref. 61)	Lowell: baseline n=593; follow-up n=524 Malden (comparison community): baseline n=636; follow up n=646	*Youth (9th-12th grade students) Flavored Tobacco Use*: Youth current use of any flavored tobacco products decreased in Lowell and increased in the comparison community, a statistically significant difference. *Youth (9th-12th grade students) Non-Flavored Tobacco Use*: Youth current use of any non-flavored tobacco products also decreased in Lowell and increased in the comparison community, a statistically significant difference.
Attleboro & Salem, MA	Restriction includes all flavored products (except menthol, mint, or wintergreen)	2016 (Attleboro) 2017 (Salem)	Adult-only (21+ years old) retail tobacco stores with ≥90% of sales from tobacco products All smoking bars	Pre/Post Design with Comparison (Ref. 110)	Attleboro: baseline n=1413; follow up n=1565 Salem: baseline n=480; follow up n=620	*Youth (9th-12th grade students) Flavored Tobacco Use:* Statistically significantly smaller increases in current use of flavored in Attleboro and Salem than in the comparison municipality.

Jurisd-iction	Policy[1]	Effective or Enforcement Year	Retailer Exemptions	Study Design & Reference	Sample Size	Key Outcome Measures[2] and Findings
					Gloucester (comparison municipality): baseline n=539; follow up n=629	*Youth (9th-12th grade students) Non-Flavored Tobacco Use:* Significantly smaller increases in current use of non-flavored or menthol tobacco in Attleboro and Salem than in the comparison municipality.
Twin Cities, MN	Restriction includes all flavored products (except menthol, mint, or wintergreen).	2016	Minneapolis: Adult-only (18 years and older) licensed tobacco product shops with ≥90% revenue from sale of tobacco St. Paul: Adult-only (18 years and older) retail stores with ≥90% revenue from sale of tobacco	Pre/Post Design with Comparison (Ref. 111)	Minnesota Youth Tobacco Survey: more than 4,000 students participated in the 2017 survey statewide	*Youth (6th-12th grade students) Cigar Use*: Before and after the 2016 restriction on flavored tobacco products (except menthol, mint, and wintergreen), cigar use did not change in the Twin Cities but increased in the rest of the State.
	Restriction expanded to include menthol, mint, and wintergreen in 2018.	2018	Minneapolis: Sales of mint-, menthol-, and wintergreen-flavored tobacco products at adult only (21 years and older) liquor stores St. Paul: Sales of mint-, menthol-, and wintergreen-flavored tobacco products at liquor stores that also hold a license for tobacco sales	Pre/Post Design with Comparison (Ref. 111)	Minnesota Student Survey (8th, 9th, 11th grade students): more than 170,000 participating students in 2019	*Youth (8th, 9th, 11th grade students) Cigar Use*: Before and after the 2018 restriction on flavored tobacco products, including menthol, mint, and wintergreen, cigar use declined more in the Twin Cities compared to the rest of the State.
San Francisco, CA	Restriction includes all flavored products (including menthol)	2019	None	Post-only Design (Ref. 62)	n=247	*Young Adult (aged 18-24 years) Cigar Use*: Statistically significant decrease in flavored cigar use. Decrease in overall cigar use, but the decline was not statistically significant.

Jurisd-iction	Policy[1]	Effective or Enforcement Year	Retailer Exemptions	Study Design & Reference	Sample Size	Key Outcome Measures[2] and Findings
						Young Adult (aged 25-34 years) Cigar Use: Decreases in overall cigar use and flavored cigar use, but the declines were not statistically significant.
				Pre/Post Design with Comparison (Ref. 52)	N/A	*Sales*: Statistically significant decreases in overall tobacco and flavored tobacco unit sales. Statistically significant decreases in overall cigar and flavored cigar unit sales. The comparison cities had more modest decreases or no statistically significant change.
Canada	Restriction includes flavored little cigars/cigarillos (except menthol); unflavored cigarillos minimum packs of 20	2010	None	Pre/Post Design (Ref. 112)	N/A	*Sales*: Decreases in overall cigar and flavored cigar units sold. Increase in unflavored cigar units sold.
				Pre/Post Design (Ref. 113)	Over 46,000 observations	*Youth (aged 15-24 years) Cigarillo Use*: Decreases in past 30-day cigarillo use.

[1]Tobacco products covered under flavored tobacco restrictions differed across jurisdictions, particularly in regard to menthol status and inclusion of ENDS.
[2]Outcome measures differed across studies, with some focused specifically on sales data, whereas others measured tobacco use (cigar specific and/or all tobacco use), across differing age groups.

In November 2010, NYC began enforcing a restriction on sales of 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 on total cigar sales of NYC's flavor restriction found a considerable reduction in overall sales, a proxy for overall consumption, after controlling for temporal trends in sales and the potential for purchases across the city border (Ref. 108). This evaluation used retail scanner data to assess changes in total cigar units sold before and after the NYC flavor restriction went into effect. For comparison, the analysis also examined sales in nine counties in New York and New Jersey proximal to NYC, as well as sales in the United States overall, over the same timeframe. In NYC, sales of all flavored tobacco products combined declined 27.1 percent, and sales of

flavored cigars declined 22.3 percent at policy implementation. The NYC flavor restriction was associated with a statistically significant 11.6 percent decrease in total cigar sales in NYC immediately following policy implementation, while cigar sales in the comparison area and nationally did not statistically significantly change. The decrease in overall cigar sales observed in NYC suggests that consumers did not completely substitute non-flavored cigars for flavored cigars because of the restriction (Ref. 108). This study showed that the concurrent decrease in unit sales of flavored tobacco products and flavored cigars observed in NYC was not offset by an increase in non-flavored cigars or tobacco products not included in the restriction. Furthermore, these findings were similar to results from an earlier analysis of the NYC policy that used more limited data (Ref. 51). This more limited study analyzed data from stores with overall sales of at least $2 million per year in NYC and found that the restriction was associated with an 86 percent decrease in flavored cigar dollar sales and only a 5 percent increase in unflavored cigar dollar sales (Ref. 51).

An evaluation of the impact of the NYC flavored tobacco restriction on youth tobacco 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 went into effect compared to youth in 2010. Similarly, in 2013, youth had 28 percent lower odds of ever using any tobacco product compared to youth before the policy went into effect (Ref. 51), suggesting that the decreases in overall sales and consumption of flavored tobacco products, including cigars, was also reflected in declines in youth tobacco experimentation. This study illustrated that youth tobacco use declined following the NYC sales restriction.

Providence, RI, implemented a sales restriction on tobacco products with characterizing flavors other than menthol, mint, or wintergreen in January 2013 (Ref. 109). An evaluation in Providence, similar to the analysis in NYC, used retail scanner data to assess changes in total cigar units (both flavored and not flavored, including menthol, mint, and wintergreen flavors) sold before and after the Providence flavor restriction went into effect (Ref. 109). For

comparison, the analysis also examined sales over the same time period in the rest of Rhode Island (Ref. 109). Sale of explicit flavor-named cigars (e.g., “cherry”) in Providence declined 93 percent, while “concept” flavor-named cigars (e.g., “jazz”) increased 74 percent after policy implementation compared to before policy implementation. Despite the increase in “concept” flavor-named cigar sales, flavored cigar sales decreased overall, suggesting that “concept” flavor-named cigar consumption did not entirely replace explicit flavored-named cigar consumption after the policy. The analysis found that average weekly sales of all flavored cigars decreased 51 percent following policy implementation in Providence compared to before policy implementation and increased 10 percent across the rest of the state during the same time period (Ref. 109). Average weekly sales of all cigars decreased 31 percent following policy implementation in Providence and decreased 6 percent across the rest of the state during the same time period (Ref. 109). This study illustrated that flavored cigar use decreased following policy implementation alongside an increase in sales in the rest of the state. While concept-flavored cigar sales increased in Providence and the rest of the State, the overall decline in flavored sales suggests that flavored cigar use was only partially offset by an increase in concept-flavored use.

Another evaluation of the Providence restrictions examined youth tobacco use including cigar use through a school-based survey of over 2,000 10th and 12th grade students at two time points after Providence’s sales restriction was in effect: 2016 (3 years post-restriction) and 2018 (5 years post-restriction) (Ref. 60). This analysis found that youth current use of any tobacco product declined, from 22.2 percent in 2016 to 12.1 percent in 2018; and current use of cigars/cigarillos declined from 7.1 percent in 2016 to 1.9 percent in 2018 (Ref. 60). This study illustrates a decline in youth cigar use after increased enforcement of the policy in Providence, which is consistent with the analysis of sales data in Providence (Ref. 109).

Lowell, MA, enacted a restriction on flavored tobacco except for menthol-, mint-, or wintergreen-flavored tobacco products in October 2016. One study assessed short-term (6-

month) impact of the Lowell, MA, sales restriction on youth use of flavored tobacco using pre-post design with a comparison community (Malden, MA). The comparison community of Malden, MA, did not have a sales restriction and was similar to Lowell, MA, in demographics, retailer characteristics, and other point-of-sale policies (Ref. 61). The analysis evaluated youth use of flavored tobacco products in Lowell and Malden at baseline (November 2016-January 2017 in Lowell; September 2016 in Malden) and followup approximately 6 months later (May 2017 in Lowell; April 2017 in Malden). Youth current use of any flavored tobacco products decreased 2.4 percent in Lowell from baseline to followup periods and increased 3.1 percent in the comparison community without a sales restriction (Malden, MA) for a statistically significant estimated difference of -5.7 percent between the communities (Ref. 61). When considering the change in specific product use, ever use of flavored cigars and current use of flavored cigars decreased in Lowell and increased in the comparison community, although the changes were not statistically significant. In general, there were no statistically significant changes in youth use by specific tobacco products in Lowell, in the comparison city, or in the difference estimate between the communities when the models were adjusted for age, gender, and race and ethnicity (Ref. 61). Youth current use of any non-flavored tobacco products also 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. 61). This study showed that youth use of flavored tobacco products declined potentially in response to a sales restriction in a Massachusetts community compared to a similar community without a sales restriction.

Another study evaluated the impact of flavored tobacco sales restrictions (excluding menthol, mint, and wintergreen) in Attleboro and Salem, MA, on tobacco use among high school students (Ref. 110). While youth tobacco use increased from baseline to followup in Attleboro and Salem and in the comparison municipality of Gloucester, MA, the increases in flavored tobacco use and non-flavored, mint, or menthol tobacco use were statistically significantly

smaller in Attleboro and Salem than the comparison municipality, suggesting that the policy mitigated increases in tobacco use (Ref. 110). This study found that youth tobacco use increased at a lower rate within the two municipalities covered by sales restrictions compared to the municipality without a restriction. Therefore, the study findings suggest that the flavored tobacco restriction may have prevented increases in tobacco use.

In 2016, Minneapolis and St. Paul, Minnesota, commonly referred to as the Twin Cities, also implemented sales restrictions that included all flavored tobacco products, including ENDS but excluded menthol, mint, and wintergreen flavors. These sales restrictions exempted adult-only (18 years and older) licensed tobacco product shops with at least 90 percent or greater revenue from sales of tobacco in Minneapolis and adult-only (18 years and older) retail stores with at least 90 percent or greater revenue from sales of tobacco in St. Paul. In 2018, the Twin Cities expanded the restrictions to include mint-, menthol-, and wintergreen-flavored tobacco products. However, sales of mint-, menthol-, and wintergreen-flavored tobacco products were permitted in adult-only (aged 21 years and older) liquor stores in Minneapolis and liquor stores that also hold a license for tobacco sales in St. Paul. An analysis of the Minnesota restrictions examined youth tobacco use prevalence in the seven-county Twin Cities metropolitan area, including Minneapolis and St. Paul, and compared it to the rest of the State of Minnesota using data from two cross-sectional surveys: the Minnesota Youth Tobacco Survey (MYTS) and the Minnesota Student Survey (MSS) (Ref. 111). The analysis used MYTS data from students in grades 6-12 to estimate tobacco use before (2014) and after (2017) the Twin Cities implemented flavor policies in 2016 that included all tobacco products but excluded menthol, mint, and wintergreen flavors. The analysis used MSS data from students in grades 8, 9, and 11 to assess changes in tobacco use before (2016) and after (2019) when the flavor restrictions were expanded to include mint, menthol, and wintergreen flavors. Using the MYTS data to assess youth tobacco use while the 2016 flavor restriction (excluding menthol, mint, and wintergreen) was in effect, the prevalence of tobacco product use overall and cigar use did not change in the

Twin Cities among 6-12th graders; however, e-cigarette use increased 34.1 percent. In contrast, tobacco use prevalence overall, cigar use, and e-cigarette use increased at greater rates in the rest of the state (+26.6 percent, +71.3 percent, and +114 percent, respectively). Using the MSS data to assess youth tobacco use after the 2019 flavor restriction (including menthol, mint, and wintergreen) was implemented, tobacco use and e-cigarette use among students in grades 8, 9, and 11 increased in the Twin Cities; however, the increase was smaller than the rest of the state (34.6 percent vs. 44.6 percent tobacco use increase; 49.5 percent vs. 88.9 percent e-cigarette increase). Cigar use declined more in the Twin Cities compared to the rest of the state (-42.4 percent and -23.7 percent, respectively). Cigarette use decreased more in the Twin Cities relative to the rest of the State (-40.5 percent and -22.6 percent, respectively). Use of any menthol or mint tobacco product decreased in both areas (-5.9 percent Twin Cities and -15.7 percent rest of state), and use of non-cigarette tobacco products (e.g., cigars, smokeless tobacco, e-cigarettes, hookah) with flavors other than mint or menthol increased in both areas (+5 percent Twin Cities and +10.2 percent rest of state) (Ref. 111).

Given the differences in survey items, timing of data collection, and that the MYTS and MSS data included all seven counties of the Twin Cities metropolitan area, including some counties not implementing flavor restrictions, the observed prevalence changes may reflect contextual factors beyond the restrictions in the cities of Minneapolis and St. Paul. For example, the 2019 MSS data collection was shortly after the policies including mint, menthol, and wintergreen went into effect; therefore, the study may underestimate the effect of the policy on youth behavior change. However, the study observed stable and decreasing cigar use among youth across the surveys in the Twin Cities relative to the rest of the state, which suggests the sales restriction slowed youth cigar use.

In 2018, San Francisco, CA, enacted restrictions on flavored tobacco products. Changes following the 2018 San Francisco restriction on all flavored (including menthol) tobacco product sales were evaluated and compared with sales in two California comparison cities without such

sales restrictions: San Jose and San Diego (Ref. 52). The analysis used Nielsen retail scanner sales data to estimate within-city changes in average weekly unit sales of tobacco products for San Francisco and comparison cities for three time periods: pre-policy (June 2015-July 2018; pre-policy); policy enactment (July 2018-January 2019) and policy enforcement (January 2019-December 2019).[14] Sales of flavored tobacco products overall and of flavored cigars specifically decreased a statistically significant 96 percent from the pre-policy period through the enforcement period in San Francisco (Ref. 52). In the comparison cities, average weekly sales of flavored tobacco products either decreased more modestly, yet still statistically significantly (e.g., 10 percent for all flavored products and 13 percent for flavored cigars in San Diego), or did not have a statistically significant change from pre-policy to policy enforcement, with the exception of flavored ENDS (which statistically significantly increased by 195 percent in San Jose and 118 percent in San Diego) and flavored smokeless tobacco (which statistically significantly increased by 3 percent in San Diego). Predicted average weekly total cigar sales decreased by 51 percent in San Francisco from pre-policy to policy enforcement, suggesting that there was not complete substitution of flavored cigars for non-flavored cigars (Ref. 52). This study observed a decline in overall tobacco product sales and flavored tobacco product sales, suggesting that there was not complete substitution of tobacco or non-flavored products for flavored products following the flavor restriction in San Francisco.

Another study evaluated the impact of the San Francisco restriction on all flavored (including menthol) tobacco products on use of cigars among a small convenience sample (n=247) of young adults aged 18-34 years who used tobacco products prior to the restriction (Ref. 62). After implementation of the flavor restriction in San Francisco, among young adults aged 18-24 years, there was a statistically significant decrease in use of flavored cigars (from 19.4 percent to 6.5 percent) and decrease in cigar use overall that was not statistically significant

[14] Although enforcement of this policy was slated to begin in January 2019, compliance inspections with penalties did not commence until April 2019.

(Ref. 62). There were decreases in the prevalence of cigar use overall and use of flavored cigars among 25-34-year-old respondents, but the declines were not statistically significant. Among the 25-34 age group, there was a statistically significant decrease in flavored e-cigarette use (from 56.2 percent to 48.1 percent) and dual use of e-cigarettes with cigars (from 14.1 percent to 9.7 percent). This study showed among young adults, flavored cigar use may have declined following the San Francisco sales restriction, and the decrease was not offset by an increase in non-flavored cigar use.

One study of San Francisco's flavored tobacco policy using 2019 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. 114). 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. 115). As noted above, 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. 52).

In addition to the local U.S. jurisdictions discussed previously, a study of local level restrictions across Massachusetts from 2011-2017 found that counties with 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 high school students smoked cigarettes in the past 30 days and a decrease in the likelihood of their e-cigarette use (Ref. 116). This study illustrates the potential for flavor restrictions to reduce youth tobacco use.

Evaluations of a national flavored tobacco policy in Canada reinforce trends observed in jurisdictions that enacted flavored tobacco policies in the United States, including a decrease in cigar sales and a decrease in use of cigars among young people. In 2009, the government of Canada prohibited the use of characterizing flavors (excluding menthol) in cigarettes and cigars

under 1.4 grams, or in any cigar that had a filter or non-spiral wrap. Using wholesale sales volumes, one evaluation examined trends in sales of flavored cigars during the 2004-2016 period, with equal periods of 6 years before and 6 years after enactment of the 2009 restriction (Ref. 112). The analysis found that overall cigar sales decreased 49.6 million units and sales of flavored cigars decreased 59 million units in the quarter immediately following policy enactment (i.e., first quarter of 2010). Sales of cigars with no flavor descriptors increased 9.6 million units in the quarter immediately after policy implementation (Ref. 112). Another evaluation assessed the impact of Canada's 2010 ban on the sale of flavored cigarillos (Ref. 113). This evaluation analyzed data from the 2007 to 2011 Canadian Tobacco Use Monitoring Survey and found that the policy was associated with a statistically significant 2.3 percentage point decrease in past 30-day cigarillo use and a statistically significant 4.3 percentage point increase in past 30-day abstinence, defined as no cigar use in the prior 30 days among previous cigarillo users among young people aged 15 to 24 years. Cigarillo use declined in the older age group, 25 to 65 years, but the decline was not statistically significant. The study noted that there was some evidence of a small increase in use of cigars other than cigarillos or little cigars that were not included in the policy, and the analysis did not distinguish flavored cigarillo from unflavored cigarillos (Ref. 113).

Taken in totality, these studies of the impact of real-world restrictions on flavored tobacco products provide insight into the likely responses of youth and young adults as well as current cigar smokers to the proposed standard, including decreases in youth and adult cigar use. However, we acknowledge there are limitations to the application of these findings. One limitation includes the timing of data collection on cigar use. Some of the evaluation studies rely on data collection only after the policy with retrospective recall of cigar use prior to policy implementation. Furthermore, the duration of followup time varied between studies, and those with shorter followup times (e.g., Refs. 61 and 62) may have underestimated the impact on cigar use. Limitations also include that some studies rely on aggregate tobacco sales information as a

proxy for consumption, rather than data concerning individual-level tobacco use behaviors. Certain analyses used cigar sales as a proxy for consumption, given that sales and consumption tend to be highly correlated (Refs. 117-119). Furthermore, a number of noted studies used state or nationally representative surveys of youth and young adults to assess differences in tobacco use before and after policy implementation. Some of these studies were able to assess changes in cigar use specifically, while others assessed changes in overall tobacco use or flavored tobacco use more broadly. Lastly, smokers may have obtained flavored cigars through alternate means (e.g., internet sales) that would not have been captured in sales data in these studies, or smokers may have switched to tobacco products not subject to restrictions, which may have resulted in an overestimation of the impacts of the restrictions, unless changes in overall tobacco use was accounted for. Despite these limitations, these real-world evaluations provide important insight into how sales and tobacco use change in response to restrictions on flavored tobacco products, including cigars. These evaluation studies further demonstrate that the proposed prohibition on characterizing flavors (other than tobacco) in cigar products would reduce the rate of youth and young adult experimentation and progression to regular tobacco use and increase cessation among current cigar smokers. Section VI of this document draws on such findings to estimate the impact of the proposed rule on population health, including the likelihood that existing cigar smokers would stop smoking as well as the likelihood that nonusers would start smoking cigars.

G. Flavored Cigars 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 companies and their products among youth, young adults, and other vulnerable populations (Refs. 37, 120, and 121). With regard to cigars, decades of targeted marketing activities have helped make cigars more appealing and affordable and contributed to the pervasive and enduring nature of disparities in cigar use in vulnerable populations.

A robust body of scientific evidence shows that tobacco is disproportionately marketed in underserved communities and to vulnerable populations, such as youth and young adults, some racial and ethnic populations, individuals who identify as LGBTQ+, pregnant persons, those with lower household income and educational attainment, and individuals with behavioral health conditions. Storefront and outdoor tobacco marketing as well as point-of-sale marketing are all disproportionately present in African American/Black, Hispanic/Latino, and low-income communities (Refs. 122-129). Additionally, tobacco companies have historically targeted African Americans, LGBTQ+ communities, and low-income populations by using strategies such as offering coupons and other price promotions to entice these groups to use tobacco products (Refs. 122 and 130). This evidence holds true for combusted tobacco products, including cigar and flavored cigar products.

Industry documents reveal that tobacco companies have for many decades strategically marketed flavored cigars to encourage trial and initiation among vulnerable populations. For example, a 1969 industry report noted the introduction of new flavored cigar products "aimed directly at youth," as well as marketing campaigns targeting youth by including special offers, such as record albums (Refs. 16 and 79). Similarly, a 1972 report on the findings of an industry consumer research study concluded that adding menthol and mint flavor to little cigars was appealing to young (not defined) study participants and recommended marketing this flavored cigar product at a lower price point than cigarettes in order to attract young users (Refs. 16 and 131). Industry documents also disclose that tobacco companies targeted Black consumers, including by offering sampling and distribution opportunities as well as publishing advertisements in Black-only newspapers (Refs. 16, 132, and 133). Furthermore, hip-hop artists, DJs, and music events are all avenues tobacco companies have used to attract African Americans to use flavored little cigars and cigarillos (Ref. 16). Industry market research also studied how to increase cigar use among young women, including the addition of flavors to improve palatability and mildness and thereby promote product trial. Segments of the industry used this information

to inform marketing and product development targeted at women such as adding appealing flavors, reducing cigar size so they could fit into purses or pockets, and including celebrities in advertisements (Refs. 16 and 131).

The tobacco industry's historic practice of marketing to vulnerable populations has resulted in long-term consequences for these communities. Scientific evidence indicates that tobacco marketing influences social norms around tobacco use, making tobacco use more socially acceptable and increasing the likelihood of tobacco use (Refs. 134-137). In underserved communities where the tobacco industry has disproportionately marketed over decades, these social norms are transferred through social networks of peers and generations of families, thereby contributing to present-day tobacco-related health disparities in these populations (Refs. 134, 135, 138, and 139). Furthermore, recent scientific evidence indicates that tobacco companies continue to target populations from underserved communities with cigar marketing, including flavored cigar marketing (see, e.g., Refs. 140-146). Across diverse marketing platforms, ranging from traditional print media to online platforms, populations from underserved communities are disproportionately exposed to cigar advertisements.

Brick-and-mortar tobacco retailers are present in disproportionate numbers in neighborhoods of underserved communities, particularly in Black communities. Studies have found that the more Black residents there are in a census tract, the more tobacco retailers there are in that census tract, with a statistically significant positive association between tobacco retailer density and the proportion of residents who are Black (Refs. 124-127). Two systematic reviews and several studies found that tobacco retailers in predominately African American/Black neighborhoods were statistically significantly more likely to sell cigars and cigarillos, were statistically significantly more likely to have exterior advertisements for cigars and cigarillos, and were statistically significantly more likely to sell cigars and cigarillos at a lower price, as compared to tobacco retailers in other neighborhoods (Refs. 125, 127, and 146-149). Furthermore, two nationally representative studies found that retailers in Black

neighborhoods were more likely to place interior advertisements at or below 3 feet off the floor, at a point where cigar advertisements are more visible to youth, compared to tobacco retailers in predominately non-Hispanic White neighborhoods (Refs. 143 and 144).

Higher exposure to tobacco advertisements and retailing are associated with disparities in tobacco use susceptibility and tobacco use among youth. For example, a nationally representative study of youth found that exposure to cigar advertisements at the point-of-sale was statistically significantly associated with high curiosity about using cigars, with non-Hispanic Black (14.8 percent) and Hispanic youth (11.9 percent) being statistically significantly more likely to be highly curious about cigars as compared to non-Hispanic White youth (7.6 percent). This finding raises concern because curiosity about using tobacco products predicts tobacco use susceptibility, tobacco use initiation, and progression to regular tobacco use among youth (Ref. 150). Similarly, a longitudinal study of middle and high school students found that recall of tobacco advertisements and products at the point-of-sale at baseline predicted current cigar use at a 6-month followup (Ref. 151). Additionally, one cross-sectional study found that youth who reported going to a corner, convenience, or other retail store on the way to or from school frequently had statistically significantly higher odds of current use of cigars, little cigars, and cigarillos (Ref. 152).

Taken together, scientific evidence indicates that cigars and flavored cigars historically have been and continue to be disproportionately marketed in underserved communities and that the presence of flavors in cigars is intended to encourage trial and initiation and deter tobacco cessation. The differences found in exposure to flavored cigar marketing contribute to observed disparities in tobacco use and associated tobacco-related health disparities and health outcomes among vulnerable populations, as further discussed in section V.F of this document. While targeted marketing is only one factor in the development and perpetuation of flavored cigar 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 great concern to FDA. FDA remains

committed to improving health outcomes across the population as a whole, including within groups that experience disproportionate levels of tobacco use, such as the vulnerable populations discussed in this section.

V. Cigar Use Is Common, Addictive, and Harmful

A. Prevalence of Cigar Use Among Youth, Young Adults, and Older Adults in the United States

Patterns of cigar use differ markedly by age group, race and ethnicity, household income and educational attainment, and among others who have systematically experienced greater obstacles to health based due to the inequitable distribution of social, political, economic, and environmental resources, such as individuals who identify as LGBTQ+ and persons with disabilities.

1. Cigar Use Prevalence in Youth and Young Adults

Evidence from national surveys, including the Monitoring the Future study of 8th, 10th, and 12th grade students and the NYTS of middle and high school students, has suggested that, similar to cigarettes, cigar use has been on the decline among U.S. youth in recent years (Refs. 153 and 154). However, in 2020, cigars were the most commonly reported combusted tobacco product used by youth (Ref. 7). Nationwide, in 2020, nearly 1 million youth had smoked a cigar on at least 1 day during the past 30 days (Ref. 7). According to the 2020 NYTS, an estimated 960,000 middle and high school students (3.5 percent), including 5.0 percent (770,000) of high school students (grades 9-12) and 1.5 percent (180,000) of middle school students (grades 6-8), had smoked a cigar (cigar, cigarillo, or little cigar) in the preceding 30 days (Ref. 7). The most recent NYTS data also found that, of those youth who use cigars, the largest proportion use cigarillos (44.1 percent), followed by regular cigars (33.1 percent), and little cigars (22.6 percent) (Ref. 8). Of note, 21.8 percent of youth who are current users report not knowing which cigar type they use (Ref. 8).

While there has been an overall downward trend in cigar use among youth in general, cigar use--particularly flavored cigar use--remains significant, and this decrease has not been

equitably experienced as the popularity of cigar use remains disproportionately high among non-Hispanic Black youth (Ref. 7). Tobacco-related health disparities result, in part, from inequitable practices and denial of opportunities that prevent some communities from fully participating in aspects of economic, social, and civic life. These inequities influence vulnerabilities that some populations experience across the continuum of tobacco use. For example, disparities in initiation and prevalence of cigar use that are connected to inequitable treatment and opportunities likely contribute to and reinforce the continued tobacco-related vulnerabilities of Black youth as subsequent disparities are observed along the continuum of tobacco use for these youth. The 2020 NYTS data show that the popularity of cigars is especially high among non-Hispanic Black middle and high school students, as 6.5 percent reported past 30-day cigar use compared to 2.8 percent of non-Hispanic White students (Ref. 7). Additionally, the findings show that cigar use was statistically significantly higher than cigarette use among non-Hispanic Black high school students in 2020, with 9.2 percent reporting having smoked cigars during the past 30 days, compared with 2.8 percent reporting having smoked cigarettes (Ref. 7). Data also indicate that non-Hispanic Black youth have a higher risk than White youth of initiating cigar use at earlier ages. An analysis of 2013-2017 PATH Study youth (aged 12-17 years) data indicated that, when compared to non-Hispanic White youth, non-Hispanic Black youth were 47 percent more likely to initiate past 30-day cigarillo or filtered cigar use and 111 percent more likely to be "fairly regular" users of these products (Ref. 25). These observed disparities in cigar use initiation are associated with higher levels of current cigar use and frequency of cigar use among Black youth and young adults. An analysis of data from a longitudinal cohort study found that once Non-Hispanic African American youth and young adults had initiated cigar use, they had twice the odds of current cigar use within 6 months relative to non-Hispanic Whites (Ref. 100). Also, within 6 months of initiation, the average frequency of use and days per month used was higher for non-Hispanic African Americans compared to non-Hispanic Whites (Ref. 100). Findings from the 2013 Cuyahoga County Youth Risk Behavior Survey indicate that non-

Hispanic Black youth had statistically significantly higher odds of using cigars as compared to non-Hispanic White youth (Ref. 155). Disparities in cigar use among Black youth may also pose additional concerns due to the increased risk associated with polyuse with other combusted tobacco products. Cigarette smoking being perceived as harmful reduced the likelihood of cigar use among all racial and ethnic categories of youth except for non-Hispanic Black youth, who were statistically significantly more likely to be current cigar users if they perceived smoking cigarettes as harmful (Ref. 155). Moreover, use of cigars among Black youth disproportionately leads to cigarette smoking. In a nationally representative longitudinal study of youth, ever cigar use statistically significantly increased the odds of subsequent past-30-day cigarette use among non-Hispanic Black youth (Ref. 156). However, ever cigar use did not increase the odds of subsequent past 30-day cigarette use among non-Hispanic White youth (Ref. 156). This study found that 9.1 percent of cigarette initiation among non-Hispanic Black youth was directly attributable to cigar use, compared with only 3.9 percent among non-Hispanic White youth (Ref. 156).

Youth and young adults who identify as LGBTQ+ also face tobacco-related health disparities when compared with non-LGBTQ+ counterparts, including higher prevalence of tobacco product use as well as cigar use.[15] In 2020, NYTS analysis found that past 30-day use of any tobacco product was higher among youth identifying as lesbian, gay, or bisexual than heterosexual youth (25.5 percent vs. 15.1 percent) (Ref. 7). Past 30-day cigar use was nearly twice as prevalent among youth identifying as lesbian, gay, or bisexual than heterosexual youth (6.0 percent vs. 3.1 percent) (Ref. 7). Findings from an analysis of Wave 3 PATH Study data (2015-2016) indicated that, similar to patterns among adults, lesbian and bisexual girls have even higher disparities and are more than twice as likely than their heterosexual peers to report ever

[15] FDA acknowledges that sexual orientation is distinct from gender identity and that discussion and consideration of these factors in the context of public health should recognize and account for that distinction. However, 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.

using cigars (11.3 percent vs. 5.2 percent) and to have used cigars in the past 30 days (3.2 percent vs. 1.0 percent) (Ref. 157). An analysis of the 2015 YRBS data found that lesbian and bisexual girls have statistically significantly higher current use prevalence of cigars than their heterosexual peers (16.4 percent for lesbian girls, 10.2 percent for bisexual girls, 5.4 percent for heterosexual girls), as do gay and bisexual boys (20.0 percent for gay boys, 16.9 percent for bisexual boys, and 13.5 percent for heterosexual boys) (Ref. 158). Findings from a nationally representative cohort study indicated that young adults who identified as homosexual reported higher ever cigar use compared to young adults who identified as heterosexual (Ref. 159). Transgender youth also are statistically significantly more likely than non-transgender youth to report ever using any tobacco product (53.6 percent vs. 31.5 percent) including cigars (16.1 percent vs. 7.5 percent) and past 30-day use of more than one tobacco product, including cigars (10.2 percent vs. 3.5 percent) (Ref. 157). Study findings from a young adult cohort study indicated that past 30-day little cigars/cigarillos/bidis use was greater for young adults who identified as LGBT in comparison to those who did not identify as LGBT (Ref. 160).

Youth with disabilities also have higher rates of cigar use than their nondisabled peers. In one study of more than 20,000 11th graders in Oregon that controlled for sociodemographic risk factors of tobacco use, the proportion of little cigar use among students with at least one reported disability (7.0 percent) was statistically significantly higher than among students without a disability (5.4 percent) (Ref. 161).

2. Cigar Use in Adults

Cigars are also a popular tobacco product among adults. In the 2019 National Health Interview Survey (NHIS), 3.6 percent of adults 18 or older reported currently using cigars some or every day, behind cigarettes (14 percent) and e-cigarettes (4.5 percent) (Ref. 68). Comparing 2011 to 2019, while past month cigarette smoking and cigar use were both statistically significantly lower in young adults (aged 18-25 years), the absolute decline in cigar use was less than the decline in cigarette use (33.5 percent in 2011 to 17.5 percent in 2019 for cigarettes; 10.9

percent in 2011 to 7.7 percent in 2019 for cigars) (Ref. 59). For adults (aged 26 years or older), cigarette use in 2011 was statistically significantly higher compared to in 2019; however, cigar use remained relatively stable and did not significantly change (21.9 percent in 2011 to 18.2 percent in 2019 for cigarettes; 4.2 percent in 2011 to 4.0 percent in 2019 for cigars) (Ref. 59). The 2019 NSDUH found that among adults aged 26 or older in 2019, 1,420 individuals initiated cigar use each day, considerably more than the 247 who initiated cigarette smoking each day in that year (Ref. 59).

Prevalence of cigar smoking, however, varied by the type of cigar smoked. Analysis of Wave 5 (2018-2019) data from the PATH Study found that, 4.8 percent of young adults (aged 18-24 years) used traditional cigars; 7.9 percent used cigarillos, and 2.4 percent used filtered cigars in the past 30 days (Ref. 63). According to the most recent data from the PATH Study (2018-2019), 3.5 percent of adults (aged 25 years and older) used traditional cigars, 3.3 percent used cigarillos, and 1.6 percent used filtered cigars in the past 30 days (Ref. 63).

Similar to youth and young adults, adults (aged 25 years and older) reported use of flavored cigars and are expected to benefit from the proposed product standard if finalized. Wave 5 (2018-2019) data from the PATH Study showed that 36.0 percent of adult cigar smokers (aged 25 years and older) reported past 30-day use of flavored cigar from 2018-2019 (Ref. 63). Among adult cigar smokers, a statistically significantly greater proportion of adult traditional cigar smokers (19.7 percent) reported use of a flavored cigar in the past 30 days compared with adult smokers of all other cigar types (46.5 percent for cigarillos and 48.7 percent for filtered cigars) (Ref. 63). The proportion of adults using flavored cigars within each of the cigar types did not differ over time across recent PATH Waves 4-5 (2016-2019) (Ref. 63).

A disproportionate proportion of cigar smoking occurs among vulnerable populations; this burden has grown over the past two decades. In the 2019 NHIS, 4.4 percent of non-Hispanic Black, 3.8 percent of non-Hispanic White, and 3.0 percent of Hispanic adults reported some or everyday cigar use (Ref. 68). In an analysis of 2002-2016 NSDUH data for individuals aged 12

and older, non-Hispanic Black individuals were statistically significantly more likely than all other racial and ethnic groups to have used cigars in the past 30 days (Ref. 162). Decreases in prevalence of cigar use have not been observed in non-Hispanic Black adults as they have for other racial and ethnic groups (Ref. 162). There were no statistically significant changes in past 30-day use prevalence between 2002-2016 in the NSDUH data among non-Hispanic Black and non-Hispanic other/mixed race adults while there were decreases among both non-Hispanic White and Hispanic adults. Further, over this same time period, cigar use decreased among non-Hispanic White men and stayed the same among non-Hispanic White women, but it increased among non-Hispanic Black women and remained the same among non-Hispanic Black men (Ref. 162). When considering more recent NSDUH data, these racial and ethnic disparities have persisted, with the prevalence of past 30-day cigar smoking remaining statistically significantly higher among non-Hispanic Blacks compared to non-Hispanic Whites through 2019 (Ref. 59).

A recent analysis of PATH Study data from Wave 3 (2015-2016) showed differences in daily cigar smoking by racial and ethnic group (Ref. 163). Non-Hispanic Black individuals are statistically significantly more likely to report that they have ever been a "fairly regular" cigar smoker (5.4 percent) than non-Hispanic White cigar smokers (2.5 percent) and to report that they smoke cigars daily (1.9 percent), compared to non-Hispanic White cigar smokers (0.5 percent), with these differences being most pronounced for cigarillos (3.7 percent vs. 0.9 percent) (Ref. 163). Hispanic adults were more likely to smoke cigars within 30 minutes of waking, when compared with non-Hispanic Whites (Ref. 163). The analysis found a consistently higher prevalence of use for non-Hispanic Blacks, compared with non-Hispanic Whites for three cigar-smoking outcomes (past 30-day use, daily use, and established use) across all the cigar types (Ref. 163).

Differences in prevalence have been observed across cigar type and in the use of flavors across racial and ethnic populations. In the PATH Study, past 30-day cigarillo use was statistically significantly higher among non-Hispanic Black young adults (aged 18-24 years) and

adults (aged 25 years and older) compared with non-Hispanic Whites and Hispanics at all waves (2013-2019) (Ref. 63). Past 30-day use of flavored traditional cigars was statistically significantly higher among non-Hispanic Black older adults (aged 25 years and older) compared to non-Hispanic White adults at Waves 2-5 (2014-2019) and compared to Hispanic adults at Waves 2-3 (2014-2016) and Wave 5 (2018-2019) (Ref. 63). An analysis of survey data on college students indicated that Black young adults were three times more likely to smoke flavored cigars than White young adults (Ref. 66). Hispanic and Asian participants were also more likely to use flavored cigars over non-flavored cigars compared to non-Hispanic White participants (Ref. 66). Younger participants (aged 18-24 years) had greater odds of using flavored cigars when compared to older participants (aged 25-29 years) (Ref. 66).

Differences in prevalence of cigar use have also been observed across other population groups. Research indicates social gradient effects (where higher levels of household income and educational attainment are linked to better health outcomes and lower levels of household income and educational attainment are linked to poorer health outcomes) for cigar use. Data from the 2012-2013 NATS show that higher educational levels and higher annual household income generally were associated with lower prevalence of usual use of cigarillos, other mass market cigars, and of little filtered cigars (Ref. 164). Data from the PATH Study in 2018-2019 show that there was a statistically significant difference in past 30-day cigar use by education level as 7.3 percent of adults (aged 25 years and older) with less than a high school diploma smoked cigars in the past 30 days, compared to 3.8 percent of adults with a college degree or higher (Ref. 63). Among adults who used any cigar in the past 30 days, individuals with a college degree were statistically significantly less likely to use a flavored cigar (20.0 percent) than individuals categorized as having less than a high school diploma (44.9 percent), a high school diploma (37.4 percent), or some college (42.9 percent) (Ref. 63).

Tobacco-related cancers are a leading cause of death among adults experiencing homelessness (Ref. 165). In a study of 470 unhoused individuals, the analysis found that past 30-

day use of all tobacco products was high and that 74.0 percent of respondents reported use of cigars and over half (55 percent) reported use of flavored cigars in the past 30 days (Ref. 166).

Adults over 18 with at least one chronic health condition (e.g., heart disease, hypertension, stroke, diabetes, asthma, lung cancer, hepatitis, human immunodeficiency virus infection, anxiety, depression, substance abuse) have been shown in one study to be more than one and a half times more likely than those without a chronic health condition to use cigars, with no statistically significant changes over time (Ref. 167). In particular, adults who have anxiety, depression, or substance use disorders have cigar use rates statistically significantly greater than those with no chronic health conditions (Ref. 167). This association holds for mentholated tobacco products, including cigars, which are used disproportionately by young adults (aged 18-34 years) who report mental health disorders, with past 30-day menthol tobacco product use being associated with greater odds of anxiety and depression when controlling for other tobacco and mental health risk factors (Ref. 168). Likewise, using Waves 1-4 (2013-2017) of PATH Study data, adults who reported past-year severe internalizing problems were more likely to have initiated use of flavored cigarillos since the prior PATH wave, and were also more likely to be past-30-day users of flavored cigarillos (Ref. 169).

Adults who identify as LGBTQ+ are more likely to use tobacco products, including cigars, and to meet the criteria for nicotine dependence when compared to their heterosexual and cisgender peers, with these associations being stronger for some racial and ethnic populations (Refs. 68, 157, 159, 160, and 170-173). For example, while adults who identified as gay/lesbian, bisexual, and "conflicting" (defined by study authors as those who identified as "heterosexual, had engaged in either no sexual behavior or exclusively heterosexual behavior, but reported some levels of same-sex attraction") are more likely than their heterosexual peers to use tobacco and meet tobacco use disorder criteria, Hispanic and non-Hispanic Black bisexual adults have even stronger associations for current tobacco use than do their White bisexual peers (Ref. 172). Overlapping forms of disadvantage can interact to create and exacerbate tobacco-related health

disparities. For example, discrimination experienced on the basis of gender identity or sexual orientation often overlaps with discrimination experienced on the basis of race or disability.[16] As discussed in section IV.G of this document, the tobacco industry disproportionately targets its marketing to those who identify as LGBTQ+ and some racial and ethnic populations. For example, adults who identify as lesbian, gay, bisexual, or transgender report higher rates of tobacco media exposure compared to their peers who do not identify as lesbian, gay, bisexual, or transgender (Ref. 141), which can lead to use of tobacco products, including cigars (Refs. 141 and 172).

Generally, findings indicate that adults who identify as lesbian, gay, bisexual, or transgender have a higher prevalence of experimental and current cigar use compared to their heterosexual peers (Refs. 159 and 173-175). Findings from an analysis of the 2012-2013 NATS data indicated that among women who identified as lesbian or gay, bisexual, or "something else" (an option provided in the study), cigar use was more than triple the rate of heterosexual women (Ref. 176). Data from the 2015-2017 NSDUH, indicate that lesbian and bisexual women had more than twice the odds of using cigars in the past year relative to heterosexual women (Ref. 170). These findings are consistent with those from a 2013 cross-sectional survey study showing that lesbian and bisexual women had more than twice the odds of current cigar use relative to heterosexual women (Ref. 173).

Adults who identify as transgender are more likely to use tobacco products, including cigars, than their cisgender peers. In a national cross-sectional online survey, transgender adults reported higher current (past 30-day) use of any cigarette/e-cigarette/cigar product (39.7 percent vs. 25.1 percent) (Ref. 177). This study also found that transgender adults had higher current use of cigars (26.8 percent vs. 9.3 percent), specifically, when compared with cisgender adults as

[16] See, e.g., E.O. 13988, "Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation" (86 FR 7023, January 25, 2021).

well as statistically significantly higher odds of past 30-day tobacco product use for any cigarette/e-cigarette/cigar product and for cigars, compared to cisgender adults (Ref. 177).

These disparities also exist for flavored cigar use, as data from the 2009-2010 NATS indicated that adults who identify as lesbian, gay, bisexual, or transgender have a higher prevalence of flavored cigar use (8.2 percent) compared to the national prevalence (2.8 percent) and when compared to cigar users nationally (42.9 percent) (Ref. 70). Data from the 2011-2015 Truth Initiative Young Adult Cohort Study showed that respondents who identified lesbian, gay, or bisexual had higher odds of reporting past 30-day flavored large cigar and LCC use compared to respondents who identified as straight/heterosexual (Ref. 67).

3. Polyuse of Tobacco and Cigar Prevalence

FDA finds that recent trends toward polyuse of tobacco (i.e., the use of two or more tobacco products) also support the Agency's conclusion that this proposed rule would have positive impacts on public health. Polyuse increases exposure to nicotine (Ref. 178) and other harmful constituents of tobacco products and tobacco smoke. Using data from the 2017-2018 NYTS survey, one study found that 40.8 percent of middle and high school aged youth past 30-day tobacco users were using two or more tobacco products in the past month (Ref. 107). Among youth using cigars in the past 30 days, a majority, 76.1 percent, used cigars in combination with one or two additional tobacco products (Ref. 107). Among youth in the 2017-2018 NYTS data, cigarettes and e-cigarettes were the most common products used alongside cigars (Ref. 107).

The cumulative exposure from polyuse can sustain and may increase levels of tobacco dependence. A 2017-2018 analysis of NYTS data found that 43.1 percent of youth current cigar smokers, including polyusers, reported nicotine dependence, including feeling strong craving to use a tobacco product or using a tobacco product within 30 minutes of waking (Ref. 107). When looking at the association between cigar use and dependence, frequent cigar use (i.e., use on 20 to 30 days in the past 30 days) was associated with increased odds of nicotine dependence as compared to less frequent users (Ref. 107). Exclusive use of cigars was associated with lower

odds of dependence relative to exclusive use of another tobacco product. However, most youth cigar users in the study used cigars and one or more other tobacco products. When cigar use included polyuse and exclusive use, youth cigar use was associated with twice the odds of nicotine dependence (Ref. 107). Given the role of frequent and polyuse in the relationship between cigar use among youth and dependence, the authors note "…the importance of examining behaviors related to use, as they can affect and/or exacerbate the risk of nicotine dependence" (Ref. 107).

An analysis of tobacco dependence among daily cigarette, cigar, and e-cigarette users in the United States, using data from the 2012-2013 NATS, found that compared to cigarette-only smokers, dual cigarette and cigar smokers exhibited greater dependence, with a higher average number of cigarettes smoked per day (17.3 vs. 15.8), shorter times to first tobacco use after waking (21.4 minutes vs. 25.9 minutes), and more frequent reporting of withdrawal and craving symptoms compared to exclusive cigarette smokers (Ref. 179). In addition, data from Wave 1 (2013-2014) of the PATH Study demonstrates that high nicotine dependence is two to three times more likely among poly users compared to dual and single product users (Ref. 180). Data from the 2012 and 2019-2020 NYTS also noted that reports of dependence were consistently associated with polyuse (Refs. 181 and 182).[17] FDA anticipates this proposed product standard would help to reduce the number of cigar users and, therefore, the number of tobacco users who are poly users and likely even more tobacco dependent.

B. Flavored Cigar Use Exposes Users to Additional Toxicants

All cigar users, including flavored cigar users, are exposed to toxicants, including more than 50 carcinogens in mainstream and sidestream cigar smoke (Ref. 183). In flavored combustible tobacco products, including cigars, additional toxicity can result from the chemicals formed when flavors are heated or burned (Refs. 184-187). For example, acetaldehyde, formaldehyde, and benzene were found during pyrolysis (i.e., thermal decomposition or the

[17] FDA is not aware of additional analyses that examine dependence in youth in NYTS data using 2013-2018 data.

process of breaking down a product under the presence of heat) of 18 different cigarette flavor additives, and various polycyclic aromatic hydrocarbons (PAHs) were also detected during pyrolysis of cocoa (Ref. 188). Similar results would be expected for cigar flavor additives (Ref. 189). A study conducted by the Centers for Disease Control and Prevention (CDC) identified benzyl alcohol, piperonal, methyl cinnamate, and vanillin in strawberry cigar filler (Ref. 190). The table below summarizes examples of known respiratory and other relevant toxicities associated with these ingredients (and subcomponents) and their potential pyrolysis products.

Table 2.--Flavor Ingredient Pyrolysis and Potential Health Hazards

Flavor Ingredient	Chemical Reaction Product	Health Hazard of Flavor Ingredient
Benzaldehyde	Benzene, Carbon monoxide (CO) (Refs. 191 and 192)	Respiratory irritant and toxicant (Ref. 193)
Benzyl alcohol	Benzene, toluene (Refs. 194 and 195)	Acute inhalation toxicant; Nose, throat, and respiratory tract irritant (Ref. 196)
Ethyl maltol	Acetaldehyde, acrolein, CO, formaldehyde, 1,3-butadiene, acetone, propionaldehyde, crotonaldehyde, methyl ethyl ketone (Refs. 197 and 198)	Mutagen (Ref. 199)
Ethyl vanillin	Benzene, naphthalene (Ref. 200)	Respiratory irritant (Ref. 201)
Hexyl acetate	CO (Ref. 202)	Respiratory irritant (Ref. 203)
Methyl cinnamate	Styrene (Ref. 185)	Sensitization (Ref. 204)
Piperonal	1,3-butadieneButadiene, benzene (Ref. 188)	Mutagenic; hepatoxic in rats (Ref. 205)
Vanillin	Benzene, catechol, naphthalene, phenol, o-cresols, toluene (Refs. 200 and 206)	Respiratory irritant (Ref. 207)

FDA expects that the proposed product standard, if finalized, would result in reduction or removal of such flavoring ingredients in cigars. Reducing flavoring ingredients in cigars and, thereby, reducing these toxicant levels in such products would reduce consumer exposure to these toxicants and help to protect consumers from the health effects of these toxicants.

C. Cigar Use Is Addictive

Through cigar smoke, nicotine can be absorbed by inhalation (like cigarettes) or through the oral mucosa (like smokeless tobacco). Multiple studies found that cigar smokers inhale (as evidenced by CO levels), and plasma nicotine levels are similar to those of cigarette smokers (Refs. 101-104 and 208).

All cigars contain nicotine, a highly addictive chemical. The Surgeon General has long recognized that the addictive nature of tobacco products is due to the presence of highly

addictive nicotine that can be absorbed into the bloodstream and pass into the brain (e.g., Ref. 121). Nicotine is "one of the most addictive substances used by humans" (Ref. 209). Given that nicotine is highly addictive and present in all cigars, as experimenters continue to use these products, there is a risk of nicotine dependence and progression to regular use, resulting in an increased risk of developing the many negative health consequences associated with regular cigar use. Prohibiting characterizing flavors (other than tobacco) in cigars is an important step toward reducing experimentation and progression to regular use since it can reduce the appeal and ease of use of such products and, consequently, the likelihood of nicotine addiction.

The amount of nicotine delivered, and the means through which it is delivered, can either reduce or enhance nicotine's potential for abuse and physiological effects (Ref. 6). Generally, the quicker the nicotine delivery, rate of absorption, and attainment of peak concentrations, the greater the potential that an individual will become addicted to nicotine (Ref. 6). Research has found that little cigars deliver nicotine levels that are similar to cigarettes and also reduce users' urge to smoke cigarettes (Ref. 6). Large cigars can deliver as much as ten times the nicotine of a filtered cigarette (Ref. 183). Factors determinative of cigars' ability to deliver nicotine at a level capable of producing dependence include the age of initiation, the rate of nicotine absorption, the duration of exposure, the degree of cigar smoke inhalation, and the development of tolerance to nicotine (Ref. 210).

Cigar smoke contains many of the same harmful constituents as cigarette smoke--including nicotine (Ref. 183). A single cigar can contain as much tobacco as an entire pack of cigarettes, and nicotine yields from smoke from a cigar can be up to roughly eight times higher than yields from smoke from a non-filtered cigarette in machine smoking regimens--with delivery of 1.7 milligrams (mg) in non-filtered cigarettes compared to 3.8 mg in little cigars, 9.8 mg in cigarillos/other mass market cigars, and 13.3 mg in "premium" cigars (Ref. 183). Although the amount of nicotine taken in by a cigar user depends on various factors, such as how long the individual smokes the cigar, the number of puffs taken, and the degree of inhalation, a

leading review of the science of cigar smoking concluded that "[c]igars are capable of providing high levels of nicotine at a sufficiently rapid rate to produce clear physiological and psychological effects that lead to dependence, even if the smoke is not inhaled" (Ref. 210).

Research indicates that most cigar smokers unknowingly inhale some amount of smoke, including cigar smokers who report that they do not inhale (Ref. 211; see Ref. 212). Youth more commonly use cigarillos and little filtered cigars that are designed to be inhaled, which may increase their risk of poor health outcomes as well as addiction (Refs. 32 and 183). Little cigars are often indistinguishable from cigarettes given their shape, size, filters, and packaging, and are perceived as being healthier than cigarettes (Refs. 48 and 49). Even if cigar smokers do not breathe or inhale smoke into their lungs, they are still subject to nicotine's addictive effects through buccal absorption of nicotine or nicotine absorption through the lips due to cigar tobacco's alkalinity (Refs. 211, 213-215). Cigar smoke dissolves in saliva and makes it possible for smokers to absorb sufficient amounts of nicotine to create dependence (Ref. 213).

Nicotine can exist in protonated and freebase, or unprotonated, forms; in the freebase form, it is most addictive because it is readily absorbed by the buccal mucosa, respiratory tissues, skin, and the gastrointestinal tract (Refs. 6 and 121). Freebase, unprotonated nicotine amounts are generally higher in cigars than cigarettes due to the higher pH of cigar smoke (Ref. 183). Nicotine absorbed across the buccal mucosa, the mouth's membrane lining, can provide sustained amounts of freebase nicotine to the tobacco product user, which, along with the harshness of cigar smoke, may explain why cigar smokers are less likely to intend to inhale than cigarette smokers (Ref. 183). Cigars can deliver nicotine much like chewing tobacco or oral snuff, with nicotine extraction from the unburned tobacco absorbed directly through the buccal mucosa and lips (Ref. 183).

In addition, characterizing flavors may impact the effects of nicotine. In particular, characterizing flavors, including menthol, can activate the brain's reward circuit, producing rewarding effects that, when added to tobacco products, can reinforce the effects of nicotine

(Refs. 13 and 14). The use of sweet/candy and other characterizing flavors that appeal to youth produces a robust reinforcing effect in young populations (Refs. 13 and 14). One animal study found that flavors can enhance the reinforcing effects of low nicotine doses in rodents (Ref. 216). The authors of this study suggest this effect may influence nicotine exposure and subsequent dependence. While flavors can activate the brain's reward circuit and produce rewarding effects on their own (Ref. 14), these findings suggest that flavors and nicotine can interact to enhance the reinforcing effects of nicotine (Refs. 13, 216, and 217). Further studies demonstrate that menthol, like nicotine, binds to nicotinic receptors in the brain (Refs. 218 and 219) and menthol alone can increase the number of nicotinic receptors in the brain (Refs. 220 and 221). Increases in nicotinic receptors can lead to greater withdrawal and cravings (Ref. 222). Evidence demonstrates that menthol's effects on nicotine in the brain are associated with behaviors indicative of greater addiction to nicotine (Refs. 220 and 223). In an analysis of 2019-2020 NYTS data, use of one or more flavored tobacco products, including menthol, during the past 30 days was associated with higher odds of reporting strong cravings and desire to use tobacco within 30 minutes of waking compared to use of an unflavored tobacco product (Ref. 182).

A cigar smoker's age is another factor that affects susceptibility to nicotine addiction. The Surgeon General has noted that nicotine dependence in cigar smokers could result from even a limited exposure to nicotine during adolescence (Ref. 6). Analyses of data from the 2012 and 2019-2020 NYTS found that, although the percentage of middle and high school students reporting various measures of dependence was lower for cigars than for cigarettes, youth reported measures of nicotine dependence when exclusively using cigars (Refs. 181 and 182). The analysis of 2019-2020 NYTS data found that 14.8 percent of middle and high school students who only smoked cigars reported strong cravings for a tobacco product during the past 30 days (Ref. 182).

Prohibiting characterizing flavors (other than tobacco) in cigars would reduce the appeal of cigars, particularly among youth and young adults, and decrease the likelihood that nonusers

would experiment with cigars. It also would decrease the likelihood that current experimenters would continue to use these products. Reducing the appeal of cigars and experimentation is particularly important because, as experimenters continue to use these products, they can develop dependence, leading to regular use and increasing their risk of developing the many negative health consequences associated with regular cigar use.

D. Research Clearly Demonstrates a Causal Relationship Between Cigar Smoking and Death and Disease

Flavored cigar smokers, like all cigar smokers, are at increased risk for developing cancers of the mouth and throat, lung cancer, heart disease, and many other adverse health consequences, with some groups with higher rates of use at greater risk than others. As discussed in section V.C of this document, those who experiment with flavored cigars (due to their appeal and ease of use) can develop nicotine dependence, placing infrequent cigar smokers at risk of progression to regular use and to tobacco-related disease and death. Studies demonstrate that not only is cigar smoking causally associated with many of the same diseases as cigarette smoking, but cigar smoking risks can also exceed those causally associated with cigarette use depending on the number of cigars smoked and the depth of smoke inhalation (Ref. 32).

Cigar smoke contains many of the same harmful constituents as cigarette smoke, and cigar smoke may have even higher levels of several harmful compounds (Refs. 3, 23, and 224). For example, cigar smoke contains higher amounts of carcinogenic, tobacco-specific N-nitrosamines than cigarette smoke due to the relatively high concentration of nitrate in cigar tobacco, which leads to formation of cancer-causing nitrosamines during the fermentation process (Refs. 23; 183 at Chapter 3; and 224). Researchers have found urinary concentrations of NNAL (a hazardous tobacco-specific nitrosamine) measured in daily cigar smokers to be as high as those measured in daily cigarette smokers (Refs. 225 and 226). Like exposure to cigarette smoke, exposure to higher levels of cigar smoke for longer time periods increases the adverse health risks caused by cigar smoking (Ref. 6).

Using NATS data for 2009-2010, researchers have estimated that regular cigar smoking caused approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older (Ref. 3). A study of healthcare expenditures from 2000-2015 found that cigar-attributable health care expenditures for adults totaled $1.75 billion per year, with $284 million attributed to exclusive cigar smoking and $1.5 billion attributed to non-exclusive cigar smoking (i.e., cigar plus cigarette or smokeless tobacco use) (Ref. 4). The overall mortality rates for cigar smokers who inhale generally approach the same mortality rates observed for cigarette smokers (Ref. 183 at 110-112). In addition, overall mortality rates for all cigar smokers (i.e., those who report inhaling as well as those who report not inhaling cigar smoke) are higher than rates for those who have never smoked, although they are generally lower than the rates observed for cigarette smokers (Ref. 183 at 112). A recently published analysis using more contemporary data from the National Longitudinal Mortality Study, following participants for mortality from 1980 through the end of 2011, also found that exclusive cigar smokers had an elevated risk of all-cause mortality compared to never tobacco users, but lower than exclusive cigarette smokers (Ref. 227). Another similar analysis using the restricted-use National Health Interview Survey-Linked Mortality Files (NHIS-LMF), following participants for mortality from 2000 through 2015, observed that current, daily cigar smokers had elevated risk of all-cause mortality compared to never tobacco users (Ref. 228). In addition, researchers studying cigar smokers in 2009 and 2010 found that the average cigar or pipe smoker loses approximately 15 life-years (Ref. 3).

Given this causal relationship between cigar smoking and all-cause mortality, it is critical that FDA propose action to decrease the appeal and ease of cigar use, making it less likely that youth and young adults will experiment with cigars or progress to regular use. FDA also expects that the proposed product standard, if finalized, will cause a large number of existing cigar smokers to cease combusted tobacco product use (as discussed in section VI of this document) and, therefore, be less likely to suffer the negative health consequences of cigar smoking.

1. Cancers of the Mouth and Throat

The National Cancer Institute's (NCI's) Tobacco Control Monograph No. 9, which provides a comprehensive, peer-reviewed analysis of the trends in cigar smoking and potential public health consequences, identified a dose-response relationship for cigar smoking and certain types of cancer (Ref. 183 at 120-130). Specifically, NCI's Tobacco Control Monograph No. 9 identified a dose-response relationship for cigar smoking and oral, laryngeal, pharyngeal, and esophageal cancers, finding an increased risk of these diseases with greater numbers of cigars smoked per day and deeper inhalation (Refs. 183 and 229-232). Likewise, a systematic review of the mortality risks associated with cigar smoking that identified 22 studies observed similar dose trends (Ref. 32).

Cigar smoking can cause cancers of the mouth and throat even in smokers who report they do not inhale (Ref. 183). According to the NCI's Tobacco Control Monograph No. 9, the data clearly establish that cigar smoking is a cause of oral cancer (Ref. 183). Regular cigar smokers who have never smoked cigarettes, including those who report that they do not inhale, experience elevated risks for oral, laryngeal, pharyngeal, and esophageal cancers (Ref. 183). Although former cigarette smokers who currently smoke cigars are more likely to inhale more deeply than cigar smokers who never smoked cigarettes, "the mouth and oral cavity are exposed to the carcinogens in smoke whether the smoke is inhaled or not" (Ref. 183). The systematic review of the mortality risks associated with cigar smoking also noted that the relative mortality risk was still highly elevated for oral, esophageal, and laryngeal cancer among primary cigar smokers reporting no inhalation (Ref. 32). Cigar smokers, including those who do not inhale, have a similar risk of death from mouth and throat cancer as do cigarette smokers, with an overall risk 7 to 10 times higher than for those who have never smoked (Ref. 183). This similarity in risk is likely due to the similar doses of tobacco smoke delivered directly to the oral cavity and esophagus by cigars and cigarettes (Ref. 210). Cigar smokers are also more likely to develop mouth and throat cancer than those who have never smoked. In a large retrospective

cohort study that included more than 17,000 men, researchers found that cigar smokers were nearly three times more likely than nonsmokers to develop cancer of the oropharynx and twice as likely to develop cancer of the upper aerodigestive tract (which includes oral cavity, pharynx, larynx, and esophagus) (Ref. 229). Those risks increased to roughly seven and five times, respectively, among those who smoked five or more cigars per day (Ref. 229).

The NCI's Tobacco Control Monograph No. 9 concluded that cigar smoking is a cause of laryngeal and esophageal cancers (Ref. 183). The likelihood of cigar smokers developing laryngeal cancer is similar to that of cigarette smokers who smoke fewer than 20 cigarettes per day (Ref. 233). The relative risk (i.e., the risk of an outcome under study among exposed (smokers) compared to unexposed (nonsmokers)) of death from laryngeal cancer for those who smoke five or more cigars per day, or who inhale moderately or deeply, approaches the risk for cigarette smokers (Ref. 183). This similarity in risk is likely due to the similar amounts of tobacco smoke delivered directly to the oral cavity and esophagus by cigars and cigarettes (Ref. 210). Regardless of whether smoke is inhaled, the mouths and tongues of cigar smokers are exposed to a high level of smoke (Ref. 210). The esophagus is exposed to the carcinogens of tobacco smoke, which collect on the mouth's surface and are swallowed with saliva, rendering cigar smoking a cause of esophageal cancer (Ref. 210). The risk of esophageal cancer is several times higher for cigar smokers than for those who have never smoked, and the relative risk of esophageal cancer is higher for cigar smokers than for cigarette smokers, even when cigar smokers are compared to the heaviest cigarette smokers (Ref. 234).

Several multinational research studies also have found that cigar smoking can cause oral and other cancers, even in those who do not inhale smoke. For example, the European Prospective Investigation into Cancer and Nutrition (EPIC) examined 102,395 men from Denmark, Germany, Spain, Sweden, and the United Kingdom and calculated the incidence of cancer in smokers who used cigars exclusively and cigar smokers who also smoked cigarettes (Ref. 235). According to the EPIC study findings, exclusive cigar smokers who report not

inhaling had approximately a two-fold higher risk of lung, upper aerodigestive tract, and bladder cancers combined compared to those who never smoked (Ref. 235). This increased risk was raised to six- or seven-fold higher in cigar smokers who inhaled smoke compared to noninhalers (Ref. 235). This increased risk by comparison to never-smokers was lowest for smokers who had quit both cigarettes and cigars and higher for those who switched from cigarettes to only cigars, demonstrating the additional risk associated with cigar smoking compared to stopping smoking altogether (Ref. 235). Researchers confirmed a carcinogenic effect from cigar smoking with regard to upper aerodigestive tract cancers and found that the risk of these hazards increased with increased duration of smoking over the smoker's lifespan, increased intensity of use per week, and increased degree of smoke inhalation per episode (Ref. 235). A recently published international pooled cohort study found that ever cigar smokers had a non-significantly elevated risk of head and neck cancer and no elevated risk of esophageal cancer, although the numbers of cancer cases among ever cigar smokers were small at 12 for esophageal and 38 for head and neck cancer (Ref. 236). Such small sample sizes, common in cancer studies given the relative rarity of the outcome, can limit the ability to observe a statistical association in the study.

In addition, the World Health Organization (WHO) International Agency for Research on Cancer (IARC) published a monograph evaluating the carcinogenic risk to humans from tobacco smoke and involuntary smoke exposure. The IARC explained: "Cigar and/or pipe smoking is strongly related to cancers of the oral cavity, oropharynx, hypopharynx, larynx, and esophagus, the magnitude of risk being similar to that from cigarette smoking. These risks increase with the amount of cigar…smoking and with the combination of alcohol and tobacco consumption" (Ref. 224).

2. Lung Cancer

The evidence clearly establishes that cigar smoking can cause lung cancer; the risk varies by number of cigars per day and level of exposure (Refs. 32; 183 at 119-120; and 224 at 1180).

A recently published international pooled cohort study found that ever cigar smokers had a statistically significantly elevated risk of lung cancer (Ref. 236).

Like the dose-response relationship between cigar smoking and mouth and throat cancers, the risk of death and disease from lung cancer increases as the number of cigars smoked per day and the depth of smoke inhalation increases (Refs. 32, 183, and 237-239). Overall lung cancer risk for cigar smokers is lower than the overall risk for cigarette smokers (Refs. 229 and 240-243), but the risk of death from lung cancer for cigar smokers may be similar to the risk of death from lung cancer for cigarette smokers (Refs. 32, 229, and 237-242) once the rates are adjusted for differences in inhalation levels and quantity of cigars smoked daily (Ref. 183 at 120). Cigar smokers in the Cancer Prevention Study I (CPS I), conducted from 1959-1972, who smoked five or more cigars daily with moderate inhalation had a similar risk of death from lung cancer as did pack-a-day cigarette smokers (Ref. 183).

Former cigarette smokers who currently smoke cigars are more likely to inhale deeply than cigar smokers who have never smoked cigarettes, increasing their lung cancer risk (Ref. 23, citing Ref. 183). Although cigarette smokers who switch to smoking only cigars have lower lung cancer risks than they would have if they had continued smoking cigarettes, these risks appear to be substantially greater than for individuals who have quit smoking altogether (Refs. 183 at 155; 239; and 240).

Likewise, according to data from the Cancer Prevention Study II (CPS II, a 12-year study of 1.2 million men and women, in which an analysis was conducted on a subset of male participants from 1982 to 1994 who were asked about cigar use), the risk of lung cancer mortality was approximately five times higher for men who were current smokers of only cigars at the start of the followup study period compared with men who never smoked (Ref. 243). In an analysis of a subset of men who participated in the CPS II study, researchers found that men who smoked three or more cigars per day, who reported inhaling cigar smoke, or who had smoked cigars for 25 years or more experienced a statistically significantly greater risk of mortality from

lung cancer than those men who reported less frequent cigar use, not inhaling, and smoking cigars for 25 years or less (Ref. 243). Even male cigar smokers who reported that they did not inhale were approximately three times more likely to die from lung cancer than those who never smoked (Ref. 243).

The type of cigar used also may impact the risk of lung cancer in cigar smokers. One large case-control study found that lung cancer patients had 12.7 times greater odds of being an exclusive cigarillo user than controls, compared to a 5.6 times greater odds of being an exclusive user of cigars other than cigarillos (the study was conducted in Europe, where cigarillos typically weigh 1.5 to 3 grams and traditional cigars weigh 2 to 8 grams) (Ref. 239). This difference was likely due to differences in inhalation, as the researchers found that cigarillo users were more likely to inhale than users of other cigars, and inhalers were at higher risk of lung cancer than noninhalers (Ref. 239). As cigarillo and filtered cigar use has increased (and cigarette use has decreased over this same period) in the United States, it is likely that smokers are using such products as substitutes for cigarettes and inhaling them as they would cigarettes (Refs. 101 and 183). Filtered cigars, for example, share many of the design characteristics of cigarettes (Ref. 49). Therefore, the risk of lung cancer for some cigar smokers may be similar to that for cigarette smokers.

3. Heart Disease and Aortic Aneurysm

Researchers have identified a pattern of elevated rates of death from coronary heart disease and aortic aneurysm among primary cigar smokers who smoke heavily or inhale deeply (Ref. 32). The CPS I (1959-1972), which evaluated nearly one million men and women in 25 states, found that the rate of death from coronary heart disease increases with the number of cigars smoked and the depth of smoking inhalation (Refs. 32 and 183). Researchers also identified an elevated risk of developing coronary heart disease in those individuals who smoked five or more cigars per day and exhibited moderate or deep inhalation (Refs. 32, 183, and 244).

CPS I data also suggest that cigar smokers are at an increased risk for aortic aneurysm, the risk rate approaching that observed for cigarette smokers (Refs. 32 and 183).

Researchers analyzing CPS II data also examined death rates resulting from coronary heart disease related to cigar smoking. The 1999 CPS II reviewed approximately 7,000 current cigar smokers, 7,000 former cigar smokers, and 113,000 men who had never regularly smoked tobacco to determine the risk of heart disease for cigar smokers (Ref. 210). Among men younger than 75 years old, current cigar smokers experienced a coronary heart disease death rate about one-third higher than those who had never smoked (Ref. 210).

Additional studies provide supporting evidence that cigar smokers have elevated rates of developing coronary heart disease compared with nonsmokers (Refs. 229, 241, and 245). One large study examined primary (i.e., current, exclusive with no previous history of cigarette or pipe tobacco use) and secondary (i.e., current, exclusive with previous history of cigarette or pipe tobacco use) cigar smokers compared with never smokers (Ref. 241). It found that both primary and secondary cigar smokers were at increased risk of major coronary heart disease compared to never smokers (Ref. 242). Secondary cigar smokers also had a higher risk of major stroke compared with never smokers (Ref. 241). Primary and secondary cigar smokers had similar risks of major coronary heart disease and stroke and experienced outcomes similar to those who smoked less than a pack of cigarettes per day (Ref. 241). In the recently published NHIS-LMF, current, daily cigar smokers had a non-significantly elevated risk of death due to coronary heart disease compared to never tobacco users (Ref. 228).

In addition, in 2010, the Surgeon General found that for older adult cigar smokers, particularly those who smoke more than one cigar per day or inhale the smoke, the risk of heart disease is moderately higher than that for nonsmokers (Ref. 6). In support of the Surgeon General's findings, one study conducted from 1964 to 1973 involved 17,774 men ranging in age from 30 to 85, of which 1,546 smoked cigars and 16,228 did not, all of whom reported that they had never smoked cigarettes and did not currently smoke pipes (Ref. 229). This study determined

that cigar smoking was associated with a moderate, but statistically significant, increase in the risk of coronary heart disease (Ref. 229).

International researchers have reached similar conclusions about the impact of cigar smoking on the risk of developing heart disease. For example, in a study of more than 12,000 Danish people aged 30 years and older that looked at the risk of first acute myocardial infarction (MI), researchers found the risk of first acute MI escalated with increasing depth of smoke inhalation and with increasing number of cigars smoked per day (Refs. 183 and 244). Another Danish study found the highest rates of myocardial infarction for smokers of cheroots (a type of cigar with ends that do not taper that is traditionally used in India and Burma) to be for those individuals who smoked six or more cheroots per day, with a relative risk of myocardial infarction of more than four times the risk of individuals who had never smoked (Ref. 183, citing Ref. 246).

4. Other Health Outcomes

Research studies have found that cigar smokers have approximately 40 to 45 percent higher risk of COPD than never tobacco users. A cohort study of Kaiser Permanente plan members found a relative risk of COPD diagnosis of 1.45 for cigar (Ref. 229), and CPS I data found a similar elevated relative risk of COPD among primary cigar smokers of 1.42 (Ref. 247).

The risk of bladder cancer in CPS I data was also approximately 40 percent higher for cigar smokers, with a relative risk of 1.38 (Ref. 247). In a recently published study using data from the Agricultural Health Study, ever cigar use was statistically significantly associated with risk of urinary cancer (Ref. 248).

There are other health outcomes attributable to cigar smoking that were not assessed using CPS I or II mortality data. For example, one study found statistically significant increased risks of colon and rectal cancers among cigar smokers in a cohort of nearly 250,000 World War I era veterans who were followed for mortality for 26 years (Ref. 249). While most research has focused on cigar-attributable mortality, limited research has addressed cigar-attributable

morbidity. Besides dying from cigar-attributable disease, lifelong cigar smokers may live many years with serious medical conditions, such as cancers (Refs. 229 and 232), heart disease (Refs. 229 and 245), and increased airflow obstruction (Ref. 124) that can lead to major physical impairments, and substantially reduce functioning and quality of life.

5. Impact on Individuals Who Report that They Do Not Inhale Smoke

Studies suggest that even cigar smokers who do not intend to inhale smoke, and who are unaware they are doing so, nonetheless inhale some amount of cigar smoke (Refs. 124 and 212). While inhaling cigar smoke poses much higher morbidity and mortality rates than not inhaling, substantial risks still exist for those cigar smokers who may not intentionally inhale smoke. Relative mortality risks for oral, esophageal, and laryngeal cancers are high even among those primary cigar smokers who reported that they do not inhale cigar smoke (Ref. 32; see Refs. 183, 230, and 247). Researchers found that the risk of stomach cancer mortality was also higher among cigar users who reported they did not inhale smoke when compared to individuals who did not use tobacco products (Ref. 250). Regardless of whether cigar smokers inhale, they are still subject to cigars' addictive and other adverse health effects through absorption of nicotine and other harmful constituents, including those discussed in section V.B of this document (Refs. 212 and 250). Buccal absorption of nicotine occurs even if cigar smoke is not inhaled, and cigar smokers may also absorb nicotine through the lips due to the alkalinity of cigar tobacco (Refs. 214 and 215). This greater nicotine yield and absorption increases the risk of nicotine addiction from cigar smoking.

E. Secondhand Tobacco Smoke, Including Cigar Smoke, Increases the Risks of Lung Cancer, Heart Disease, and Other Adverse Health Effects in Nonsmokers

Tobacco smoke inhaled by nonsmokers in indoor and outdoor spaces is most commonly referred to today as "secondhand smoke" but has also been referred to as "environmental tobacco smoke," "passive smoke," or "involuntary smoke." Extensive data exist regarding the dangers of involuntary exposure to tobacco smoke. It is well established that exposure to secondhand

tobacco smoke causes premature death and disease in youth and adults who do not smoke (e.g., Refs. 251 and 252). Exposure to secondhand smoke has immediate adverse effects on the cardiovascular system and can cause lung cancer, coronary heart disease, and stroke (Ref. 251). By reducing the prevalence of cigar smoking, this proposed standard also has benefits for those who do not use cigars.

Tobacco smoke contains over 7,000 compounds, and cigars generate more than 50 carcinogens in mainstream and sidestream smoke (Refs. 23, 183, and 251). Mainstream cigar smoke is the smoke one draws into the mouth from the butt end or mouthpiece of a cigar; sidestream cigar smoke is the smoke emitted from the burning cone of a cigar during the interval between puffs (Ref. 183). Secondhand smoke is a combination of sidestream smoke and exhaled mainstream smoke.

While the above data on secondhand smoke are related to cigarettes, evidence supports the conclusion that these data apply to secondhand cigar smoke, as well, and there is no basis to conclude that secondhand smoke from cigars is any less hazardous than secondhand smoke from cigarettes. Cigar smoke contains the same toxic substances as cigarette smoke, with varying concentrations of these constituents found in different cigar types and sizes (Ref. 183). Even though, on average, tobacco users smoke more cigarettes than cigars, the overall level of toxicants in secondhand smoke from cigars can be quantitatively higher than in the secondhand smoke from cigarettes (Ref. 183). Cigars also produce much higher levels of many indoor pollutants than cigarettes, which can be explained, at least in part, by the larger size of cigars and therefore greater amount of tobacco burned compared to cigarettes (Ref. 183). The smoke from one cigar can take 5 hours to dissipate, exposing household members to a considerable involuntary health risk (Ref. 183).

1. Lung Cancer and Secondhand Smoke

Exposure of nonsmokers to secondhand tobacco smoke has been shown to cause a statistically significant increase in urinary levels of metabolites of tobacco-specific nitrosamines,

which are carcinogens that specifically link exposure to secondhand smoke with an increased risk for lung cancer (Ref. 251). Studies in rodents have demonstrated that 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone specifically induces lung tumors by systemic administration, which provides support that nitrosamines are major factors in the development of lung cancer (Ref. 251). According to the Surgeon General, there is sufficient evidence from which to infer a causal relationship between secondhand tobacco smoke exposure and lung cancer among lifetime nonsmokers (Ref. 251). Individuals living with smokers had a 20 to 30 percent increase in the risk of developing lung cancer from secondhand smoke exposure, compared with individuals living with nonsmokers (Ref. 251). Based on the similarity of the toxic constituents in cigars and cigarettes, and the fact that cigars commonly share similar product design and mechanisms of smoke delivery as cigarettes, FDA's scientific judgment leads the Agency to expect that secondhand cigar smoke would produce effects similar to those produced by secondhand cigarette smoke. According to the World Health Organization's International Agency for Research on Cancer, a mass balance model developed for predicting secondhand tobacco smoke was used to obtain CO, respirable suspended particle, and PAH emission (Ref. 224). These observed factors demonstrated that cigars can be more potent sources of CO than cigarettes (Ref. 224). The study also demonstrated that although a single cigar may have lower emissions of respirable suspended particles and PAHs per gram of tobacco consumed than a cigarette, a cigar's larger size and longer smoking time results in greater total respirable suspended particles and PAH emission than a single cigarette (Refs. 224 and 253). Findings from the NCI Tobacco Control Monograph No. 9 also demonstrate that carcinogens linked to lung cancer would be expected to be present at comparable levels in cigar and cigarette smoke (Ref. 183). Little cigars with filter tips and regular cigars contain higher levels of certain nitrosamines in sidestream smoke than do filtered tip cigarettes (Ref. 183).

2. Heart Disease and Secondhand Smoke

The evidence cited in Surgeon General's Reports supports the conclusion that secondhand tobacco smoke exposure can cause heart disease and stroke. Although the research examining the effects of exposure specific to secondhand cigar smoke is more limited compared to cigarettes, evidence from a recently published study suggests that the risk of experiencing negative cardiovascular effects due to secondhand cigar smoke exposure is similar to the risk from secondhand cigarette smoke exposure (Ref. 254). It is reasonable to anticipate that the cardiovascular risks from secondhand cigar smoke would be similar to those of secondhand cigarette smoke due to the similar smoke profiles for cigars and cigarettes, the excess risk of coronary heart disease associated with active cigar smoking, and the low levels of toxicant exposure that can cause coronary heart disease (Ref. 251).

In a 2006 report regarding the health effects of exposure to secondhand tobacco smoke, the Surgeon General concluded that exposure to secondhand tobacco smoke had immediate adverse effects on the cardiovascular systems and caused coronary heart disease (Ref. 251). The estimated increase in coronary heart disease risk from exposure to secondhand tobacco smoke is 25 to 30 percent above that of unexposed individuals (Ref. 251). Based on these data, the Surgeon General concluded that "the evidence is sufficient to infer a causal relationship between exposure to secondhand smoke and increased risks of coronary heart disease morbidity and mortality among both men and women" (Ref. 251).

3. Other Health Problems

Studies have concluded that secondhand tobacco smoke can cause other health problems, specifically for youth. Secondhand smoke exposure has been independently linked to increased inflammatory responses, oxidative stress, and endocrine disruption in youth (Refs. 255-257). Children exposed to secondhand smoke are also at an increased risk of sudden infant death syndrome, acute respiratory infections, ear problems, and more severe asthma (Ref. 23). In addition, smoking by parents can cause respiratory symptoms and slower lung growth in their children as compared to the children of non-smoking parents (Ref. 23). It is expected that these

health effects would apply to secondhand cigar smoke exposure specifically, given the stated similarities between cigar smoke and other forms of tobacco smoke.

For all of these reasons and based on extensive evidence, it is clear that cigar use causes severe negative health consequences among users and nonusers. As discussed in section VI of this document, this proposed rule, if finalized, would help to prevent experimentation with cigars and progression to regular use, and increase cessation among current users, which would help to lessen the incidence of cigar-related negative health consequences.

F. Disparities in Tobacco Use, Including Cigar Use, Lead to Disparities in Tobacco-Related Morbidity and Mortality

As previously discussed, cigar smoking exposes users to the same toxic and carcinogenic compounds identified in cigarette smoke and is associated with many of the same health risks as cigarette smoking. As such, this section discusses the evidence to support how disparities in tobacco use shape disparities in tobacco-related morbidity and mortality. While the prevalence of cigar use has decreased over time for non-Hispanic White persons, data from the 2002-2016 NSDUH show that cigar use has remained stable for non-Hispanic Black persons (aged 12 years and older) (Ref. 162), while 2000-2015 NHIS data show increased prevalence for non-Hispanic Black adults (aged 18 years and older) (Ref. 258). In addition, differences in cessation and quit attempts have been observed across population groups. Despite more attempts at quitting, Black cigarette smokers are less successful at quitting than White and Hispanic cigarette smokers (Refs. 38, 259, and 260). While less is known about disparities in cigar cessation, findings from 2013-2016 PATH data indicate that non-Hispanic Black cigar users had lower odds of discontinuing cigar use than non-Hispanic White users (Ref. 261). Collectively, these factors contribute to the disparities in tobacco-related health outcomes. While the etiology of chronic health conditions is multifactorial in nature, smoking has been found to be an important causal factor (Ref. 23) African American adults, and in particular African American men, experience the highest rates of incidence and mortality and lowest rates of survival from many tobacco-

related cancers, such as lung and bronchus cancer and head and neck cancer, compared to those from other racial and ethnic groups (Refs. 262 and 263). Deaths from other tobacco-related conditions such as heart disease, stroke, and hypertension are higher among African Americans compared to other racial and ethnic groups (Refs. 264-269).

The higher levels of flavored cigar use among non-Hispanic Black cigar users exacerbate already-existing health disparities experienced by the Black community (Refs. 163 and 270). Levels of nicotine and other carcinogens in cigars may be higher than those in cigarettes and may be at levels that lead to increased risk of morbidity and mortality from conditions such as cancer, cardiovascular disease, and COPD (Refs. 3, 32, and 210).

Additionally, American Indians or Alaskan Natives (AI/ANs) have the highest prevalence of overall tobacco use compared to members of other racial and ethnic groups (Refs. 37, 38, 68, and 271). Prevalence of cigar smoking among AI/ANs is lower than prevalence among Blacks, but higher than among Hispanics and Asians (Ref. 271). It is well documented that AI/ANs suffer disproportionately from both lung cancer and cardiovascular diseases (Refs. 272 and 273). An analysis of 2001-2009 mortality data for people living in the Indian Health Service Contract Health Service Delivery Area counties in the United States indicated that age-adjusted death rates, smoking-attributable fractions, and smoking-attributable mortality for all-cause mortality were statistically significantly higher among AI/AN populations than among Whites for adult men and women aged 35 years and older (Ref. 274). Cigarette smoking caused 21 percent of ischemic heart disease, 15 percent of other heart disease, and 17 percent of stroke deaths in AI/AN men, compared with 15 percent, 10 percent, and 9 percent, respectively, for White men (Ref. 274). Among AI/AN women, smoking caused 18 percent of ischemic heart disease deaths, 13 percent of other heart diseases deaths, and 20 percent of stroke deaths, compared with 9 percent, 7 percent, and 10 percent, respectively, among White women (Ref. 274).

Disparities in tobacco-related morbidity and mortality have also been observed for other population groups that have higher levels of tobacco use. Those with low household income and educational attainment bear a disproportionate burden of heart disease and stroke incidence and mortality (Refs. 275 and 276). National Health and Nutrition Examination Survey (NHANES) data from 2007 to 2010 indicate that prevalence of co-occurring obesity and smoking was linearly associated with educational attainment as women with the lowest levels of education had greater likelihood of being obese smokers than women with the highest levels of education (Ref. 277). Research has also demonstrated that individuals with behavioral health conditions and other medical comorbidities have higher prevalence of combusted tobacco use compared to those without these conditions (Refs. 167 and 278) and have increased risk of tobacco-related morbidity and mortality (Refs. 23, 279, and 280). Inpatient hospital admission data from 1990 to 2005 from California indicate that approximately half of the deaths in those who had been hospitalized for schizophrenia, bipolar disorder, or major depressive disorder were due to diseases causally linked to tobacco use (Ref. 279) and that the majority of deaths for those hospitalized for opioid-related conditions were related to tobacco and alcohol, not to opioids (Ref. 281). In a study of 470 unhoused individuals, the analysis found that past 30-day use of all tobacco products was high and that 74.0 percent of respondents reported use of cigars and over half (55 percent) reported use of flavored cigars in the past 30 days (Ref. 166). Tobacco-related cancers are a leading cause of death among adults experiencing homelessness (Ref. 165).

Additionally, the burden of secondhand smoke exposure is experienced disproportionately among members from some racial and ethnic groups and people from lower household income and educational attainment backgrounds. Among nonsmokers ages 3 and older, findings from 2011-2018 NHANES data indicate that non-Hispanic Blacks 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. 282). From 1999 to 2012,

the percentage of the nonsmoking population ages 3 and older with detectable serum cotinine levels (defined in the study as levels ≥0.05 ng/mL to indicate secondhand smoke exposure) declined across all racial and ethnic groups (Ref. 283). However, a 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. 283).

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. 183). 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. 284). 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. 285). While secondhand smoke exposure in homes and vehicles declined from 2011 to 2018, secondhand smoke exposure in homes among non-Hispanic Black students did not change (Ref. 285). Home smoking bans (i.e., 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 and annual household income were associated with the higher reporting of a complete home ban as compared to lower levels of parental educational and annual household income (Ref. 286). Such findings are consistent with a higher degree of autonomy over the 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. 287). 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. 287).

The disparities observed in tobacco and cigar use, as well as disparities in secondhand smoke exposure, contribute to the disparities in tobacco-related morbidity and mortality experienced by some population groups. This proposed product standard is anticipated to reduce smoking-related morbidity and mortality for these vulnerable populations.

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

The Tobacco Control Act authorizes FDA to adopt tobacco product standards by regulation if it finds that a tobacco product standard is appropriate for the protection of the public health (section 907(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 it would reduce the appeal of cigars, particularly to youth and young adults, thereby decreasing the likelihood both that nonusers would experiment with cigars and that current and future experimenters would continue to use cigars, develop an addiction to nicotine, and progress to regular use of cigars and/or other tobacco products. Additionally, FDA anticipates that the proposed standard would improve the health of some current smokers of flavored cigars by increasing the likelihood of cessation. Decreased experimentation, progression to regular use, and consumption would lead to lower disease and death in the U.S. population, including in certain populations that are disproportionately marketed to and bear a disparate burden of tobacco-related morbidity and mortality. In addition, the population as a whole would likely experience health benefits based on a likely decrease in morbidity and mortality resulting from secondhand smoke exposure.

A. The Likelihood That Nonusers Would Start Using Cigars

Flavors are a significant driver for youth and young adults to try cigars. In section IV of this document, we summarize evidence from multiple study designs, incorporating findings from qualitative research, and nationally representative cross-sectional and longitudinal observational studies that illustrate the appeal of flavored cigars among young people and the role characterizing flavors play in experimentation and continued cigar use. In this section, we discuss how, given this evidence and findings from policy evaluations of local and national jurisdictions, FDA expects the proposed standard on characterizing flavors (other than tobacco) in cigars would decrease experimentation and progression to regular use of cigars among current nonusers.

Youth and young adults consistently identify the availability of characterizing flavors as a leading reason for their cigar use (Refs. 64 and 65). In 2018-2019, 50.4 percent of youth (aged

12-17 years) participants in the PATH Study who reported past 30-day cigar smoking identified flavors as a reason for use (Ref. 12). Four systematic reviews of the scientific literature concluded that flavored tobacco products attract youth to the tobacco product (Refs. 86-89). Two of the reviews that included discussion of cigars concluded that characterizing flavors were an appealing feature of tobacco products and that flavors influence perceptions, initiation, and progression to use of tobacco products, particularly among youth (Refs. 88 and 89). Similarly, results from qualitative research indicate that youth and young adults themselves acknowledge that flavorings impact their cigar use, making smoking flavored cigars more palatable than smoking non-flavored cigars (Ref. 82). The appeal of flavors is also consistent with physiological studies assessing youth preference for flavors, including studies assessing the similarities between flavor chemicals in tobacco products with drink mixes and candy (Refs. 95 and 96). Overall, the literature is consistent on the appeal of flavors in tobacco products, including cigars (see section IV.D of this document). Diminishing the appeal of cigars by prohibiting the use of characterizing flavors (other than tobacco) is, therefore, appropriate for the protection of the public health, as it would decrease the likelihood of experimentation at younger ages and reduce the potential for onset of tobacco dependence during the progression to regular tobacco use. Furthermore, flavored cigar use exposes users to more toxicants than are present in non-flavored cigars and there is no evidence that flavored cigars present any countervailing benefits to public health.

Experimentation with cigars can lead to nicotine dependence and regular use, as discussed in section IV.E of this document. Based on nationally representative Truth Longitudinal Cohort data from 2014 to 2019, 44.7 percent of youth and young adults (aged 15-25 years) who initiated cigar use reported current (i.e., past-30-day) cigar use 6 months after initiation (Ref. 100). When trying a cigar for the first time, the majority of youth cigar smokers report that the first cigar they used was flavored. Data from Wave 5 (2018-2019) of the PATH Study revealed that 60.4 percent of youth (aged 12-17 years) and 63.2 percent of young adults

(aged 18-24 years) who reported ever using cigars said that the first cigar they used was flavored (Ref. 12).

Using nationally representative longitudinal data from Waves 1 (2013-2014) and 2 (2014-2015) of the PATH Study, one study found that first use of a flavored cigar was associated with more likely subsequent cigar use 1 year later compared to first use of a non-flavored cigar in young adults (aged 18-24 years) and adults (aged 25 years and older) (Ref. 28). This analysis was extended using Waves 1-4 (2013-2017) of PATH Study data to assess the relationship between new use of a menthol- or mint-flavored cigar or other flavored (e.g., fruit, alcohol, chocolate, candy, and other flavor) cigar with subsequent use compared to first use of a non-flavored cigar. The analysis found that among youth (aged 12-17 years) and young adults (aged 18-24 years), first use of any menthol- or mint-flavored or other flavored cigar was associated with current past 30-day use of flavored cigars at a later wave compared with first use of a non-flavored (i.e., tobacco) cigar (Ref. 29). Specifically, youth who used a menthol/mint-flavored cigar or other flavored cigar were 72 percent (menthol/mint) and 47 percent (other flavor) more likely, respectively, to be using a cigar a year or more later compared to those first using a non-flavored cigar. Similarly, young adults (aged 18-24 years) who used a menthol/mint-flavored cigar or other flavored cigar were 71 percent (menthol/mint) and 52 percent (other flavor) more likely to be using a cigar a year or more later compared to those first using a non-flavored cigar. For both youth and young adults, the association between the first flavor used and subsequent cigar use was not statistically significantly different for menthol- or mint-flavored compared to other flavored cigars. These results are consistent with the evidence that flavors enhance the addictive effects of nicotine and make cigars easier to use, as discussed previously. FDA finds that eliminating flavored cigar varieties likely would decrease the number of youth and young adults experimenting and progressing to regular, sustained use of cigars.

Given that nicotine is highly addictive and present in all cigars, as experimenters continue to use these products, there is a risk of development of nicotine dependence and progression to

regular use. Several studies found that cigars reduce craving and urge to smoke similar to cigarettes (Refs. 101-103). The adolescent brain is more vulnerable to developing nicotine dependence than the adult brain. Nicotine can disrupt brain development and have long-term consequences, including decreasing attention and increasing impulsivity, which could promote the maintenance of nicotine use behavior (Ref. 288). Therefore, progressing to regular use during adolescence can have lasting consequences and signs of nicotine dependence are evident in young cigar users. Researchers analyzing data from the 2017-2018 NYTS found that 43.1 percent of middle and high school students using cigars in the past 30 days reported nicotine dependence, including feeling a strong craving to use a tobacco product or using a tobacco product within 30 minutes of waking (Ref. 107). 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 cigar experimentation among youth and young adults in the United States.

It is also important to note the role that cigars play in polyuse patterns, and the subsequent development of dependence, among youth tobacco users. As polyuse increases, youth exposure to nicotine increases (Ref. 17), increasing the risk of dependence among young people (Refs. 181 and 182). When looking at the association between cigar use and dependence, exclusive use of cigars among youth in the 2017-2018 NYTS was associated with lower odds of nicotine dependence relative to exclusive use of another tobacco product. However, when youth cigar use included polyuse, which was more common for youth cigar users, current cigar use was associated with twice the odds of nicotine dependence compared to current use of any other tobacco product (Ref. 107). See section V.A.3 of this document for additional discussion regarding polyuse.

Similar to cigarette smoking, first cigar use often occurs during youth or young adulthood (Refs. 24 and 25). A longitudinal analysis of Waves 1-4 (2013-2017) of PATH Study data found

an increasing probability of initiating cigar use between ages 15 and 20 years, with the greatest increase in first use between 17 and 18 years of age (Ref. 25).

FDA expects a substantial reduction in youth and young adult initiation and progression to regular use of cigars, which would ultimately protect many youth and young adults from a lifetime of addiction, disease, and death attributable to cigar smoking. There are multiple sources of evidence to inform the Agency's analysis of how the proposed standard would affect the likelihood that nonusers would start to experiment and continue using cigars (Refs. 28, 29, and 100). First, many individuals who initiate cigar use transition to more regular use. One analysis of data from a nationally representative cohort found that 44.7 percent of youth and young adults who initiated cigar use became a regular user 6 months after first trying a cigar (Ref. 100). Next, several studies suggest that when individuals initiate cigar use, it is often with a flavored product. PATH researchers found that 60.4 percent of youth (aged 12-17 years) and 63.2 percent of young adults (aged 18-24 years) who reported ever using cigars said that the first cigar they used was flavored (Ref. 12). Lastly, analyses of PATH data also suggest that initiation with a flavored cigar is associated with a greater likelihood of progressing to regular use compared to initiation with a non-flavored cigar. In a cross-sectional analysis of the PATH study, young adult (aged 18-24 years) and adult ever tobacco users (aged 25 years and older) who initiated with a flavored cigar were more likely that those who initiated with a non-flavored cigar to be a current regular cigar user, after controlling for demographics, education, income, age at first tobacco use, substance use, and mental health indicators (Ref. 289). In a longitudinal analysis using Waves 1 to 4 (2013-2017) of PATH Study data, youth and young adults who used a mint or menthol cigar or other flavored cigar were more likely to be past-30-day cigar users at a subsequent wave compared to those first using a non-flavored cigar, after controlling for sociodemographics (Ref. 29). Together these study results indicate that experimentation with cigars is associated with progression to regular use, the majority of youth and young adults who initiate cigar use do so with flavored cigars, and initiating with flavored cigars (compared to non-flavored cigars) is

associated with an increased risk of current and ongoing tobacco use, as compared to experimentation with non-flavored cigars. To the extent that youth and young adult cigar users using a flavored cigar on their first use would not otherwise initiate with non-flavored cigars or other tobacco products, the proposed standard would prevent future tobacco-related disease and death among these youth and young adults.

In addition to longitudinal studies illustrating the role of flavors in youth and young adults progressing from experimenting with flavored cigars to regular use, policy evaluations from local jurisdictions throughout the United States illustrate how a flavor restriction can decrease youth cigar use. Section IV.F of this document discusses results from evaluation studies of restrictions on the sale of tobacco products with characterizing flavors in jurisdictions throughout the United States and in Canada. Studies of policies implemented in Providence, RI; New York, NY; Lowell, MA; Attleboro and Salem, MA; Minneapolis and St. Paul, MN; San Francisco, CA; and Canada focused on the impact of flavored tobacco sales restrictions on youth use of tobacco products, including cigars and are informative to FDA's consideration of how the proposed standard would impact the likelihood of tobacco use among youth.

In Providence, RI, at 3 years and 5 years following implementation of the city's restriction on flavored tobacco products except menthol, mint, and wintergreen, youth current use of any tobacco product had declined, from 22.2 percent in 2016 to 12.1 percent in 2018; and current use of cigars/cigarillos had declined from 7.1 percent in 2016 to 1.9 percent in 2018 (Ref. 60). Three years after implementation of a restriction on flavored tobacco products except menthol, mint, and wintergreen, in NYC in 2010, youth (13-17 years) had 37 percent lower odds of reporting having ever tried a flavored tobacco product, and 28 percent lower odds of ever using tobacco products in 2013 compared to 2010 (Ref. 51). Six months after enacting a restriction on flavored tobacco products except menthol in 2016, researchers in Lowell, MA, found that youth current use of any flavored tobacco products decreased in Lowell from baseline to followup (-2.4 percent), with a statistically significant difference between Lowell and an

observed increase in flavored tobacco use in the comparison community (3.3. percent) (Ref. 61). In the Twin Cities, MN, two cross sectional studies were administered before and after implementation of a restriction on flavored tobacco products first excluding menthol, mint, and wintergreen in 2016 and then after the policy was expanded to include menthol, mint, and wintergreen in 2018 (Ref. 111). Comparing the two cities to the rest of the State, the study found that when the first policy was implemented the prevalence of cigar use did not change in the Twin Cities among 6th to 12th grade students, but cigar use increased 71.3 percent in the rest of the State. The analysis also found that between 2016 and 2019, when the flavor restriction also included menthol, cigar use among 8th, 9th, and 11th grade students declined more in the Twin Cities compared to the rest of the State (Ref. 111). In San Francisco, CA, following implementation of the city's restriction on flavored tobacco products, including menthol, among a small convenience sample of young adults ages 18 to 24 years surveyed after policy implementation there was a statistically significant decrease in flavored cigar use (from 19.4 to 6.5 percent) (Ref. 62). An evaluation of a national flavored tobacco policy in Canada that restricted flavored tobacco products except menthol cigarettes and cigars under 1.4 grams (or in any cigar that had a filter or non-spiral wrap) is consistent with local flavored tobacco policies in the United States regarding decreased use of cigars among young people and found a statistically significant 2.3 percentage point decrease in past 30-day cigarillo use among young people aged 15 to 24 years 1 year after policy implementation (Ref. 113). Most of these studies of local flavored tobacco policies in the United States describe concerns with compliance and enforcement of the policies, noting potential increases in cross-border sales and observed retail sales of flavored product in defiance of implemented policies. FDA anticipates that a nationwide standard that prohibits the manufacture and sale of flavored cigars would likely have a greater impact in decreasing youth cigar 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 for youth to easily travel to neighboring jurisdictions that do not have a flavor prohibition or use online retailers to purchase flavored cigars.

As described in section IV.B of this document, an estimated 960,000 youth reported past 30-day use of cigars in 2020, with an estimated 550,000 youth, reported using a flavored cigar during the past 30 days (Ref. 8). Given the measured decrease in youth tobacco use consistent across U.S. localities that have recently implemented restrictions on the sale of flavored tobacco, FDA expects that many of these youth would be discouraged from continued experimentation with cigars as a result of the proposed standard. In contrast to the locality restrictions discussed previously, FDA's proposed product standard would result in a comprehensive regulation restricting both the manufacturing and sale of cigars with characterizing flavors in the United States. Evaluations of retailer compliance following implementation of local flavor restrictions suggest that incomplete compliance led to availability of violative products in retail environments, which likely diminished the impact of the restrictions (Refs. 108 and 109). Unlike a restriction on sales alone, the proposed standard would prohibit both the manufacture and sale of cigars with characterizing flavors (other than tobacco), and as a result, it would allow for a more complete prohibition of flavored cigar products from the market. It is therefore likely that the impact of the FDA product standard on youth and young adult cigar smoking would be greater than that observed among the evaluation studies discussed previously.

In summary, across varying study populations and research study designs, evidence shows that the presence of characterizing flavors in tobacco products enhances the appeal of tobacco products to young people and is associated with experimentation and progression to regular tobacco use. Characterizing flavors also can activate the brain's reward circuit and reinforce tobacco use. Prohibiting characterizing flavors (other than tobacco) in cigars would eliminate rewarding and reinforcing associations with the product among youth and would result in a marketplace that solely consists of (mostly already existing) cigar products that have harsher, more astringent cigar smoke that are likely less appealing to novice users. Evidence

from five U.S. localities and Canada consistently indicate that prohibiting sales of flavored tobacco decreased youth and young adult use of tobacco, including cigars. In nationally representative estimates, most youth and young adults report initiating use with a flavored cigar (Ref. 12). In addition, results from a large national study observed a relationship between first use of a flavored cigar and regular cigar use in youth and young adults (Refs. 28 and 29). Therefore, a prohibition on characterizing flavors (other than tobacco) in cigars would reduce the likelihood that youth and young adults would initiate cigar use and also mean fewer youth and young adults progressing to regular cigar use. For these reasons, FDA expects that prohibiting characterizing flavors as described in this proposed rule would reduce the likelihood that youth would experiment with and continue to use cigars and would ultimately reduce future disease and death associated with long-term cigar smoking.

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

FDA expects that the prohibition of characterizing flavors (other than tobacco) in cigars, as proposed, would result in changes in tobacco use patterns among current smokers of flavored cigars. In addition to the long-term public health benefits that would accrue from the prevention or reduction of cigar smoking among youth and young adults, FDA anticipates that the proposed standard would increase the likelihood that some existing flavored cigar smokers would find tobacco-flavored cigars unappealing and consequently stop smoking cigars altogether, yielding health benefits from smoking cessation. For instance, current flavored cigar smokers may quit cigar use altogether, transition to tobacco-flavored cigars or other combusted tobacco products, or switch to other potentially less harmful tobacco products. Given the substantial proportion of existing cigar users using flavored cigars, the consistently high endorsement of characterizing flavors as a reason for use, empirical evidence of lower tobacco sales (as a proxy for consumption) following a flavored tobacco product restriction in multiple localities, and evidence suggesting decreased cigar use among adult consumers following implementation of

flavor restrictions in two studied localities, FDA expects that the proposed standard would lead many flavored cigar smokers to reduce or stop using cigars.

In section IV.D of this document, we discussed how the addition of characterizing flavors improves the taste of tobacco and decreases the harshness of tobacco smoke. While the evidence shows that use of flavored tobacco products, including flavored cigars, is particularly concerning among youth and young adults, millions of adults report using flavored tobacco products (Ref. 63). According to Wave 5 (2018-2019) data from the PATH Study, among young adult past 30-day cigar smokers 18-24 years old, 38.3 percent reported that the cigar product they smoked in the past 30 days was flavored (Ref. 63). Similarly, among adult cigar smokers aged 25 years and older, 36.0 percent reported past 30-day use of a flavored cigar (Ref. 63). Many adult cigar consumers consistently identify the availability of characterizing flavors as a reason for their cigar use. An analysis of Wave 5 (2018-2019) PATH Study data indicated that among young adults (aged 18-24 years) who used cigars some or every day, 54.1 percent of traditional cigar users, 66.5 percent of cigarillo users, and 65.1 percent of filtered cigar users reported flavoring as a reason for cigar use (Ref. 12). Similarly, among adults over 25 years old who used cigars every or some days, 54.8 percent of traditional cigar users, 69.6 percent of cigarillo users, and 71.4 percent of filtered cigar users reported flavoring as a reason for cigar use (Ref. 12). There was not a statistically significant difference by age group in reporting flavors as a reason for use (Ref. 12). In totality, such data from large national observational studies show that the availability of flavors is a contributing factor to young adult and adult cigar use. In addition, proprietary data gathered by Euromonitor International in March 2021 reveals that, in 2020, flavored cigars accounted for nearly half of all cigar sales in the United States (41.9 percent).

Data from three U.S. localities (Providence, RI; New York, NY; and San Francisco, CA)[18] as well as Canada provide real-world evidence of the potential behavioral impacts the

[18] Study data from the Twin Cities, MN, Lowell, MA, and Attleboro and Salem, MA, only looked at youth use and not sales data and thus is not included in this aspect of the discussion.

proposed product standard could have on cigar sales as a proxy for consumption with two localities (San Francisco, CA, and Canada) providing additional data suggesting a decline in cigar use among current cigar smokers. In Providence, following implementation of the city's restriction on flavored tobacco products, except menthol, mint, and wintergreen, there was a 31 percent decrease in total cigar sales of flavored and unflavored cigars and a 51 percent decrease in average weekly sales of flavored cigars in Providence following policy implementation (Ref. 109). Sale of explicit flavor-named cigars (e.g., cherry) declined after policy implementation while concept flavor-named cigars (e.g., "jazz") increased (Ref. 109). However, the increase in sales of concept flavor-named cigars did not completely offset the decrease in explicit flavor-named cigars (Ref. 109).

In New York, following implementation of a restriction on flavored tobacco products except menthol, mint, and wintergreen, in NYC in 2010, researchers found that the flavor restriction was associated with an approximate 15 percent to 20 percent reduction in total cigar sales in NYC, relative to the proximal area (Ref. 108). Flavored cigar sales in NYC declined 28 percent while sales of flavored cigars increased in the 10 non-NYC comparison counties surrounding the city (+3.2 percent) pre-post policy implementation (Ref. 108).

In San Francisco, CA, following implementation of the city's restriction on flavored tobacco products, including menthol, sales of flavored tobacco products overall and of flavored cigars specifically decreased a statistically significant 96 percent from the pre-policy period and overall cigar sales decreased a statistically significant 51 percent (Ref. 52). There was a statistically significant decrease in the prevalence of flavored cigar use in a small convenience sample of young adults aged 18 to 34 years who used tobacco products prior San Francisco's restriction (Ref. 62). In Canada, following implementation of a national flavored tobacco policy that restricted flavored tobacco products except menthol cigarettes and cigars under 1.4 grams (or in any cigar that had a filter or non-spiral wrap), cigar sales decreased when comparing 6 years before policy enactment to 6 years after enactment (Ref. 112). In addition, following

Canada's restriction on flavored cigarillos, young people aged 15 to 24 reported a significant increase in past 30-day abstinence in cigarillo use among prior cigarillo smokers (Ref. 113).

The findings from evaluations in these three U.S. localities and Canada, drawing on both changes in sales data as well as behavioral changes, including increased abstinence in use of cigars among previous smokers as discussed in this section, are applied by FDA to inform our conclusions about the extent to which flavored cigar smokers would quit smoking cigars under the proposed standard. The findings from Canada also, as discussed in section IV.F of this document, help to support these conclusions by FDA regarding the impact of the proposed standard on current cigar smokers. These data provide evidence of the general behavioral responses we would expect to see in response to the proposed standard; however, we acknowledge there are limitations to these findings. These limitations include a reliance on aggregate tobacco sales information as a proxy for consumption, rather than data concerning individual-level tobacco use behaviors; the potential that smokers obtained flavored cigars through alternate means (e.g., internet sales) or switched to non-cigar products, which may have resulted in an overestimation of the impacts; and evidence of incomplete compliance with the restriction and exemptions for some retail establishments (e.g., tobacco bars), which may have resulted in an underestimation of the impacts of the prohibition. In addition, evidence from the evaluations of the impact of local restrictions on the sale of flavored tobacco products suggest that enforcement of such restrictions was not complete (see Refs. 108 and 109). Therefore, the estimated effect of local restrictions on flavored cigars may underestimate the effect of the proposed flavor standard since such standard would apply to cigar manufacturers as well as retailers, thus reducing the probability that violative products would make their way onto store shelves. Despite these limitations in generalizing findings from local jurisdictions, these real-world evaluations provide important insight into how sales and tobacco use change in response to restrictions on flavored tobacco products, including cigars. These evaluation studies provide important insight into how the proposed prohibition on characterizing flavors (other than

tobacco) in cigar products could reduce the rate of youth and young adult experimentation and progression to regular tobacco use and increase cessation among current cigar smokers.

Additionally, the proposed product standard is anticipated to promote the public health by addressing the disproportionate burden of cigar use among current users from vulnerable populations and promoting better health outcomes within those groups. As described in section V.A of this document, compared to non-Hispanic White adults, non-Hispanic Black adults are more likely to report that they have ever been a "fairly regular" cigar smoker and to report that they smoke cigars daily (Ref. 163). Hispanic adults are more likely to smoke cigars within 30 minutes of waking than non-Hispanic White adults (Ref. 162). Adults who identify as LGBTQ+ are more likely to use tobacco products and to meet the criteria for nicotine dependence when compared to their heterosexual and cisgender peers with findings being more pronounced for some racial and ethnic groups such as LGBTQ+ persons who are Hispanic and non-Hispanic Black (Refs. 68, 157, 159, 160, and 170-173). As described in section V.F of this document, disparities in cigar use likely contribute to the disproportionate burden of tobacco-related morbidity and mortality that are observed for some population groups. For example, findings from 2013-2016 PATH data indicate that non-Hispanic Black cigar users had lower odds of discontinuing cigar use than non-Hispanic White users (Ref. 261); additionally, while cigar use has decreased over time for non-Hispanic White adults, the data indicate that cigar use has remained stable or increased for non-Hispanic Black adults over time (Refs. 162 and 179). African American adults experience some of the highest rates of morbidity and mortality from tobacco-related disease such as heart disease, stroke, and hypertension (Refs. 264-269), which may be attributed to the disproportionate levels of cigar use observed within that population. Based on these findings, the proposed product standard is anticipated to benefit the population as a whole by addressing disparities associated with cigar use, dependence, cessation, and, thus, tobacco-related morbidity and mortality.

The sum of the available evidence, including the current use of flavored cigars by millions of Americans, the consistently high acknowledgement of characterizing flavors as a reason for using cigars among youth and adults, and the empirical evidence of lower tobacco sales (as a proxy for consumption) and tobacco use prevalence data following flavored tobacco product restrictions in multiple U.S. jurisdictions as well as Canada, supports FDA's finding that the proposed product standard would lead many flavored cigar smokers to stop using combusted cigars, yielding considerable health benefits.

C. Benefits and Risks to the Population as a Whole

As discussed in section IV.D of this document, the presence of characterizing flavors enhances the appeal and ease of cigar use among youth and young adults. We expect that the proposed product standard, if finalized, would reduce tobacco-related harms by reducing this appeal and ease of use. Anticipated reductions in population harm would be realized through both long-term health benefits resulting from prevention of cigar uptake among youth and young adults as described in section VI.A of this document, as well as more immediate health benefits (e.g., improved breathing) resulting from increased cessation of cigar use among current flavored cigar smokers, as described in section VI.B of this document. In this section, we summarize the health effects of cigar smoking and describe analyses used to demonstrate anticipated population health benefits from the proposed standard in terms of decreased initiation and progression to regular use and decreased mortality attributable to cigar smoking in the United States.

Additionally, the proposed product standard is anticipated to improve health outcomes in populations that have historically experienced tobacco-related health disparities related to flavored tobacco product use and, specifically, flavored cigar use. As described in section IV.G of this document, tobacco companies have strategically marketed flavored cigars to underserved communities over many decades. The tobacco industry continues to target these populations with tailored cigar marketing practices that contribute to and reinforce these longstanding and entrenched cigar disparities. As described in section V.A of this document, prevalence of cigar

use is disproportionately high among certain population groups such as non-Hispanic Black youth (Ref. 7), youth who identify as lesbian, gay, bisexual, or transgender (Refs. 7, 157, and 158), and youth with disabilities (Ref. 161). After initiating cigar use, members of these vulnerable populations are more likely to progress to regular cigar use or display patterns of more frequent use (Ref. 100). Because nonusers, particularly youth, from vulnerable populations are more likely to experience adverse effects from prior cigar use, the proposed product standard is anticipated to promote improved health outcomes within these population groups.

1. Flavored Cigar Smoking and Adverse Health Effects

As described in section V.D of this document, cigar smoking, including flavored cigar smoking, causes many of the same serious health conditions as cigarette smoking (Ref. 32). As also noted, FDA has conducted and published a systematic review of cigar smoking-attributable mortality risks and estimates of regular cigar smoking-attributable mortality for the U.S. population (Refs. 3 and 32). NCI previously reviewed the studies that were available on cigar smoking mortality risks and reached similar general conclusions (Ref. 183). Both reviews found that cigar smoking causes oral, esophageal, pancreatic, laryngeal, and lung cancers, as well as coronary heart disease and aortic aneurysm (Refs. 32 and 183). These conclusions were based primarily on statistically significant risk estimates for primary cigar smokers who had never regularly used other tobacco products such as cigarettes that were calculated from American Cancer Society's CPS I and II data. The CPS I and II were large longitudinal cohort studies of cancer risk factors in the U.S. population that each enrolled at least one million participants (Ref. 290). The CPS I began in 1959 and the CPS II in 1982 (Ref. 290). Researchers assessed the mortality followup for participants through followup visits or linkage with the National Death Index (Refs. 243 and 290). Numerous studies have been published that analyze and quantify tobacco-attributable mortality risks using CPS I and II data, including studies of cigar smoking-attributable mortality risks (Refs. 243, 247, and 291). While findings using CPS I and CPS II data are representative of historical cohorts of U.S. residents, a more recent analysis was

conducted using data from participants in the TUS-CPS from 1992 to 2011 in the National Longitudinal Mortality Study, following participants for mortality through the end of 2011 (Ref. 227). Results from this study regarding elevated risk of all-cause and cause-specific mortality among exclusive current cigar smokers compared to never tobacco users were generally consistent with estimates from CPS I and II (Ref. 227).

Research studies have found that cigar smokers have approximately 40 to 45 percent higher risk of COPD than never tobacco users (Refs. 229 and 247). Similarly, the risk of bladder cancer in CPS I data was also approximately 40 percent higher for cigar smokers (Ref. 247).

There may be other health outcomes attributable to cigar smoking that were not assessed using CPS I or II mortality data. For example, Heineman et al. found statistically significant increased risks of colon and rectal cancers among cigar smokers in a cohort of nearly 250,000 World War I era veterans who were followed for mortality for 26 years (Ref. 249). Patterns of flavored cigar use may have also changed over time and could contribute to health risks. While most research has focused on cigar-attributable mortality, limited research has addressed cigar-attributable morbidity. Besides dying from cigar-attributable disease, lifelong cigar smokers may live many years with serious medical conditions, such as cancers (Refs. 229 and 232), heart disease (Refs. 229 and 245), and increased airflow obstruction (Ref. 124) that can lead to major physical impairments, reduce functioning and quality of life, and produce appreciable health care costs and medical expenditures.

2. Estimated Impacts of the Proposed Standard on Cigar Smoking Initiation and Progression to Regular Use

As described throughout this document, the proposed standard is expected to have substantial public health benefits. Significant benefits are expected to come from the prevention of cigar smoking initiation and progression to regular use among youth and youth adults, resulting in reduced morbidity and premature mortality. To estimate these benefits, we have updated an analysis published by Rostron et al. in 2019 that examined the potential effects of the

product standard on each cohort of 18-year-olds in the United States (Ref. 292). Beginning with the 4.26 million 18-year-olds in 2019 (Ref. 293), we estimate that 3.9 percent of these individuals were current cigar users at that age, based on PATH Study Wave 5 data of self-reported every day or someday cigar use (Ref. 12). We also use PATH data to estimate that 63.6 percent of these cigar smokers initiated cigar use with a flavored product, resulting in approximately 106,000 18-year-olds who currently use cigars and had initiated cigar use with a flavored product (Ref. 12).

We then estimate the proportion of these cigar users who would have initiated cigar smoking with non-flavored cigars in the absence of flavored cigars. Consistent with Rostron et al., we assume that the lower bound would be 35 percent, equal to the proportion of cigar users who currently initiate with non-flavored products, and that the upper bound would be 100 percent, which reflects complete substitution with non-flavored cigars. We use the midpoint of these values, 67.5 percent, as our main estimate, so 32.5 percent of those currently initiating with flavored cigars would be deterred from trying cigars, and we estimate that approximately 34,000 (106,000 × 32.5 percent) cigar smoking initiates would be prevented by the product standard from initiating cigar use in this model. We also considered the possibility that flavored cigar initiates are more likely to continue cigar use than those who initiate with non-flavored products. PATH Study data from Waves 1 (2013-2014) and 2 (2014-2015) show that adult ever cigar users who initiated with flavored cigars are more likely to be current regular cigar users than ever users who initiated with non-flavored cigars, controlling for other relevant factors related to cigar use (Ref. 28). Similar estimates were obtained from analysis of Waves 2-4 (2014-2017) PATH Study data, although results were presented separately for mint- or menthol-flavored cigars and other flavored cigars (Ref. 29). We therefore estimate that approximately 26,000 [106,000 × (1.0 - 32.5 percent) × (1.0 - (1.0/1.56[19]))] cigar smokers would be prevented from continuing to regular use

[19] This estimate is based on Reference 28 in which the adjusted prevalence ratio = 1.56, meaning that, after accounting for other factors in the model, such as demographics, individuals who initiated with flavored cigars were 56 percent more likely to currently use them.

by the product standard for a total reduction of 60,000 current cigar smokers in each cohort of 18-year-olds.

Consistent with the prior analysis (Ref. 292), we account for the uncertainty inherent in estimating the impact of the proposed policy based on these data and conducted Monte Carlo simulations using @RISK statistical software to assess the effects of varying key data inputs. We conducted 1,000 simulations, with reductions in cigar initiation ranging from 0 to 65 percent and reductions in continuing use ranging from 22.5 percent (1.0 - 1.0/1.29) to 46.5 percent (1.0 - 1.0/1.87), among those who would have otherwise initiated cigar use with flavored cigars. Ninety percent of the resulting estimates were between 42,000 and 75,000 cigar users prevented in each cohort.

3. Estimated Impacts of the Proposed Standard on Mortality

In the preceding section, we describe the longer-term benefits of the proposed standard that would include prevention of disease and premature death among youth and young adults who are discouraged from taking up cigar smoking in the absence of access to the flavored cigars covered by the proposed standard. Over a shorter term, health benefits would come from decreased tobacco product use including cessation among those who currently use flavored cigars. In this section, our estimation of public health impacts focuses on the reduction in cigar-attributable deaths that would occur if such flavored cigars were removed from the market. To be clear, these estimates significantly understate the public health benefits because they do not include lives saved of youth and young adults who, as the result of the product standard, do not begin to smoke.

To estimate the potential impact of the proposed standard on mortality, we again updated a previously published analysis (Ref. 292), which began with an estimate of the current number of deaths that are attributable to regular cigar smoking in the United States on an annual basis. We then removed deaths due to dual cigar and cigarette use to specifically estimate mortality due to exclusive cigar smoking given that dual users may continue to use combusted tobacco

products. Mortality estimates are not available for other combinations of polytobacco use involving cigars, but over 90 percent of cigar users who are polytobacco users use cigarettes (Ref. 294). Consistent with the prior analysis (Ref. 292), we applied a range of estimates for the reduction in total cigar consumption that reflects behavioral evidence from multiple localities' flavored tobacco restrictions as well as information on the size of the flavored U.S. cigar market. These estimates were then translated to potential behavior change to estimate the number of deaths in the United States that would be prevented each year among exclusive regular cigar smokers as a result of the proposed standard.

We based our estimate of the annual mortality attributable to cigar smoking in the United States on a previously published analysis (Ref. 3). This analysis modified the Smoking-Attributable Mortality, Morbidity, and Economic Costs methodology, used by the CDC to estimate cigarette smoking-attributable mortality, to quantify the mortality burden of regular cigar smoking in the United States in 2010 for adults aged 35 years or older (Ref. 3). The analysis estimated that regular cigar smoking (defined in the study as smoking cigars on 15 or more of the past 30 days) was responsible for approximately 9,000 premature deaths annually and that 5,200 of these deaths occurred among regular cigar smokers who did not also currently smoke cigarettes (hereafter referred to as exclusive cigar smokers) (Ref. 3). Because it is possible that some dual cigarette and cigar smokers might replace their cigar use with cigarette use if flavored cigars were prohibited, our analysis used the latter estimate of 5,200 deaths as the basis for quantifying the benefits of the proposed standard. This is a conservative approach because it does not account for any health benefits among dual users who quit tobacco or cigar use as a result of the proposed standard. As data from the NHIS from 2000-2019 has shown relatively stable cigar use prevalence estimates among adults, this estimate of 5,200 premature deaths also serves as a general measure of the effects of exclusive regular cigar smoking (i.e., non-dual) on mortality in the United States in subsequent years (Ref. 3). Although youth cigar smoking has declined in recent years, the long-term implications for regular cigar smoking in this population

are unclear. These estimates are based on an expectation that the number of premature deaths from cigar use would remain constant over time in the absence of regulatory action. Conceivably, the number of cigar-attributable premature deaths could rise due to population growth even if cigar smoking rates remained constant, or the number could fall if cigar-smoking rates fell by more than the population growth.

We then estimated the fraction of deaths that would be avoided if the proposed standard were in effect as proposed. As discussed in section IV.F of this document, real-world experience regarding the impact of flavored tobacco restrictions across U.S. jurisdictions suggests that the removal of flavored cigars from the U.S. market would lead consumers who now smoke flavored cigars to alter their behavior and some of these individuals would reduce their use of cigars or quit smoking cigars completely, others would product switch entirely to other tobacco products. We used data from the Providence, NYC, and San Francisco areas because these cities' restrictions on the sale of flavored tobacco products provide the best available U.S. data on the effect of real-world, implemented restrictions on cigar sales, and thus consumption.[20] Several studies conducted analyses using Nielsen retail scanner data to assess changes in the number of cigars sold (both flavored and non-flavored) in Providence, NYC, and San Francisco before and after the flavor restrictions went into effect (Refs. 52, 108, and 109). For comparison, they also examined sales over the same timeframe in the rest of Rhode Island in the Providence analysis, in nine counties proximal to NYC, as well as sales in the United States overall, in the NYC analysis, and in San Diego and San Jose in the San Francisco analysis. Using a times series analysis, the study of Providence estimated the effect of the flavor restriction to be a 31 percent reduction in overall cigar sales (Ref. 109). This analysis also found that the restriction was associated with an approximate 15 percent to 20 percent reduction in overall NYC cigar sales, relative to the proximal area or the United States overall. The study of San Francisco found that

[20] Study data from Lowell, MA, and Attleboro and Salem, MA, only looked at youth use and not sales data and thus is not included in this aspect of the discussion.

the flavor restriction was associated with a 51 percent reduction in overall cigar sales (Ref. 52). Importantly, these decreases in overall cigar sales indicate that consumers did not completely substitute non-flavored cigars for flavored cigars because of the restriction (Ref. 108). The data also suggest that cross-border purchasing of flavored cigars was limited. For example, the NYC study found that flavored cigar sales in the ten-county area surrounding NYC declined after the implementation of NYC's flavor restriction, although the change was not statistically significant (Ref. 108).

We note that the decline in flavored and overall cigar sales occurred despite incomplete compliance in some localities, such as the NYC ordinance (Ref. 108). The NYC study found that flavored cigars, specifically, continued to be sold at persistently high levels in NYC in violation of the restriction. FDA anticipates the proposed product standard would have a greater impact on public health than the NYC flavor sales restrictions. Unlike a restriction on sales alone, the proposed standard would prohibit both the manufacture and sale of cigars with characterizing flavors (other than tobacco), and as a result, it would allow for a more complete prohibition of flavored cigar products from the market. Moreover, FDA anticipates that this nationwide product standard would eliminate the opportunity for consumers to travel to local neighboring U.S.-based jurisdictions that do not have a flavor prohibition or use online retailers to purchase flavored cigars.

In our analysis, cigar sales are used as a proxy for consumption, given we expect sales and consumption to be highly correlated. We start with a 30 percent relative decrease in total cigar sales as our main estimate in the analysis, using a rounded estimate of 31 percent reduction in overall cigar sales observed in Providence, which provided the midrange of estimates from the three evaluation studies. For the reasons described in this section, FDA considers the impacts of the NYC flavor restriction on total cigar sales (i.e., 15-20 percent reduction in overall cigar sales in NYC) to be a conservative estimate of what the reduction in total cigar consumption in the United States overall would be if the proposed standard were implemented. We therefore use an

estimated 15 percent relative decline in total cigar sales as a lower bound of the impact of this proposed product standard as a conservative estimate, which would suggest some substitution with non-flavored cigars.

An alternate scenario is one in which the proposed flavored tobacco products are removed from the U.S. market after implementation of the proposed standard and no substitution of non-flavored cigars occurs among consumers. In this case, the impact of the proposed standard on total cigar consumption would be equivalent to the fraction of the total U.S. cigar market comprised of flavored cigars. Proprietary data gathered by Euromonitor International in March 2021 reveals that approximately 41.9 percent of 2020 cigar (including cigarillo) unit sales in the United States were for flavored varieties. In this alternative scenario, if there is no switching from flavored to non-flavored cigar varieties, then overall cigar sales, and subsequently consumption, would decrease by 41.9 percent. We use this figure as the upper bound for the decrease in total cigar sales following implementation of the product standard. As noted, the reduction in cigar sales observed in San Francisco following implementation of a flavored tobacco product restriction was consistent with such a decrease at 51 percent (Ref. 52).

Next, we estimate the mortality effects of these reductions in cigar consumption. The proposed standard is expected to result in some consumers quitting smoking cigars entirely, others cutting back on cigar smoking. To estimate how reductions in consumption at the population-level may be distributed across individual consumer behaviors, we use data from studies of other tobacco control policies. These studies can inform estimates of potential effects of the proposed standard on cigar use. A robust evidence base exists to characterize the impact of tobacco taxes on consumption and behavior. Data from studies on the impacts of cigarette tax increases on smoking behaviors suggest that approximately half of observed reductions in cigarette sales are due to smokers quitting, while the remainder are due to reducing or cutting back on the number of cigarettes smoked (Ref. 295). For this analysis, we assume that, among exclusive cigar smokers who would change their smoking behavior due to the standard,

approximately 50 percent would quit smoking entirely, while the other 50 percent would cut back. To be conservative, we assume there are no benefits in avoided mortality among those who cut back and avoided mortality is only counted among those who quit smoking entirely. This estimate may be somewhat conservative because some studies have found some health and mortality benefits from substantial reductions in cigarette consumption, although these benefits are less than those from complete smoking cessation (Refs. 296 and 297).

We use these inputs in our analysis. By multiplying the estimated 5,200 annual exclusive cigar attributable deaths previously described by 30 percent due to decline in cigar sales, and then reducing that value by 50 percent to reflect benefits only for those who quit entirely, we estimate that the proposed standard would result in approximately 800 annual averted deaths.[21] We again conducted Monte Carlo simulations using @RISK statistical software to assess the effect of varying key data inputs. We ran 1,000 simulations using 15 percent and 42 percent as the lower and upper bound of decreases in total cigar consumption and 25 percent and 75 percent as the lower and upper bound for the proportion of decreased consumption due to complete cessation, and 90 percent of the resulting estimates fell within a range of approximately 400 to 1,100 deaths averted annually.

FDA anticipates that a reduction in deaths attributable to cigar use would begin to accrue soon after implementation of the proposed standard (see Ref. 298 at section II.F). It would take time to fully realize the mortality benefit of the proposed standard, given that some cigar smokers may still die of a smoking-related disease due to previous use, even if they quit cigar use after the proposed standard is implemented. Given that lung cancer has been estimated to be responsible for the majority of deaths attributable to cigar smoking (Ref. 3), we base the timeframe for reduction in risk on this cause. Estimates from contemporary cohort data have found that full reductions in lung cancer risk after smoking cessation can take an extended time

[21] All estimates are rounded to the nearest 100. See FDA's Preliminary Regulatory Impact Analysis (Ref. 298) for unrounded estimates.

period; consequently, we used a time period of 30 years (Ref. 299). Reductions in risk from other causes such as cardiovascular disease are expected to be realized more quickly (Refs. 300 and 301). Benefits from reductions in cigar-related morbidity would also be expected to accrue more quickly.

We also estimate the years of life that would be gained due to the product standard. Nonnemaker et al. estimated that the approximately 9,000 annual deaths that are attributable to regular cigar smoking correspond to nearly 140,000 years of potential life lost (YPLL) (Ref. 3). This represents an average of 15.1 years of life lost per death. We multiply the approximately 774 deaths annually averted by the product standard by the 15.1 average years of life lost per attributable death and estimate that approximately 11,687 YPLLs are associated with the premature mortality that would be prevented by the product standard each year.

This analysis has concentrated on mortality effects, given the availability of specific estimates for cigar smoking-attributable mortality and mortality risks, but we also anticipate reductions in cigar smoking-attributable morbidity due to the product standard. It has been estimated that regular cigar smoking is directly responsible for approximately 9,000 deaths among U.S. adults annually (Ref. 3) and that cigarette smoking is directly responsible for approximately 437,000 deaths annually among U.S. adults (Ref. 23 at 659). It has also been estimated that U.S. adults suffer from approximately 14 million major medical conditions due to cigarette smoking (Ref. 302). These figures suggest that current and former cigarette smokers are living with approximately 30 major medical conditions due to cigarette smoking for every premature death that occurs each year. Since regular cigar smoking causes premature death from some of the same conditions as cigarette smoking, we would expect a considerable disease burden attributable to cigar smoking among U.S. adults, along with reduction in this burden as a result of the proposed standard.

In addition, the population would experience health benefits based on a decrease in morbidity and mortality resulting from secondhand smoke exposure. According to the Surgeon

General, there is sufficient evidence from which to infer a causal relationship between secondhand tobacco smoke exposure and lung cancer, as well as increased risks of coronary heart disease morbidity and mortality, among lifetime nonsmokers (Ref. 251 at 15). Individuals living with smokers had a 20 to 30 percent increase in the risk of developing lung cancer from secondhand smoke exposure (Ref. 251 at 15). Likewise, the estimated increase in coronary heart disease risk from exposure to secondhand tobacco smoke is 25 to 30 percent above that of unexposed individuals (Ref. 251 at 519). Based on the similarity of the toxic constituents in cigars and cigarettes, and the fact that cigars commonly share similar product design and mechanisms of smoke delivery as cigarettes, FDA's scientific judgment leads the Agency to expect that secondhand cigar smoke would produce effects similar to those produced by secondhand cigarette smoke, meaning that the proposed rule, if finalized, would decrease morbidity and mortality caused by secondhand exposure to cigar smoke.

These sections have focused on the potential benefit to the U.S. population as a whole from the proposed product standard, accounting for the potential decreased experimentation and progression to regular use among nonusers that would be prevented from trying flavored cigars, as well as potential decreased consumption or increased cessation among current flavored cigar smokers. Thus, we anticipate the proposed product standard would continue to produce reductions in morbidity and mortality over the long term, due in large part to the reduction in eventual adverse health effects from cigars due to reduced initiation and use among young people.

One additional potential health benefit to continuing users of cigars that could result from the proposed product standard would be decreased exposure to potentially toxic flavor compounds, as discussed in section V.B of this document. In combusted tobacco products, such as cigarettes and cigars, toxicity can result from the chemicals formed when flavors are heated or burned (Refs. 184-187). For example, a study conducted by the CDC identified benzyl alcohol, piperonal, methyl cinnamate, and vanillin in strawberry cigar filler (Ref. 190) (see table 2 in this

document for potential health hazards of these ingredients). While some flavoring compounds naturally occur in tobacco and the resulting standard may not fully eliminate such toxic exposures, reducing toxicant levels in these products would reduce consumer exposure and could protect consumers from the health effects of these toxicants, particularly from adverse respiratory effects.

4. Potential Risks to the Population as a Whole of the Proposed Cigar Flavors 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. Possible countervailing effects on current tobacco users could include continued combusted tobacco product smoking 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 such as adolescent tobacco users and other population subgroups.

With the removal of characterizing flavors (other than tobacco) in cigar products, some cigar smokers may seek other sources of tobacco and/or nicotine. These could include nicotine replacement therapy products, which are products authorized by FDA to help people quit using tobacco products. However, some smokers may also transition to tobacco-flavored cigars, other combusted tobacco products, or other potentially less harmful tobacco products. As discussed in section VI.B of this document, if youth experimenters or users of flavored cigars were to switch to cigarettes or to other tobacco products as a result of flavored cigars no longer being available, it is possible that the benefits of the rule would be reduced. The availability of menthol cigarettes, if it continues after flavored cigars are no longer available, may make this switch more likely and diminish the benefits. However, the proposed rule would not be expected to increase risks to individual or public health, since cigar and cigarette smokers suffer many of the same adverse health outcomes attributed to combusted tobacco use. In addition, FDA has considered the possibility that youth or adults will form a misperception that non-flavored cigars

are safe or pose no substantial health risks (and that this misperception would impact behavior) because FDA has not similarly prohibited their continued availability. However, FDA is not aware of any evidence suggesting such misperceptions would or would not occur and will monitor for any such effects if this product standard is finalized. Should the Agency find evidence of such misperceptions, FDA would direct public education efforts toward such misperceptions and would consider taking other action as appropriate.

FDA recognizes that, while some flavored cigar users may switch to tobacco-flavored cigars, this potential countervailing effect would not outweigh the benefits from cigar users who quit smoking completely. FDA has no reason to believe that individuals switching from flavored (other than tobacco-flavored) cigars to other combusted tobacco products would be exposed to additional harm beyond their current exposure level. There is no available data to suggest, for example, that the prohibition of characterizing flavors (other than tobacco) in cigars would increase the frequency or depth of smoke inhalation of tobacco-flavored cigars, make tobacco-flavored cigars more toxic to individual users or those who inhale secondhand smoke, lead to increased initiation, or make it more difficult for current tobacco users to quit. As explained elsewhere in this document, it is anticipated that the toxicity of flavored cigars could likely be diminished if this proposed rule is finalized. FDA requests comments regarding additional evidence on the extent and magnitude that flavored cigar users could potentially switch to other tobacco products, including tobacco-flavored cigars.

In addition, FDA is considering whether illicit trade could occur as a result of a cigar flavor 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. 303). In 2015, the NRC/IOM issued its final report entitled "Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences" and concluded that "[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. 303 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, March 16, 2018). 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. 43).

A study regarding a restriction on menthol cigarettes in Canada is instructive here. Researchers studied the effects of the first ever complete sales restriction of menthol cigarettes, which was issued in the Canadian province of Nova Scotia (Ref. 304). The researchers found that the menthol restriction did not result in an increase in illicit cigarettes seized (Ref. 304). The Nova Scotia tax authorities estimated that the "prevalence of illegal tobacco in the province had actually decreased, from 30 percent of all tobacco consumed in 2006-2007 to less than 10 percent in 2016-2017" (Ref. 304). This is evidence that a major change to the availability of certain tobacco products is not likely to lead to a surge in illicit tobacco product use.

FDA requests comments regarding whether and to what extent this proposed rule would result in an increase in illicit trade in flavored cigars and how any such increase could impact the marketplace or public health. If an illicit market develops after this proposed product 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 VIII.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 product standard is finalized and goes into effect, it would be illegal to import cigars with characterizing flavors (other than tobacco), 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 flavored cigars, including those sold online, and doing so may result in FDA initiating enforcement or regulatory actions.

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 flavored cigars. 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 concerns 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 minimal. Therefore, these potential effects would not outweigh the potential benefits 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.

D. Conclusion

In this section, we have reviewed multiple lines of evidence to assess the likely impact of the proposed prohibition on characterizing flavors (other than tobacco) in cigars on current

nonusers, tobacco users, and the U.S. population as a whole. With respect to the impact on nonusers, the Agency anticipates prevention of initiation and progression to regular tobacco use among youth and young adults, as well as reductions in exposure to secondhand cigar smoke, although this population health benefit is not quantified in our calculations. With respect to youth initiation and use, the Agency anticipates that prohibiting characterizing flavors (other than tobacco) in cigars as proposed would eliminate the availability of products that are more appealing to novice users and avoid rewarding and reinforcing associations with the characterizing flavor among youth. In addition to decreased experimentation, this is expected to lead to decreased use. The best available evidence regarding the role of flavored cigars and progression to regular use suggests that youth initiating with flavored cigars are more likely to progress to regular use. Policy evaluations from local jurisdictions throughout the United States (NYC, NY; Providence, RI; Lowell, MA; Twin Cities, MN; and San Francisco, CA) showed that youth and young adult tobacco use decreased when flavored cigars were removed from the market. In order to prevent future addiction, disease, and death associated with long-term cigar smoking, FDA proposes to prohibit characterizing flavors (other than tobacco) in cigars.

FDA also anticipates that the proposed product standard would increase the likelihood that some of the estimated 3 million adult flavored cigar smokers would reduce the number of cigars they smoke or quit smoking cigars entirely instead of completely substituting non-flavored cigars for flavored cigars. Evidence shows that flavor availability is consistently a highly endorsed reason for cigar use among youth, young adult, and adult cigar smokers (Refs. 12 and 28). Characterizing flavors in tobacco products ensure pleasant flavor and taste, reduces the harshness, bitterness, and astringency of tobacco during inhalation and soothes irritation during cigar smoking. When flavored cigar products were removed from the market in NYC, Providence, San Francisco, and Canada analyses showed subsequent reductions in total cigar sales. Taken together, this suggests the proposed standard would lead some flavored cigar smokers to smoke fewer cigars or quit cigar use entirely, decreasing total cigar consumption

notwithstanding any substitution with non-flavored cigars. Cigar smoking causes many of the same diseases as cigarette smoking, including oral, esophageal, pancreatic, laryngeal and lung cancers, as well as coronary heart disease and aortic aneurysm (Refs. 32 and 183). Our evidence review indicates that, by increasing cessation among cigar smokers who would otherwise use a flavored tobacco product, the proposed standard would reduce cigar-attributable deaths and disease in the United States and would not result in any increase in deaths or disease from the use of other tobacco products. In addition to reductions in premature death, cigar smokers who quit would gain improved quality of life from the reduced risk or prevention of major medical conditions attributable to cigar smoking.

Additionally, FDA anticipates that the proposed tobacco standard will improve health outcomes within groups that experience disproportionate levels of tobacco use, including certain vulnerable populations. Longstanding disparities in cigar use are the result of decades of cigar marketing targeted at underserved communities and the role of flavors in nicotine addiction and dependence. FDA anticipates that the prohibition of characterizing flavors in cigars will reduce initiation and experimentation with cigar smoking (particularly by youth and young adults), decrease the likelihood of nicotine dependence and addiction, and increase the likelihood of cessation. These public health benefits are expected to be particularly pronounced among vulnerable populations who experience the disproportionate impact of cigar use.

In total, this evidence supports the conclusion that a prohibition on characterizing flavors (other than tobacco) in cigars would be appropriate for the protection of the public health. The Agency anticipates the proposed standard would result in decreased experimentation and progression to regular use among youth and young adults, and increased cessation among current cigar smokers, would lead to lower disease and death in the U.S. population in both the short term and long term, due to diminished exposure to tobacco smoke among both users and nonusers of cigars.

VII. 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 a smoke constituent), or other component of a tobacco product because FDA has found that the additive, 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 parties 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 the Tobacco Products Scientific Advisory Committee (TPSAC) at the Agency's own initiative or in response to a request for good cause 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. Pathways to Market

To legally market a new tobacco product[22] in the United States, a tobacco product must receive authorization from FDA permitting the marketing of the new tobacco product under one of three pathways: (1) the applicant obtains an order under section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. 387j(c)(1)(A)(i)) (order after review of a premarket tobacco product application under section 910(b)); (2) the applicant obtains an order finding the new tobacco product substantially equivalent to a predicate tobacco product and in compliance with the requirements of the FD&C Act under section 910(a)(2)(A)(i) (order after review of a substantial equivalence (SE) report submitted under section 905(j) of the FD&C Act); or (3) the applicant makes a request under 21 CFR 1107.1 and obtains an exemption from the requirements related to SE (section 905(j)(3)(A)) (21 U.S.C. 387e(j)(3)(A)), and at least 90 days before commercially marketing the product, submits a report under section 905(j) including the information required in section 905(j)(1)(A)(ii) and (B) of the FD&C Act.

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[22] Products that were commercially marketed in the United States as of February 15, 2007 (referred to as "pre-existing tobacco products," previously referred to as "grandfathered products"), are not considered new tobacco products and do not require prior authorization to be legally marketed (section 910(a) of the FD&C Act).

Applicants may be able to use the SE exemption pathway for products seeking to comply with this proposed standard by making a minor modification to an additive in their product, if FDA finds, among other things, that: (1) the modification is "minor"; (2) an SE Report is not necessary to ensure that permitting the product to be marketed would be appropriate for the protection of the public health; and (3) an exemption is otherwise appropriate (section 905(j)(3)(A) of the FD&C Act). For example, FDA has previously issued exemption orders for tobacco products where there was deletion of casing flavor or L-menthol from a combusted cigarette. However, to the extent manufacturers change their flavored cigars to comply with this rule, FDA requests comments regarding how they might satisfy the premarket review requirements of the Tobacco Control Act.

C. Considerations and Request for Comments on Scope of Products

As indicated throughout this document, FDA has determined that the proposed standard, which would apply to all flavored cigars (other than tobacco) and their components or parts, is appropriate for the protection of the public health. The proposed scope of this rule--applying to all cigars, rather than only a subset of cigars--is important to protect public health and is justified by existing evidence. All cigars are combusted tobacco products that may be used by youth and that expose users to nicotine, a highly addictive substance, and many other toxic chemical constituents. Cigars are not a safe alternative to other tobacco products, including other combusted products such as cigarettes. In addition, these products pose no potential for positive net public health impact by means of reduced risk or harm.

Cigars may vary in size, from smaller cigars which may resemble cigarettes in size and shape, such as little cigars or cigarillos, to larger ones, such as cigars referred to as "premium" cigars. In August 2020, as part of its decision in *Cigar Association of America, et al.* v. *Food and Drug Administration, et al.* (*Cigar Association* case), the U.S. District Court for the District of Columbia "remand[ed] the [deeming final rule] to the FDA to consider developing a streamlined substantial equivalence process for premium cigars" and "enjoin[ed] the FDA from enforcing the

premarket review requirements against premium cigars…until the agency has completed its review." Under the terms of, and for the purposes of, the court's order, a premium cigar is defined as a cigar that meets all of the following eight criteria:

1. is wrapped in whole tobacco leaf;
2. contains a 100 percent leaf tobacco binder;
3. contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar);
4. is handmade or hand rolled;[23]
5. has no filter, nontobacco tip, or nontobacco mouthpiece;
6. does not have a characterizing flavor other than tobacco;
7. contains only tobacco, water, and vegetable gum with no other ingredients or additives; and
8. weighs more than 6 pounds per 1,000 units.

While products subject to this court's order meet the definition of "cigar" as set out in this proposed rule, they do not contain a characterizing flavor other than tobacco and contain no ingredients or additives outside of tobacco, water, and vegetable gum. As discussed, the proposed rule would prohibit the use of characterizing flavors other than tobacco in all cigars. Therefore, products that meet this court order's definition of "premium" cigar would not be affected by the proposed rule. All cigar products, regardless of shape and size, including those that are marketed as "premium" cigars, that include a characterizing flavor other than tobacco, would be prohibited by this proposed product standard.

FDA is also considering action to limit characterizing flavors in other tobacco products (see FDA's ANPRM regarding the role flavors play in tobacco products (79 FR 12294, March 21, 2018) and FDA's proposed rule prohibiting menthol as a characterizing flavor in cigarette

[23] A product is "handmade or hand rolled" if no machinery was used apart from simple tools, such as a scissors to cut the tobacco prior to rolling.

products, published elsewhere in this issue of the *Federal Register*). FDA is proposing to limit the scope of this proposed standard to cigars, given their well-documented harms and the fact that flavored cigars clearly appeal to youth and young adults in large numbers, while undertaking additional efforts to evaluate and determine whether to prohibit or otherwise limit characterizing flavors in other tobacco products. Research also does not indicate any countervailing public health benefit impacts from characterizing flavors in cigars that might be affected by eliminating their use, in potential contrast to some non-combusted tobacco products. We request comments, data, and research regarding the proposed scope of this rule.

FDA considered including waterpipe tobacco products within the scope of this proposed product standard based on the fact that they are combusted tobacco products with a strong appeal to youth. According to the 2020 NYTS, 2.7 percent of high school students (or approximately 420,000 students) reported using waterpipe tobacco within the previous 30 days and 1.3 percent of middle school students (or approximately 160,000 students) reported waterpipe tobacco use in the prior month (Ref. 7). In addition, waterpipe tobacco use exposes users to nicotine and many toxic chemical constituents. The WHO study group on tobacco regulation has found that a waterpipe session, which typically lasts 20 to 80 minutes, can be the equivalent of smoking more than 100 cigarettes (Ref. 305, citing Ref. 306). However, at this time due to limited data--specifically limited data on how waterpipe tobacco might be used in the absence of non-tobacco characterizing flavors--FDA is not proposing to include waterpipe tobacco within the scope of this proposed product standard. FDA requests information and data on how waterpipe tobacco might be used in the absence of non-tobacco characterizing flavors. FDA is continuing to study the health effects associated with waterpipe tobacco use, as well as use patterns generally, to evaluate and determine whether to prohibit characterizing flavors in waterpipe tobacco.

Similarly, FDA is aware of the dangers of pipe tobacco (excluding waterpipe tobacco) and considered including pipe tobacco in the proposed rule. However, FDA considered youth and young adult usage as a primary concern in determining the scope of this proposed product

standard, and at this time the data is limited and appears to suggest that youth and young adults have a much lower prevalence of pipe tobacco use compared to cigar use. According to the 2020 NYTS, 0.7 percent of high school students (or approximately 110,000 students) reported using pipe tobacco within the previous 30 days and 0.4 percent of middle school students (or approximately 40,000 students) reported pipe tobacco use in the prior 30 days (Ref. 7). FDA is concerned that current data may underestimate the number of smokers who use pipe tobacco to roll their own cigarettes or cigars, but the lack of data on RYO tobacco use and the limitations in how national surveys assess loose pipe tobacco use impact our ability to draw conclusions regarding appeal of loose pipe tobacco among youth and adults at this time. Given the inherent differences in features of use of loose pipe tobacco compared to a pre-rolled cigar, FDA does not anticipate that flavored pipe tobacco would be a ready substitution for youth seeking to use flavored cigars. The current best available evidence indicates pipe tobacco is comparatively unpopular with youth, and findings from the few studies that looked at changes in pipe tobacco use following restrictions on flavors in other tobacco products were mixed (Refs. 50, 51, and 111). While youth use of any tobacco product is of concern, we are not proposing to include pipe tobacco at this time. FDA requests information and data to further inform the above considerations. We also note that FDA has issued Warning Letters to retailers illegally selling flavored tobacco products that bear the package description "pipe tobacco" but which, based on their overall presentation, meet the statutory definition of cigarette tobacco and/or RYO tobacco.

FDA is not including non-combusted tobacco products, such as ENDS and smokeless tobacco products, in the scope of this proposed standard. As discussed previously, characterizing flavors in a variety of tobacco products have appealing effects, particularly among youth and young adults. And youth and young adult use of any tobacco product remains a significant concern for FDA. However, at this time, FDA is focusing this proposed rule on characterizing flavors in cigars because this action would help to prevent youth and young adults' use of

combusted tobacco products. Combusted tobacco products are responsible for the majority of death and disease due to tobacco use.

Accordingly, as part of its overall request for comments, FDA requests comments, including supporting data and research, regarding the following issues:

- Should this product standard cover waterpipe and/or pipe tobacco, in addition to cigars? Is there additional data or information that would support inclusion of waterpipe and/or pipe tobacco in this product standard?
- What are the advantages and/or disadvantages of covering other combusted tobacco products with this product standard? What evidence would support covering all combusted tobacco products? How should FDA define "combusted tobacco products" if the scope of the final product standard were expanded to include all combusted tobacco products?
- Is there a significant risk that, if FDA limits this standard to cigars, consumers would substitute and/or migrate to other combusted tobacco products, thereby undermining the public health benefits of this rule? What changes, if any, should FDA make to this proposal to protect against or minimize substitution and/or migration?

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

FDA is aware of concerns by some that this proposed rule could lead to illicit trade in flavored cigars, increased policing, and criminal penalties in underserved communities. 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 flavored cigars. FDA's enforcement of this proposed rule, if finalized, 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 flavored cigars. Finally, FDA requests comment on any other policy considerations related to potential racial and social justice implications of the rule.

VIII. Description of the Proposed Rule

This proposed rule would establish a new part 1166 that would prohibit characterizing flavors (other than tobacco) in cigars. Part 1166 would describe the scope of the proposed regulation, applicable definitions, and the prohibition on use of characterizing flavors (other than tobacco) in cigars.

A. Scope (Proposed § 1166.1)

Proposed § 1166.1(a) would provide that this part sets out a tobacco product standard under the FD&C Act regarding the use of characterizing flavors in cigars.

Proposed § 1166.1(b) would prohibit the manufacture, distribution, sale, or offering for distribution or sale, within the United States of a cigar 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 cigars 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 or this product standard, if it meets the criteria enumerated in section 801(e)(1) of the FD&C Act, including not being sold or offered for sale in domestic commerce. This proposed rule would prohibit the importation for sale or distribution in the United States of a finished cigar that violates this standard. As stated in section VII.C of this document, FDA is specifically requesting comment regarding the scope of this proposed rule.

B. Definitions (Proposed § 1166.3)

Proposed § 1166.3 provides the definitions for the terms used in the proposed rule. Several of these definitions are included in the FD&C Act or have been used in other regulatory documents.

- *Accessory*: FDA defined "accessory" in the final deeming final rule (81 FR 28974; codified at 21 CFR 1100.3). We are proposing to use that definition here as it applies to cigars to provide further understanding as to the scope of the proposed standard. Therefore, FDA proposes to define "accessory" in the context of part 1166 to mean any product that is intended or reasonably expected to be used with or for the human consumption of a cigar; 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 cigar or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a cigar but (i) solely controls moisture and/or temperature of a stored cigar or (ii) solely provides an external heat source to initiate but not maintain combustion of a cigar. A cigar "accessory" is not subject to chapter IX of the FD&C Act or to this proposed standard. Examples of cigar accessories include a humidor that solely controls the moisture and/or temperature of a stored product, as well as cigar tip cutters, holders, ashtrays, and cases. We note that a

humidor that does more than *solely* control the moisture and/or temperature of a stored product (e.g., imparts a mint characterizing flavor to the stored product) could meet the definition of a "component" or "part" in proposed § 1166.3 and, therefore, would be covered under this proposed standard.

- *Cigar*: FDA proposes to define "cigar" as a tobacco product that: (1) is not a cigarette and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco. This definition was used in the seven consent orders that the Federal Trade Commission (FTC) entered into with the largest mass marketers of cigars (see, e.g., *In re Swisher International, Inc.*, Docket No. C-3964 (FTC August 18, 2000)) and also is codified at 21 CFR 1143.1.
- *Component or part*: FDA defined "component or part" in the deeming final rule. We have reiterated that definition here as it applies to cigars. Therefore, FDA proposes to define "component or part" in the context of part 1166 to mean any software or assembly of materials intended or reasonably expected: (1) to alter or affect the cigar's performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a cigar. The term excludes anything that is an accessory of a cigar. Examples of cigar components or parts that would be subject to this proposed product standard include liquids intended to add flavor, cigar blunt wraps, removable tips, mouthpieces, and filters. 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.

- *Tobacco product*: As defined in section 201(rr) of the FD&C Act, the term "tobacco product" is defined as 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 is: a drug under section 201(g)(1) (21 U.S.C. 321(g)); a device under section 201(h) (21 U.S.C. 321(h)); a combination product described in section 503(g) (21 U.S.C. 353(g)); or a food under section 201(f) of the FD&C Act (21 U.S.C. 321(f)) if such article contains no 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 Characterizing Flavors in Cigars (Proposed § 1166.5)

Proposed § 1166.5 would establish a product standard prohibiting the use of characterizing flavors (other than tobacco) in cigars, similar to section 907(a)(1)(A) of the FD&C Act.[24] Specifically, proposed § 1166.5 would state that a cigar or any of its components or parts (including the tobacco, filter, or wrapper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including, but not limited to, strawberry, grape, orange, clove, cinnamon,

[24] 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 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.

pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, mint, or menthol, that is a characterizing flavor of the tobacco product or tobacco smoke.[25] As discussed in section VI of this document, FDA finds that this proposed product standard would be appropriate for the protection of the public health. FDA is proposing an effective date 1 year after the date of publication of the final rule, as discussed in section IX of this document.

We note that this proposed rule would prohibit the use of menthol as a characterizing flavor in cigars, whereas the statutory characterizing flavor ban for cigarettes excluded menthol from the prohibition. The sensory properties of menthol makes its addition to cigars concerning. Menthol is a flavor compound that when added to combusted tobacco products produces a minty taste and cooling sensation when inhaled (Ref. 71). Adding menthol to combusted tobacco products makes the products easier to inhale and less irritating. Smokers report that mentholated products have a better taste, are smoother and more refreshing (Refs. 72-74). Menthol's flavor and sensory effects reduce the harshness of smoking among new users and facilitate experimentation and progression to regular smoking of menthol products, particularly among youth and young adults (Refs. 29 and 74-76). As a result, the brain is repeatedly exposed to nicotine and susceptible to nicotine addiction (Ref. 222). Studies further demonstrate that menthol, like nicotine, binds to nicotinic receptors in the brain (Refs. 218 and 219) and menthol alone can increase the number of nicotinic receptors in the brain (Refs. 220 and 221). Increases in nicotinic receptors can lead to greater withdrawal and cravings (Ref. 222). Evidence demonstrates that menthol's effects on nicotine in the brain are associated with behaviors indicative of greater addiction to nicotine (Refs. 220 and 223).

For this proposed product standard, FDA also is concerned that a characterizing flavors prohibition that does not include menthol would shift the flavored cigar market to menthol-

[25] We note that the language in section 907(a)(1)(A) of the FD&C Act states that the characterizing flavor ban for cigarettes applies to cigarettes or "any of its component parts." For purposes of this proposed product 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).

flavored cigars. FDA is addressing the use of menthol in cigarettes in its separate proposed tobacco product standard to prohibit the use of menthol as a characterizing flavor in cigarettes, published elsewhere in this issue of the *Federal Register*. We believe that including menthol within the scope of this proposed standard prohibition of characterizing flavors in cigar products would be appropriate for the protection of the public health regardless of whether a similar prohibition of menthol as a characterizing flavor in cigarettes is in place when this rule is finalized.

FDA would enforce the requirements of this proposed product standard under various sections of the FD&C Act, including sections 301, 303, 701(a), 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) of the FD&C Act. Similar to section 907, 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.

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 consumers possession or use of flavored cigars.

Among the factors that FDA believes are relevant in determining whether a cigar product 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 a tobacco product;[26] and
- Any other means that impart flavor or represent that a 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 characterizing flavor--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 cigar has a characterizing flavor.

FDA also requests comments, including supporting data and research, regarding potential alternatives to prohibiting characterizing flavors (e.g., prohibiting all flavor additives, compounds, constituents, or ingredients).

This proposed product standard would not prohibit tobacco-flavored cigars. Flavored tobacco products may differ in youth appeal--as discussed previously in this document, for those who experiment with cigars, tobacco-flavored cigars do not currently appear as attractive as cigars with other characterizing flavors. FDA expects that the tobacco flavor in a cigar, or its

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[26] If a cigar 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 cigar 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.

components or parts, need not be naturally inherent to the product to be considered "tobacco flavored" but rather may result from the addition of ingredients or other measures by the manufacturer to produce the presence of tobacco as its characterizing flavor.

Further, we note that this prohibition also would cover flavors that are separate from the cigar (e.g., liquid flavors), including menthol, intended or reasonably expected to be added to cigars. For example, menthol can be added to the packaging of cigarettes to produce menthol cigarettes (and this can be done for cigars as well). Such flavors would be considered components or parts of cigars under § 1166.3, as they could be intended or reasonably expected: (1) alter or affect the cigar's performance, composition, constituents, or characteristics or (2) be used with or for the human consumption of a cigar, and they would not be accessories of cigars. Therefore, the manufacture, distribution, sale, or offer for distribution or sale of such flavored products would be prohibited should this proposed rule be finalized.

IX. Proposed Effective Date

In accordance with section 907(d)(2) of the FD&C Act,[27] 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, distribute, sell, or offer for distribution or sale within the United States a cigar or any of its components or parts that is not in compliance with part 1166. This 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 characterizing flavors in cigars increase appeal and makes them easier to use, which leads to an increased likelihood that youth and young adults will experiment with them and that those experimenting with cigars will become addicted and progress to regular smoking.

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[27] 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.

Additional delay, past 1 year, would only increase the numbers of youth and young adults who experiment with and become regular smokers after experimenting with flavored cigars, would delay cessation by current smokers, and would 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. Some cigar manufacturers of currently marketed flavored cigars have tobacco-flavored versions that are either pre-existing tobacco products or new tobacco products that are required to obtain premarket authorization. FDA does not expect that this rule, if finalized, would result in many new tobacco products or would require extensive changes to manufacturing.

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, including information concerning the existence of patents that make it impossible to comply in the proposed 1-year time frame. While FDA does not expect that the proposed product standard would prompt extensive changes to manufacturing (given the likely compliance method of ending the addition of flavoring additives to cigar products), FDA requests comments and data regarding whether 1 year is sufficient to comply with this rule or whether this compliance period should be extended to provide additional time.

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 cigars with characterizing flavors (other than tobacco).

X. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under 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 businesses would incur costs to reallocate resources to products other than flavored cigars, we tentatively find that the proposed rule would 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 would result in an expenditure in at least 1 year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The summary of costs and benefits is presented in table 3. The main quantified benefits of this proposed rule, if finalized, come from reduced smoking-attributable mortality that is the result of cigar use among adult cigar smokers, and reduced mortality from secondhand smoke among non-users. Additional unquantified benefits include reduced smoking-attributable mortality among youth who are deterred from initiating under the proposed rule. Unquantified benefits also include medical cost savings, productivity loss savings, improved quality of life, and environmental impacts. These benefits occur because the proposed rule, if finalized, would discourage non-users from initiating flavored cigars, as well as decrease consumption and/or increase cessation among current flavored cigar users, and thus reduce the health consequences associated with such use. Reduced exposure to secondhand smoke would also produce such benefits among non-users. We estimate that the present value of the quantified benefits over a 40-year time horizon ranges between $111,807 million and $286,124 million, with a primary estimate of $198,203 million at a 3 percent discount rate, and between $52,827 million and $135,188 million with a primary estimate of $93,647 million at a 7 percent discount rate. The primary annualized quantifiable benefits equal $8,575 million at a 3 percent discount rate and $7,024 million at a 7 percent discount rate. Unquantified benefits are expected to provide additional benefits beyond those amounts.

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, in a form not necessarily reflected in budgets, to enforce this product standard. Retailers, manufacturers, and wholesalers face a one-time cost of $239.9 (range of $80.0 million to $399.8 million) million to read and understand the rule and manufacturers face a one-time adjustment, or friction cost, of $21.5 million (range of $0.3 million to $43.7 million) to reallocate productive resources currently devoted to the manufacture of flavored cigars to other tobacco products. Consumers who continue to use tobacco products will face a one-time search cost of $61.7 million (range of $30.8 million to $92.5 million) to find new tobacco products as a replacement for the banned flavored cigar products. In addition,

producers face annual lost producer surplus of $88 million (range of $0 million to $175 million). Additional unquantified costs include the costs to consumers who switch from flavored to tobacco-flavored cigars and consumer surplus losses. The present value of the costs over a 40-year time horizon ranges between $126 million and $4,612 million with a primary estimate of $2,368 million for a 3 percent discount rate, and between $118 million and $2,883 million with a primary estimate of $1,500 million at a 7 percent discount rate. The primary estimates for the annualized cost are $102 million at a 3 percent discount rate and $112 million at a 7 percent discount rate.

In addition to benefits and costs, this rule, if finalized, will cause transfers from state governments, Federal Government, and firms to consumers in the form of reduced revenue and tax revenue. The primary estimate for the annualized transfers from the Federal Government to consumers, in the form of reduced excise tax, is $85 million. The primary estimate for the annualized transfers from state governments to consumers, in the form of reduced excise tax, is $129 million. The primary estimate for the annualized transfers from the firms to consumers, in the form of reduced revenue, is $1,979 million. Transfers are summarized in table 3.

Table 3--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 $/year	$7,024	$3,962	$10,140	2020	7%	40	Reduced mortality among adult cigar smokers and non-users
		$8,575	$4,837	$12,378	2020	3%	40	
	Annualized Quantified					7%		
						3%		
	Qualitative	Medical cost savings, productivity loss savings and improved quality of life, environmental impacts						
Costs	Annualized Monetized $/year	$112	$9	$216	2020	7%	40	
		$102	$5	$200	2020	3%	40	
	Annualized Quantified					7%		
						3%		
	Qualitative	Changes in consumer surplus for some flavored cigar smokers, including potential utility changes for consumers who switch from flavored to non-flavored cigars.						

Transfers	Federal Annualized Monetized $/year	$85	$42	$119	2020	7%		
		$85	$42	$119	2020	3%		
	From/To	From: Federal Government			To: Consumers			
	Other Annualized Monetized $/year	$129	$64	$180	2020	7%	40	
		$129	$64	$180	2020	3%	40	
	From/To	From: State Governments			To: Consumers			
	Other Annualized Monetized $/year	$1,979	$1,033	$2,717	2020	7%	40	
		$1,979	$1,033	$2,717	2020	3%	40	
	From/To	From: Firms			Consumers			
Effects	State, Local or Tribal Government: States would transfer some cigar excise tax revenue back to consumers. We are not aware of any cigar manufacturers that are tribally-affiliated and/or operate on tribal land.							
	Small Business: There are about 50 small businesses. Each small business would experience about $1.9 million in annual costs at both a 3 and 7% discount rate.							
	Wages: No effect							
	Growth: No effect							

We have developed a comprehensive Preliminary Regulatory Impact Analysis 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. 298) and at https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.

XI. 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. 307 and 308) and may be seen in 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.

XII. 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 (OMB) under the Paperwork Reduction Act of 1995 is not required. This proposed rule refers to previously approved collections of information. The collections of information in 21 CFR part 1114 have been approved under OMB control number 0910-0879 (expires December 31, 2024); the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910-0684 (expires September 30, 2022); the collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910-0673 (expires November 30, 2024); and the collections in FDA's guidance entitled "Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States As of February 15, 2007," have been approved under OMB control number 0910-0775 (expires August 31, 2022).

XIII. 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 Executive order and, consequently, a federalism summary impact statement is not required.

This rule is being issued under section 907(a) 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 of the FD&C Act broadly preserves the authority of states and localities to protect the public against the harms of tobacco use. Specifically, section 916(a)(1) of the FD&C Act 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) limits the applicability of section 916(a)(2)(A) of the FD&C Act, 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) of the FD&C Act 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) of the FD&C Act, and/or excepted under section 916(a)(2)(B) of the FD&C Act (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, including flavored cigars, would not be preempted by this rule, if finalized, because such prohibitions would be preserved by section 916(a)(1) of the FD&C Act or, as applicable, excepted from express preemption by section 916(a)(2)(B) of the FD&C Act. FDA invites comments on how state or local laws may be implicated if this proposed rule is finalized.

XIV. 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.

XV. 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 1166

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 1166 to subchapter K to read as follows:

PART 1166--PRODUCT STANDARD: FLAVORS IN CIGARS

Subpart A--General Provisions

Sec.

1166.1 Scope.

1166.3 Definitions.

Subpart B--Tobacco Product Standard for Flavors in Cigars

1166.5 Prohibition on use of characterizing flavors in cigars.

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

Subpart A--General Provisions

§ 1166.1 Scope.

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

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

§ 1166.3 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 cigar; 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 cigar; or

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

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

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

Cigar means a tobacco product that:

(1) Is not a cigarette; and

(2) Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

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

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

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

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

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--Tobacco Product Standard for Flavors in Cigars

§ 1166.5 Prohibition on use of characterizing flavors in cigars.

A cigar or any of its components or parts (including the tobacco, filter, or wrapper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including, but not limited to, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, mint, or 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.

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