DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Tobacco Product Standard for Characterizing Flavors in Cigars

Docket No. FDA-2021-N-1309

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 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 Executive Order 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, if finalized, would result in an expenditure in at least one year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The summary of costs and benefits is presented in Table 1. 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.[1] 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

[1] Within this document, "cigar" refers to products meeting the definition in the proposed rule. Such definition generally includes all traditional cigars, little cigars, cigarillos, and any other cigar subcategory.

$239.9 million (range of $80.0 million to $399.8 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 may include changes in consumer surplus for some flavored cigar smokers, including potential utility changes for consumers who switch from flavored to tobacco-flavored[2] cigars. 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 1.

[2] Throughout this document, we use both the terms "tobacco-flavored" and "non-flavored." We rely on the specific term used by researchers when citing to individual studies; however, we generally consider a cigar that does not have a characterizing flavor other than tobacco to be "tobacco-flavored."

Table 1. Summary of Benefits, Costs, and Distributional Effects of Proposed Rule (Millions of 2020 Dollars over a 40-year Time Horizon)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $/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 tobacco-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 percent discount rate.							
	Wages: No effect							
	Growth: No effect							

Table 2 defines key terms used in this document. We provide definitions for several terms we use in this document. We note that these definitions only apply to this document.

Table 2**.** Key Terms and Definitions

Term	Definition
Internality	"Within-person externality…which occurs when a person underweighs or ignores a consequence of his or her own behavior for him- or herself." (1)
Externality	"An effect that production or consumption has on third parties – people not involved in the production or consumption of the good." (2)
Price Elasticity	A measure of how the quantity supplied or demanded changes as a result of a change in price.

II. Preliminary Economic Analysis of Impacts

A. Background

Congress passed the Family Smoking Prevention and Tobacco Control Act (referred to as the Tobacco Control Act or TCA) in 2009 to address the premature death, disease, and other serious health conditions caused by tobacco use. The Tobacco Control Act gave the Food and Drug Administration (FDA) the authority to address issues of particular concern to public health officials, especially the use of tobacco among youth.[3] Of particular relevance for this proposed product standard, the Tobacco Control Act established a ban on most characterizing flavors in cigarettes.[4] The legislative history of the Tobacco Control Act shows that the goal of the TCA's cigarette characterizing flavor ban was to eliminate one emerging group of tobacco products that particularly appealed to youth.[5] Congress determined that banning cigarettes with characterizing flavors would benefit youth and young adults because flavored cigarettes were typically used by individuals experimenting with tobacco products, such as youth, and noted that regular, addicted adult smokers typically did not use such products.[6]

[3] Section 3(2) of the Tobacco Control Act
[4] Section 907(a)(1)(A) of the FD&C Act
[5] H.R. Rep. 111-58, at 37-38
[6] H.R. Rep. 111-58, at 37-38

FDA is proposing a tobacco product standard that would prohibit characterizing flavors, except tobacco, in all cigars. We can use the research and data concerning characterizing flavors in cigarettes that informed Congress's decision to ban flavored cigarettes for purposes of informing cigars' characterizing flavors and this proposed product standard. Like cigarettes with characterizing flavors, cigars with characterizing flavors expose users to the highly addictive chemical nicotine and other toxic and carcinogenic chemicals found in all combusted tobacco products. Regular cigar smokers 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) (3).

In 2010, an estimated 9,000 premature deaths were attributed to cigar smoking; approximately 5,200 of these premature deaths occurred in those users who exclusively smoked cigars (4). According to the 2020 National Youth Tobacco Survey (NYTS), an estimated 960,000 adolescents, including 5.0 percent (770,000) of high school students and 1.5 percent (180,000) of middle school students, had smoked a cigar (cigar, cigarillo, or little cigar) in the preceding 30 days (5). Data from the 2020 NYTS, the most recent data available analyzing flavored cigar use among youth, indicate that 58.3 percent of youth cigar smokers, or approximately 550,000 youths, reported using a flavored cigar during the past 30 days (6).

Many cigars with characterizing flavors have complex flavor profiles, partially due to added ingredients used to impart or layer flavors.[7] Depending on the manufacturing process and the cost of the cigar, the techniques for applying the ingredients vary widely. In addition, the ingredients may be added to a number of different cigar components. For example, the flavor

[7] Complexity of flavor profile of cigars: Krüsemann EJ, Visser WF, Cremers JW, Pennings J, Talhout R. Identification of flavour additives in tobacco products to develop a flavour library. Tobacco Control. 2018; 27(1):105–11. Available at https://doi.org/10.1136/tobaccocontrol-2016-052961. (126)

ingredients may be added individually and in combination to the tobacco filler, the wrapper and binder, the filter, or the tip. 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. Flavors are added to cigars for various reasons, such as to reduce the harshness, bitterness, and astringency during inhalation and to soothe irritation during use (7) (8) (9). 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 tobacco dependence and progression to regular use, and the resulting tobacco-related disease and death.

Adults report use of flavored cigars, although at lower levels than youth and young adults. According to Wave 5 data published in 2021 from the Population Assessment of Tobacco and Health (PATH) Study, the most recent published data regarding adult use of flavored cigars among adult cigar smokers aged 25 and older, 36 percent reported past 30-day use of flavored cigars in 2018-2019. Adult cigar users who reported use of a flavored cigar in the past 30 days include 19.7 percent of adult traditional cigar smokers, 46.5 percent of adult cigarillo users, and 48.7 percent of adult filtered cigar users (10). These data indicate that the proposed product standard also could have a positive public health impact on existing adult flavored cigar users by increasing the likelihood of cessation and decreasing flavored cigar consumption. Health benefits from the latter may occur through cutting back or switching to less harmful tobacco products.

B. Need for Federal Regulatory Action

The large and preventable health toll from cigars and other tobacco products suggests that an internality problem leads to inefficiency in this market. An internality is defined as a "within-person externality…which occurs when a person underweighs or ignores a consequence of his or her own behavior for him- or herself" (1). This internality occurs for two reasons. First, the

market price does not reflect the full health cost of using tobacco products. Second, the addictiveness of tobacco products and the fact that most tobacco users become addicted as youth or young adults causes consumers to misestimate the cost of negative health effects that may be known in an abstract sense but lack the immediate salience of the money and time associated with current consumption. The true or full price of smoking would include the value a fully-informed and nonaddicted consumer would place on the negative health effects of consumption and the impacts to non-users. Because the prices of tobacco products do not fully reflect their social costs, consumers may instead make suboptimal choices. This internality results in a market failure, which contributes to baseline levels of cigar consumption and ongoing social welfare losses. Policy interventions, such as this proposed rule, that close the gap between the market cost and the full social cost enhance social welfare.

The psychology and economics literatures suggest several sources of internality-related market failures. Many smokers have varying preferences, either over time or at the same time, making it difficult to determine the true preferences underlying their consumption choices. Nicotine dependence and initiation in adolescence complicates the notion of consumer preference in this context. Myopia and time inconsistency may be sources of internalities. Myopia, or a strong present bias, can explain the use of a product that yields utility in the present but whose continued use leads to health problems later. For instance, smokers' decisions at early stages of use may impose significant costs on their future selves. Time inconsistency exists when consumers use lower rates of discount for consequences far in the future than for consequences close to the present. Time-inconsistent consumers make current decisions that they would not make from the perspective of their future selves. Time inconsistency is particularly relevant in

the case of tobacco products, for which the overwhelming majority of users initiate in adolescence, when their still-developing brains tend to assess risks and rewards differently.

Nicotine is the primary addictive chemical in tobacco (11), and numerous Surgeon General Reports from 1988 through 2020 have documented the many ways in which nicotine affects the brain and nicotine addiction drives smoking behavior. The 2020 Surgeon General's report explains that "[n]icotine addiction is now increasingly emphasized as a main driver of both the initiation and continuation of smoking" (12). Addiction increases the difficulty of incorporating the full costs of future negative health effects into the decision to continue cigar smoking and makes it more difficult to quit.

Almost all baseline tobacco product users started in adolescence when the brain's critical areas for decision-making are not fully developed, creating an environment for impulsive behavior and time inconsistency. Based on over 50 years of published and peer-reviewed scientific evidence and data, the 2014 Surgeon General's Report concluded that 87 percent of adult smokers start smoking before age 18 (11). Previous Surgeon General's reports indicate that the percentage of smokers initiating tobacco products before the age of 18 has remained mostly constant. The 1994 and 2012 Surgeon General's reports on smoking and health note that almost 90 percent of current adult regular smokers initiated smoking before age 18, and 99 percent initiated smoking before the age of 25, which is the approximate age at which the brain has completed development (13) (14). Given that the brain continues development into an individual's mid-twenties, such users are more vulnerable to nicotine addiction (15). Youth may have problems with accurately processing and acting on information about risky activities by overestimating short-run benefits of engaging in the activity while underestimating potential adverse effects of the activity on health, safety, or well-being. For addictive goods like cigars,

this misprocessing of information puts youth who experiment with cigars at risk of becoming dependent on them before they fully understand the consequences of their actions (16; 17; 14). This proposed product standard would prohibit the use of characterizing flavors other than tobacco in all cigars. Because flavored cigars have disproportionally high use rates among youth and young adults, the product standard would decrease the likelihood of experimentation, development of nicotine dependence, and progression to regular use. Further, for adult users, this proposed rule would decrease the appeal of cigars and provide an additional incentive to stop using cigars. This is anticipated to decrease cigar consumption and increase the likelihood of cessation.

The reduction in use of cigar products would lead to social welfare gains, including reductions in mortality and morbidity (illness) associated with tobacco use. Without federal regulatory action, individuals would likely continue to consume flavored cigars at their baseline levels, increasing their risk of adverse health outcomes directly related to the consumption of this tobacco product (18).

Reducing the appeal and use of cigars by eliminating characterizing flavors, except tobacco, is also expected to decrease tobacco-related health disparities across population groups. Tobacco-related health disparities are observed for cigar use as members from underserved communities[8] experience a disproportionate share of cigar use in initiation, prevalence of use, current use, and frequency of use (see section V.A of Preamble). Because cigar smoking exposes users to many of the same harmful constituents as cigarette smoking and is associated with many of the same health risks as cigarette smoking, disparities in cigar use contribute to tobacco-

[8] As defined by Executive Order 13895 "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," 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.

related health disparities observed in morbidity and mortality (see section V.F of Preamble) for vulnerable populations.[9] This proposed product standard is anticipated to benefit the population as a whole and decrease disparities associated with flavored tobacco product use and, specifically, flavored cigar use.

The use of combusted tobacco products also causes negative externalities, as an individual's smoking creates negative effects for others (both within and outside the smokers' household) not captured in the price of the product (19). Secondhand smoke is the most well-known example of an externality from combusted tobacco products. Other externalities include cigar litter. Reductions in cigar smoking would lessen the impact of these tobacco-related externalities.

State or local bans on flavored cigar products may reduce consumption of flavored cigars. However, these locality bans would not be as effective as a nationwide ban because consumers could still purchase flavored cigars in other locations without bans. Thus, for state and local regulatory actions to be as effective as federal regulation, each state or local government would require a ban as stringent as the one in the proposed rule. Therefore, mitigating the adverse public health impacts from consumption of cigar products resulting from information processing failures and addiction requires federal regulatory action.

[9] Throughout the Preamble of this proposed rule, the term "vulnerable populations" refers to groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation. Examples of vulnerable populations include those with lower household income and educational attainment, certain racial or ethnic subpopulations, 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.

C. Purpose of the Proposed Rule

FDA proposes a product standard that would prohibit characterizing flavors, except tobacco, in all cigars. This proposed product standard would reduce the appeal of cigars, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, progression to regular use, development of nicotine dependence, and resulting tobacco-related disease and death. Additionally, FDA anticipates that the proposed rule, if finalized, would improve public health by decreasing cigar consumption and increasing the likelihood of cessation among existing cigar smokers.

D. Baseline Conditions

i. Introduction

As our primary baseline, we use the current market for cigar products as of 2020. We chose not to include a market trend based on evidence of market and use trends from varying data sources. Surveys of individuals collecting self-reported data on cigar use have yielded relatively constant results for many years. For example, the National Survey on Drug Use and Health (NSDUH) reports from 2015, 2017 and 2019 (20) (21) (22), which collectively provide data on 2014-2019, show that the percent of 12+ year-olds who have used cigars in the past month ranges from 4.5 percent in 2014 to 4.3 percent in 2019 with a maximum of 4.7 percent in 2015. Data from Euromonitor continue to show slow but steady sales growth both in unit sales and dollar sales. Further, Euromonitor continues to forecast growth in the cigar market both in unit sales and dollar sales through 2024. Given the ever-changing landscape of tobacco, we are unable to forecast trends beyond 2024 and therefore assume that the relatively stagnant market that we have seen in recent years will continue into the future. The current market reflects

changes in cigar use due to other regulations and policies in effect prior to this proposed standard.

The proposed rule states that multiple factors are relevant to identify cigar products with characterizing flavors other than tobacco. These factors include the presence and amount of artificial or natural flavor additives, the multisensory experience of a flavor, flavor representations (including descriptors) on products, and any other means that impart flavor (see the Preamble of the proposed rule for a complete description). However, because data on chemical analysis and multisensory experience are not readily available for cigars, we limit our estimation of affected cigar products to products that have flavor descriptors on the product packaging. This approach may to some degree underestimate the number of flavored cigar products impacted by the proposed rule for products with labeling that does not clearly describe the characterizing flavor other than tobacco. We seek comment on the data we use to identify the market of affected cigar products and the extent to which this data may underestimate the number of flavored cigar products impacted by the proposed rule.

ii. Sales Revenue and Market Trends

We estimate the effect of this proposed rule on the market using 2020 data from Euromonitor International (Euromonitor) (23), the most recent data available at the time of the analysis. Euromonitor provides estimates for total cigar sales and estimates for flavored and tobacco-flavored sales. The Euromonitor data reports Retail Selling Price (RSP) which includes retailer and wholesaler markups and excise taxes.

Euromonitor estimated that the total value of cigar sales in the U.S. equaled $16.67 billion and the total number of sticks equaled 13.99 billion in 2020. The dollar sales of tobacco-flavored cigar products in 2020 equaled $13.48 billion and the sales for flavored cigar products equaled $3.19 billion. See Table 3 for a summary of the market. The total number of sticks sold

of tobacco-flavored cigar products in 2020 was 8.12 billion, and the number of sticks sold for flavored cigar products was 5.87 billion.

Table 3. Cigar Sales Baseline ($ Billions, 2020)

Measure:	Estimate ($ Billion)	% of Market
Total Cigar Sales	$16.67	100%
Cigars Sales of Tobacco-Flavored	$13.48	80.9%
Cigars Sales of Flavored	$3.19	19.1%

Sources: Euromonitor 2020 Data

According to Euromonitor, cigar dollar sales have grown by 2.1 percent from 2018 to 2020 and unit sales have grown 0.2 percent during the same period. Given the relative stability of the cigar market for the last few years and uncertainty around the future cigar market, we estimate that the cigar market would remain at its current size under the baseline scenario.

iii. Consumption Trends

Data from the NSDUH indicate that in 2019 11.70 million, or 4.3 percent, of Americans over 12 years of age had smoked a cigar in the past 30 days. Cigar use is highest among young adults, with 7.7 percent of 18-25-year-olds reporting past 30-day use compared to 4.0 percent of respondents 26 years and older in 2019. For 12-17-year-olds, past 30-day cigar use has dropped from 4.5 percent in 2002 to 1.4 percent in 2019 (24). Data from the 2020 NYTS reported past 30-day cigar use of 5.0 percent among high school students and 1.5 percent among middle school students (5). Further, 58.3 percent of middle and high schoolers who use cigars reported using a flavored cigar during the past 30 days (5). In total, there are approximately 3 million flavored cigar smokers as estimated by PATH and discussed in the Preamble.

iv. Number of Affected Entities

1. Current Cigar Manufacturers

While the proposed rule, if finalized, would primarily affect firms producing flavored cigar products, we expect the proposed rule would affect all cigar producers because all cigar

producers will need to read and understand the rule to ensure compliance. We use the Center for Tobacco Products (CTP) Tobacco Registration and Listing (TRLM) data to identify the number of affected entities, and Dun & Bradstreet (D&B) firm data to determine which manufacturers meet the Small Business Administration's (SBA) definition of small (i.e., having 1,500 or fewer employees – see Section III.A.i). From the TRLM data, we find 57 domestic cigar firms in 2021, including manufacturers and importers. Of these 57 firms, 5 firms produce only flavored products, 26 firms produce only tobacco-flavored products, and 26 firms produce both flavored and tobacco-flavored products. We note that, of the 5 firms only producing flavored cigars, all 5 had other lines of business, either producing non-cigar tobacco products or non-tobacco related businesses. We find that under the SBA definition of small, 50 of the firms are small, 2 are large, and 5 were missing data to make a size determination. We recognize that this may be an underestimate of the number of firms as the Alcohol and Tobacco Tax and Trade Bureau (TTB) data finds that in 2020 there were 74 manufacturers of tobacco products that produced cigars and 114 importers that imported cigars. However, TRLM and TTB have slightly varying definitions of manufacturers which likely accounts for the difference. We use the TRLM data in the analysis as the TTB data do not provide the information to distinguish between firms that produce flavored and tobacco-flavored products or between small and large firms.

2. *Other Affected Entities*

In addition to manufacturers, entities that sell flavored cigar products, either as wholesalers or as retailers, will also be impacted by this rule, if finalized. To estimate the number of these affected entities, we use the Statistics of U.S. Business (SUSB) data from 2019 (25). Although data for wholesalers of tobacco products are identified in a specific NAICS industry code in the 2019 SUSB data (424940, Tobacco and Tobacco Product Merchant Wholesalers), data for retailers of tobacco products are not identified in a specific NAICS industry code in the

SUSB data (i.e., SUSB groups all retailers, including those that sell tobacco products and those that do not sell tobacco products, together).

We incorporate product by industry data from the 2017 Economic Census to estimate the percent of establishments in each retail category that reported non-negligible retail sales of tobacco products (North American Product Classification System (NAPCS) code 5000325000, Retail sales of tobacco products and smoking accessories), as it is the most recent data available (26). Multiplying these percentages by the count of establishments from the 2019 SUSB data, we estimate the number of tobacco-selling retail establishments in 2019. Assuming the distribution of tobacco-selling establishments approximates the distribution of tobacco-selling firms, we also multiply these percentages by the number of firms to estimate the number of tobacco-selling firms in 2019. If firms that have multiple establishments are more or less likely to sell tobacco products than firms with only one establishment, this could introduce some uncertainty into our estimates. Table 4 presents the NAICS codes and descriptions for wholesalers and retailers potentially affected by the proposed product standard, estimates of firms and establishments from the 2019 SUSB data, data from the 2017 Economic Census on establishments that sell tobacco products within each retail category, and our estimates of 2019 firms and establishments that sell tobacco products.

Table 4. Affected Entities Other than Tobacco Manufacturers

NAICS	NAICS Description	Firms - 2019	Total Estab. - 2019	2017 Economic Census Data - Retail sales of tobacco products			Apply to 2017% to	
				Estab. Sell Tobacco - 2017	Total Estab - 2017*	% of Estab. with sell tobacco -2017	2019 Firms Data	2019 Establishment Data
42494	Tobacco and Tobacco Product	1,308	1,493				1,308	1,493

	Merchant Wholesalers							
44511	Supermarkets and Other Grocery (except Convenience) Stores	38,753	62,932	30,814	65,141	47.30%	18,332	29,769
44512	Convenience Stores	27,998	30,330	25,264	28,460	88.77%	24,854	26,924
44530	Beer, Wine, and Liquor Stores	30,531	34,618	18,700	34,440	54.30%	16,578	18,797
44611	Pharmacies and Drug Stores	19,486	44,902	19,247	45,358	42.43%	8,269	19,054
44711	Gasoline Stations with Convenience Stores	56,460	99,299	91,667	98,788	92.79%	52,390	92,141
44719	Other gasoline stations	9,525	13,331	3,725	16,581	22.47%	2,140	2,995
452311	Warehouse Clubs and Supercenters	34	8,307	6,735	8,202	82.11%	28	6,821
452319	All other general merchandise stores	7,720	43,640	31,194	41,241	75.64%	5,839	33,009
453991	Tobacco Stores	9,667	11,655	10,415	10,415	100.00%	9,667	11,655
	Total	201,482	350,507	237,761	348,626		139,404	242,657

[a] By definition, all firms in NAICS 42494 sell tobacco products.

We are unable to assess if establishments that sell tobacco products sell flavored cigar products and, therefore, for the purposes of the calculations in this document, we assume all establishments that sell tobacco products sell flavored cigar products. Given the complexities of growth and contraction in various industries, as well as the regularly changing landscape of state and local tobacco policies that may impact the types of establishments that sell tobacco products, we do not predict a trend in the number of tobacco-selling establishments beyond 2019. Furthermore, given that 2017 is the most recent year providing disaggregated data on retailers that sell tobacco, we assume the distribution of tobacco-selling retailers using 2017 tobacco establishment data approximates the distribution of tobacco-selling retailers in 2019. We request

comment on these assumptions and on more recent data to estimate the number of wholesalers and retailers that sell tobacco products by NAICS code.

v. Cigar Excise Taxes

1. Current Federal Cigar Excise Taxes

There is no single source for federal cigar excise tax data. Therefore, we use several data sources to estimate total federal cigar excise taxes paid in the U.S. We request comment on these data sources and our estimates.

The U.S. Internal Revenue Service (IRS) reports federal excise taxes collected for tobacco products. Through 2018, IRS reports the data for domestically produced tobacco products by cigarettes, cigars, papers and tubes, chewing tobacco and snuff, pipe and roll-your-own tobacco, and floor stocks.[10] These data show that federal excise taxes on domestically produced cigars equal about $211 million in 2018 (27).

Federal excise taxes on imported cigars must be estimated using data from multiple sources. Excise taxes on all imported tobacco products totaled nearly $909 million in 2018 (27). However, the IRS does not report the taxes on imports at the product level as it reports for domestically produced tobacco products. Therefore, we produce our own estimates of the product breakdown using two methods. Both methods start with data from TTB (28), which reports domestic taxable removals[11] (which we treat as equivalent to domestic taxable unit sales), imports from foreign countries, and numbers released to domestic factories without payment of tax, all disaggregated by tobacco product category. We subtract the units released to domestic

[10] Data from 2019 and 2020 do not report taxes for tobacco product categories, including cigars.
[11] This refers to the quantity removed from the factory for domestic distribution.

factories without payment of tax from the total units imported to estimate taxable unit sales of imports.

Our first method uses the ratio of imported to domestic taxable quantities to estimate taxes on imports as a proportion of domestic excise taxes. We first obtain a preliminary estimate of the taxes paid on imports within each tobacco product category by multiplying the total domestic excise taxes for that product category by the ratio of imported to domestic taxable unit sales.[12] In this step, the taxable quantity data has more granular detail than the excise tax information; we aggregate the taxable quantity data to match the categories in the excise tax data, which involves combining categories that have different tax rates. We note that the mismatch in data granularity may introduce some uncertainty. The total excise taxes reported by the IRS exceed the sum of our category-specific estimates of preliminary excise taxes on imports. Therefore, we obtain our final estimate by assuming that total reported excise taxes for imported tobacco products have the same proportional distribution across product categories as our preliminary estimates. Based on these calculations, we estimate that excise taxes on imported cigars equal $363 million in 2018. We use these estimates as a lower bound; our calculation assumes that the average tax per cigar is the same for domestic and imported cigars, whereas imported cigars are more skewed towards relatively higher-priced large cigars, resulting in a higher average tax per cigar on imports (29).[13]

[12] Two small categories included in the domestic excise tax data are excluded from the removals data (papers and tubes, and floor stocks). However, each of these accounts for only a small fraction of a percent of domestic excise taxes.

[13] We estimate the average excise tax per domestic cigar by dividing total cigar excises taxes by the number of domestic cigars removed from the factory for domestic distribution. This was $0.039 in 2018. We estimate the average tax per imported cigar using U.S. International Trade Commission data covering U.S. Imports for Consumption of cigars, cheroots and cigarillos containing tobacco. These data are more disaggregated than the IRS and TTB data described above. Within each category of large cigars, we estimate the average price by dividing the total customs value by the number of units. We then take a weighted average of the estimated unit tax across cigar categories by applying the $0.05033 unit tax to small cigars and the 52.75 percent ad valorem tax to large cigars, up

Second, we use the tax rates for tobacco products (30) to calculate excise taxes based on the reported imports of cigarettes, small cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco, which are all tobacco products subject to a unit tax.[14] Because large cigars have a 52.75 percent federal ad valorem tax (up to the maximum of $0.4026 per cigar) and the average price is not reported in these data, we attribute the difference between total reported taxes for imported tobacco products and the taxes calculated for all other tobacco product categories to the excise tax on large cigars. Using this method, we estimate that taxes on imported cigars (small and large combined) equal $461 million in 2018. We use this as our upper bound because attributing the residual amount to large cigars likely overestimates total excise taxes for large cigars. Adding our lower and upper bound estimates for excise taxes on imported cigars with reported taxes on domestic cigars yields a lower bound total federal excise tax of $575 million for 2018 and an upper bound of $672 million. Table 5 shows our estimates for years 2015 through 2018.

Table 5**.** Estimated Cigar Excise Taxes ($ Millions, 2015-2018)

	2015	2016	2017	2018
Federal, Domestic	248	241	222	211
Federal, Imported	301 to 381	351 to 424	360 to 440	363 to 461
Federal, Total	**550 to 629**	**592 to 666**	**582 to 662**	**575 to 672**
State	673 to 769	751 to 856	789 to 917	861 to 1,014
Total, State and Federal	1,223 to 1,398	1,343 to 1,522	1,370 to 1,579	1,436 to 1,686

2. Current State Cigar Excise Taxes

to the maximum of $0.4026. This yields an estimated average tax per cigar of $0.055 in 2018. However, we do not use these data for this analysis because we lack sufficient information to determine how well customs value corresponds to the price upon which the ad valorem tax is paid.

[14] Federal excise tax rates on tobacco products have not changed during the period under consideration.

States that impose an excise tax on cigars use numerous formulas to assess the tax. We lack enough information to calculate individual state cigar taxes without making additional assumptions for each state. The U.S. Census Bureau, however, reports total tobacco product excise taxes by state for selected years. Therefore, we estimate total state excise taxes for cigars by assuming cigars' share of state tobacco excise taxes is the same as cigars' share of federal excise taxes, using the information calculated above for federal excise taxes. Since cigars may be sold in small or large sizes and by unit or pack, we do not attempt to calculate taxes based on sales volumes. For 2018, our estimated federal excise taxes on cigars were 4.4 percent to 5.2 percent of total reported federal excise taxes for all tobacco products. Assuming this proportion holds for the $19 billion in state tobacco excise taxes collected in 2018 (31), we estimate that state cigar excise tax collections ranged from $861 million to $1,014 million in 2018. Results for years 2015 through 2018 are shown in Table 5. We request comment on these data sources and our estimates.

vi. Cigar Attributable Deaths

As discussed in the Preamble, we identify the annual mortality attributable to cigar smoking in the United States from a previously published analysis (4). This analysis modified the Smoking-Attributable Mortality, Morbidity and Economic Costs methodology, used by the Centers for Disease Control and Prevention (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. 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).

Because it is possible that some dual cigarette and cigar smokers might replace their cigar use with cigarette use if flavored cigars were prohibited, we consider 5,200 as our baseline measure of cigar attributable deaths. As data from the National Health Interview Survey (NHIS) from 2000-2019 has shown relatively stable cigar use prevalence estimates among adults (22), 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. Adult cigar smoking prevalence has remained relatively constant over time, although youth prevalence has declined in recent years. Alternative assumptions about youth prevalence trends over time and their potential implications on mortality rates are considered in a sensitivity analysis.

E. Changes in Cigar Smoking Behavior Attributable to the Rule

We expect the proposed rule, if finalized, would change the behavior of baseline cigar smokers and future smokers who would have initiated with cigars. We identify four likely behavioral changes as shown in Table 6.[15] The first is tobacco cessation, which we define as baseline cigar users who quit tobacco use because of the proposed rule. Second, baseline cigar users may switch to a different tobacco product (tobacco-flavored cigars or non-cigar tobacco products) because of the proposed rule. We refer to this response as switching. The third type of behavioral response is dissuaded tobacco initiation. This involves future users who would have initiated smoking with cigars in the baseline but, because of the proposed rule, do not begin using tobacco products. Finally, future smokers who initiate with cigars in the baseline may

[15] We do not address another possible behavior change: incomplete switching, or dual use. These users may respond to a prohibition on flavored cigars by continuing to smoke available cigars while also switching to a different tobacco product. Our estimates treat these users as not experiencing health benefits relative to the baseline. However, we acknowledge that partial switching to less harmful products may result in some health benefits, which is not quantified in this analysis.

initiate with a different tobacco product because of the rule. We refer to this behavior change as switched initiation.

Table 6. Behavioral Changes Caused by the Proposed Rule

Behavioral Change	**Definition**
Tobacco Cessation	When baseline cigar users quit all tobacco products
Switching	When baseline cigar users switch to different tobacco products (tobacco-flavored cigars or non-cigar tobacco products)
Dissuaded Tobacco Initiation	When non-tobacco users who would have initiated with cigars no longer initiate tobacco use
Switched Initiation	When non-tobacco users who would have initiated with cigars initiate with a different tobacco product (tobacco-flavored cigars or non-cigar tobacco products)

Note: We provide definitions for several terms we use in this document. We note that these definitions only apply to this document.

To determine the number of baseline and future cigar users who change their behavior because of the proposed rule, we use evidence from studies of similar policies prohibiting tobacco products with flavors.[16] These studies investigate the effects of flavored tobacco bans on both sales and tobacco use, with studies of tobacco use focusing on adolescent and young adult populations. Given the appeal of flavored tobacco products to these groups, we use estimates from these studies to forecast the likely impact of a flavored cigar prohibition.

The Preamble discusses detailed results from recent evaluations of restrictions on the sale of tobacco products with characterizing flavors, except tobacco, in U.S. localities including New York, NY (NYC) (32) (33); Providence, RI (34) (35); Lowell, MA (36); Attleboro and Salem, MA (37); San Francisco, CA (38) (39); and Minneapolis and St. Paul, MN (40). In addition, the Preamble discusses impacts of the national flavored tobacco policy in Canada (41) (42). Table 1

[16] Some of these studies of similar policies evaluate prohibitions on tobacco products with flavors that exempt menthol. Because this proposed rule would not exempt menthol, these studies could understate the impact of this policy.

and Section IV.G. of the Preamble summarizes key findings from these studies. In this section, we focus on the studies used to develop our benefits analysis.

Of all analyses in Table 1, the Preamble notes that studies in Providence (34), New York City (33), and San Francisco (39) provide the best available data on the effect of real-world, implemented prohibitions on cigar sales and, thus, consumption. Compared to other evaluations, these were the only studies with pre/post designs that included comparison groups.

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 (33) (34) (39). 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 (34). 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, even though compliance in NYC was incomplete. The study of San Francisco found that the flavor restriction was associated with a 51 percent reduction in overall cigar sales (39). Importantly, these decreases in overall cigar sales indicate that consumers did not completely substitute non-flavored cigars for flavored cigars because of the restriction (33). 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 nine-county area surrounding NYC declined after the implementation of NYC's flavor restriction, although the change was not statistically significant.

We note that the decline in flavored and overall cigar sales occurred despite incomplete compliance in some localities, such as the NYC ordinance (33). 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 that we expect sales and consumption to be highly correlated. Based on the Providence sales data, which provided the midrange of estimates from the evaluation studies, we use a 30 percent relative decrease in total cigar unit sales as our main estimate in the analysis. This figure is a rounded estimate of the 31 percent reduction in overall cigar sales observed in Providence.

For a lower bound estimate of consumption, we rely on evidence from the NYC flavor ban, as discussed in the Preamble. Due to evidence of incomplete compliance, we consider the impacts of the NYC flavor ban on total cigar unit sales to be an underestimate of what the reduction in total cigar consumption in the U.S. overall would be if the proposed standard were implemented. 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 (33), which would suggest some substitution with non-flavored cigars. We therefore use an estimated 15 percent relative decline in total cigar unit sales as a lower bound of the impact of this proposed product standard.

We consider an upper bound to be a scenario in which flavored cigars are removed from the U.S. market after implementation of the proposed standard and no substitution of tobacco-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 41.9 percent of 2020 cigar and cigarillo unit sales (defined as sticks) in the United States were for flavored varieties. If there is no switching from flavored to tobacco-flavored cigar varieties, then overall cigar unit sales, and thus consumption, would decrease by approximately 42 percent following implementation of the proposed standard. We use this figure as the upper bound for the decrease in total cigar sales following implementation of the product standard. As noted in the Preamble, this bound is consistent with the 51 percent reduction in average weekly total cigar unit sales observed in San Francisco following implementation of a flavored tobacco product restriction (39).

As discussed in the Preamble, these studies of the impact of real-world restrictions on flavored tobacco products provide insight into the likely responses of baseline cigar smokers to the proposed standard, including decreases in cigar consumption. However, we acknowledge there are limitations of applying these findings to our benefits analysis. First, local bans may not have the same impacts on behavior as a nationwide prohibition because consumers can avoid a local ban by purchasing products from a different location. We note that Courtemanche et al. (43) found a 6 percent reduction in youth use of tobacco products following implementation of

the cigarette flavor ban in the Tobacco Control Act. However, due to data limitations this study was limited in its ability to attribute changes in tobacco use, particularly flavored use, directly to the federal restriction. Moreover, 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 (33) (34). Therefore, the estimated effect of local prohibitions on flavored cigars may underestimate the effect of the proposed flavor standard since such a standard would apply to cigar manufacturers as well as retailers, thus reducing the probability that violative products would be available for purchase.

Second, the available data are mixed regarding the extent to which flavored cigar smokers switched to e-cigarettes, tobacco-flavored cigars, or other tobacco products including cigarettes. 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 (44). 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 (45). 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 (39). Findings from analyses of flavor restrictions in Minnesota and Massachusetts also observed decreases in cigarette smoking (40) (46). Despite the limitations in generalizing findings from local jurisdictions, these real-world evaluations provide important insight into how the proposed prohibition on characterizing flavors (other than tobacco) in cigar products may impact baseline cigar smokers

as well as reduce the rate of youth and young adult experimentation and progression to regular use of cigars.

Finally, we note that the proposed standard is expected to result in some consumers quitting cigars entirely, either through product switching or complete cessation, and others cutting back on cigar smoking, and potentially supplementing with other non-cigar tobacco products. To estimate how reductions in consumption at the population-level may be distributed across individual consumer behaviors, we utilize data from studies of other tobacco control policies. A robust evidence base exists to characterize the impact of tobacco taxes on consumption and behavior. Data from studies of the impacts of cigarette tax increases on smoking behaviors suggests that approximately half of observed reductions in cigarette sales are due to smokers quitting, while the other half are due to reducing or cutting back on the number of cigarettes smoked (47).[17] As noted in the Preamble, for this analysis we assume that among regular, 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. The 50 percent that cut back are referred to as "switchers" as they are estimated to switch to other tobacco products. Our estimates do not reflect potential benefits in avoided mortality among those who cut back. Instead, avoided mortality is only counted among those who quit smoking entirely. This estimate may understate the full benefits because some studies have found health and mortality benefits from substantial reductions in cigarette consumption, and we assume that the same would be the case for cigars, although these benefits are far less than those derived from complete smoking cessation (48) (49). We request comment and data that could further inform these estimates.

[17] We refer the reader to p.176 of the referenced report.

F. Benefits of the Proposed Rule

This proposed tobacco product standard, if finalized, would prohibit characterizing flavors (except for tobacco) in cigars. We expect this proposed rule to reduce cigar use and the number of cigar-attributable deaths. We quantify the health benefits associated with these behavioral changes.[18] In addition, we discuss other benefits, including medical cost savings, averted productivity losses, and environmental impacts. We request comment on all estimates in this section.

i. Health Gains from Changes in Cigar Smoking Behavior

As discussed in the Preamble, we expect the proposed rule would affect the behavior of two groups: baseline smokers of flavored cigars, and non-users, particularly youth and young adults, who would start smoking flavored cigars in the absence of regulation. Both cessation and dissuaded initiation will result in public health benefits, as these behavioral changes reduce the number of smokers now and in the future, eliminating their exposure to the harmful constituents found in cigars. However, switching, switched initiation, and incomplete switching (dual- or poly- tobacco product use) may not generate these same magnitude of public health benefits. Similarly, some flavored cigar smokers may switch to noncombustible tobacco products which could yield public health benefits because they are potentially lower health risk products. Because we lack information to estimate the proportion of users likely to switch to potentially lower health risk products, we focus on those users who reduce or cease smoking. We discuss switching in the uncertainty and sensitivity section (see Section I.K).

[18] We note that, as discussed in the Preamble, the flavorings in cigars may have health consequences beyond those of a tobacco-flavored cigar. We do not have available data to account for the resulting potential additional benefits, though they are expected to be minimal in relation to the larger health gains estimated here.

1. *Health Gains from Reduction in Cigar Use*

We expect the proposed rule would affect the behavior of two groups: baseline smokers of flavored cigars, and non-users, particularly youth and young adults, who would start smoking cigars in the absence of regulation. Our analysis models how behavior would change in response to the elimination of flavored cigars covered by the proposed rule and compares health outcomes generated by this behavioral change to health outcomes in the absence of this regulatory action. In this section, we estimate the proposed rule's public health impact on baseline adult smokers of flavored cigars over a period of 40 years. Because the health impact of averted initiation on baseline youths occurs far in the future, beyond 40 years, we estimate these benefits separately from adults by using a cohort approach. The cohort approach captures the lifetime mortality benefits from dissuaded initiation, even though they occur outside the 40-year time horizon, by discounting future benefits back to the 40-year period when their associated costs occur. However, due to uncertainty about the 2019 Tobacco 21 law's effect on baseline youth initiation, and thus baseline cigar-attributable premature deaths for this population, we estimate these health impacts in a sensitivity analysis.

The Preamble also outlines some additional potential benefits associated with the proposed rule, including reduced morbidities in those that use cigars and reduced exposure to secondhand smoke for non-users. We quantify reduced mortality among non-users associated with reduced exposure to secondhand smoke in this section. Regarding reduced morbidities, we lack sufficient data to quantify any monetary value associated with reduced initiation, cessation, reduced use, or reduced exposure to secondhand smoke. We expect that accounting for these unquantified impacts, including direct medical costs, would significantly increase the overall monetary value of the benefits of this rule. For these reasons, our quantified estimates undervalue

the eventual public health benefits of the proposed rule. We request comment and data on these unquantified benefits.

As discussed in the Preamble, in 2010 approximately 9,000 premature deaths were attributed to regular cigar smoking, and 5,200 of these premature deaths occurred among regular cigar smokers who did not currently smoke cigarettes (i.e., "exclusive cigar smokers") (4). Because it is possible that some dual cigarette and cigar smokers may replace their cigar use with cigarette use after flavored cigars covered by the proposed rule are prohibited, our analysis uses the latter estimate of 5,200 deaths as the basis for quantifying the benefits of the proposed standard. We use 9,000 deaths as an alternative measure in a sensitivity analysis. We then estimate the fraction of deaths that would be avoided if the proposed standard were in effect. Because we expect cigar sales and consumption to be strongly related, we use cigar unit sales as a proxy for consumption. We use the estimates discussed in the Preamble and described earlier of a 30 percent decrease in total cigar consumption as our primary estimate, though evidence from published studies suggests a plausible range of 15 to 42 percent.

By multiplying the estimated 5,200 exclusive cigar-attributable deaths previously described by a 30 percent decline in cigar sales, then reducing that value by 50 percent to reflect benefits only for those who quit smoking entirely, we estimate that the proposed standard would result in 780 annual averted deaths (= 5,200 * 0.30 * 0.50). As described in the Preamble, due to the uncertainty inherent in estimating the impact of the proposed policy based on these data, we conducted Monte Carlo simulations using @RISK statistical software to assess the effect of varying key data inputs. Using a triangular distribution for all parameters, we ran 1,000 simulations using 15 percent and 42 percent as the lower and upper bounds of decreases in total cigar consumption and 25 percent and 75 percent as the lower and upper bounds for the

proportion of decreased consumption due to complete cessation. Ninety percent of the resulting estimates fell within a range of 440 to 1,126 deaths averted annually due to the proposed standard. We summarize this estimation in Table 7, which is also referenced in Preamble Section IV.C.3.

Table 7. Derivation of the reduction in adult cigar-attributable deaths due to the proposed rule

Row	Description	Point Estimate and Distribution	Supporting Discussion or Calculation
1	Exclusive cigar-attributable deaths	5,200	Section II.F.i.1 and Preamble Section VI.C.3
2	Percent decrease in cigar consumption represented by cigar unit sales	30% [15, 42][1]	Section II.F.i.1 and Preamble Section VI.C.3
3	Percent of adult cigar users likely to quit entirely	50% [25, 75][1]	Section II.F.i.1 and Preamble Section VI.C.3
4	Estimated averted deaths due to proposed rule	780 [440, 1,126][2]	row 1 x row 2 x row 3

[1] These are the minimum and maximum values.
[2] These are the simulated 5th and 95th percentile outcomes for this row.

Table 8 summarizes our assumptions about the timing and magnitude of the avoided premature deaths of exclusive cigar smokers over the 40-year period following a final rule's effective date, using our estimate of affected products. 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 (4), 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 period; consequently, we assume that it would take 30 years to realize the full mortality benefits of the proposed standard (50).

To allow for a gradual phase-in of health effects, we assume that avoided premature deaths begin to occur two years after the rule's effective date. Knoke, Burns, and Thun (50) assume, given the biology of lung cancer, that the risk of death from lung cancer would begin to decrease two or more years following smoking cessation.[19] To estimate the timing of the impact of the proposed rule, we use research on the rate at which excess mortality from cigarette smoking declines after smoking cessation. Knoke, Burns, and Thun (50) estimate that excess mortality from lung cancer for cigarette smokers who quit before developing cancer, relative to those who continue to smoke, scales down by an exponential factor that depends on the number of years since the smoker has quit and the age of quitting. They estimate this factor as:

$$e^{-(0.274-\ .00279\times\text{age at smoking cessation})\times(\text{years since quitting}-2)}$$

To apply this factor to avoided cigar-attributable premature deaths, we assume 40 years as the average age of quitting. Using household survey data of U.S. adults over 18 years of age, Schauer, Malarcher, and Asman showed that the average quitting age of 40 years did not change over time between 1997 and 2012 (51). We also assume that quitting occurs immediately, meaning that years since quitting equals the number of years since the rule has taken effect. Subtracting the estimated factor from one for a given year after the rule takes effect provides an estimate of the share of avoided cigar-attributable premature deaths that would have occurred by that year. Using these assumptions, Table 8 shows the estimated number of avoided cigar-

[19] While Knoke, Burns, and Thun assume mortality risk reductions from lung cancer begin two years following cessation to account for former smokers quitting ill and the rate of tumor growth, a meta-analysis by Reitsma et al. (2020), which assessed data from 49 prospective cohort studies, generally supports this assumption (125). During their review of the literature, Reitsma et al. found that after the first year following smoking cessation, the risk of lung cancer mortality had declined by approximately 12% when excluding data from participants that were "sick quitters." However, risk reduction decreased once sick quitter data was incorporated, supporting Knoke, Burns and Thun's lag adjustment for former smokers quitting ill. Consistent with Knoke, Burns, and Thun, the meta-analysis also found that after 5 years following smoking cessation, lung cancer mortality risk had declined by approximately 38%, and by 58% after 10 years following smoking cessation.

attributable deaths expected to result from the product standard, holding all other factors constant. We note these estimates likely represent an underestimate of impacts since this research looked only at lung cancer deaths of cigarette smokers and not at other smoking-related mortalities such as those linked to cardiovascular impacts, pulmonary disease, or other cancers—all of which are associated with cigar use.[20] As stated in the Preamble, we do not expect an appreciable difference in the risk of cigar-related mortality from flavored vs. tobacco-flavored cigars. Other assumptions about the timing of the effect of the elimination of flavored cigars would affect the magnitude of our benefits estimate. We request comments and data on this approach.

Table 8. Estimates of the Magnitude and Timing of Reduction in Adult Deaths

Years after Effective Date of Rule (from 2024 to 2063)	Baseline Annual Deaths	Policy Impact Phase-in	Annual Deaths Under Proposed Standard			Annual Deaths Avoided Due to Proposed Standard		
			Low	Primary	High	Low	Primary	High
1	5,200	0.0%	5,200	5,200	5,200	0	0	0
2	5,200	0.0%	5,200	5,200	5,200	0	0	0
3	5,200	15.0%	5,134	5,083	5,031	66	117	169
4	5,200	27.7%	5,078	4,984	4,888	122	216	312
5	5,200	38.6%	5,030	4,899	4,766	170	301	434
6	5,200	47.8%	4,990	4,827	4,662	210	373	538
7	5,200	55.6%	4,955	4,766	4,574	245	434	626
8	5,200	62.3%	4,926	4,714	4,499	274	486	701
9	5,200	67.9%	4,901	4,670	4,435	299	530	765
10	5,200	72.7%	4,880	4,633	4,381	320	567	819

[20] Substantial reductions in cardiovascular disease have been observed within a few years of smoking cessation, which may occur faster than reductions in lung cancer. For example, results from the Nurses' Health Study (Table 3) find reductions in heart disease and stroke mortality risk of 46% within 5 years, 61% in 5-10 years, and 58% for 10-15 years compared to reductions in lung cancer mortality risk of 34%, 53%, and 29% in these periods. See https://tobaccocontrol.bmj.com/content/19/3/248.short. (127)

11	5,200	76.8%	4,862	4,601	4,335	338	599	865
12	5,200	80.3%	4,847	4,574	4,296	353	626	904
13	5,200	83.2%	4,834	4,551	4,263	366	649	937
14	5,200	85.8%	4,823	4,531	4,234	377	669	966
15	5,200	87.9%	4,813	4,514	4,210	387	686	990
16	5,200	89.7%	4,805	4,500	4,190	395	700	1,010
17	5,200	91.2%	4,799	4,488	4,173	401	712	1,027
18	5,200	92.6%	4,793	4,478	4,158	407	722	1,042
19	5,200	93.7%	4,788	4,469	4,145	412	731	1,055
20	5,200	94.6%	4,784	4,462	4,135	416	738	1,065
21	5,200	95.4%	4,780	4,456	4,125	420	744	1,075
22	5,200	96.1%	4,777	4,450	4,118	423	750	1,082
23	5,200	96.7%	4,775	4,446	4,111	425	754	1,089
24	5,200	97.2%	4,772	4,442	4,106	428	758	1,094
25	5,200	97.6%	4,771	4,439	4,101	429	761	1,099
26	5,200	98.0%	4,769	4,436	4,097	431	764	1,103
27	5,200	98.3%	4,768	4,433	4,093	432	767	1,107
28	5,200	98.5%	4,766	4,431	4,091	434	769	1,109
29	5,200	98.8%	4,765	4,430	4,088	435	770	1,112
30	5,200	98.9%	4,765	4,428	4,086	435	772	1,114
31	5,200	100.0%	4,760	4,420	4,074	440	780	1,126
32	5,200	100.0%	4,760	4,420	4,074	440	780	1,126
33	5,200	100.0%	4,760	4,420	4,074	440	780	1,126
34	5,200	100.0%	4,760	4,420	4,074	440	780	1,126
35	5,200	100.0%	4,760	4,420	4,074	440	780	1,126
36	5,200	100.0%	4,760	4,420	4,074	440	780	1,126
37	5,200	100.0%	4,760	4,420	4,074	440	780	1,126
38	5,200	100.0%	4,760	4,420	4,074	440	780	1,126
39	5,200	100.0%	4,760	4,420	4,074	440	780	1,126
40	5,200	100.0%	4,760	4,420	4,074	440	780	1,126
Total	208,000		193,749	182,737	171,530	14,251	25,263	36,470

Note: To allow time for implementation, we assume that avoided premature deaths begin to occur two years after the rule's effective date. After year 30, we assume that the full mortality benefit for baseline exclusive cigar smokers of 780 will be realized. Avoided deaths could increase with an increase in cigar use prevalence and decrease with a decrease in use prevalence.

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.

ii. Monetary value of benefits, including health gains

1. VSL Approach

We value the reduction in mortalities from the use of cigars using a value of a statistical life (VSL) approach, which uses a range of VSL estimates to measure the monetary value of reduced mortality. We complement our VSL analysis with a life-years approach in a subsequent sensitivity analysis. VSL estimates do not represent the dollar value of a person's life but instead represent the amount individuals are willing to pay for small reductions in mortality risk. We use VSL estimates recommended by the Department of Health and Human Services, which are based on a review of published studies. The estimates of VSL following the final rule's effective date (which, for the purposes of this analysis, we estimate to be 2024) range from $5.5 million to $17.9 million, with a mid-point value of $11.8 million. We use the mid-point value in this section and present the VSL range in a sensitivity analysis. These estimates are presented in 2020 dollars. The first year and all subsequent values are adjusted for projected real income growth.[21] The Congressional Budget Office (CBO) currently projects real income growth at 0.8 percent per year through 2051.[22]

These VSL values are multiplied by the corresponding estimated number of avoided premature deaths. Table 9 shows the number of avoided deaths each year over the first 40 years

[21] The Department of Health and Human Services provides VSL values for changes in mortality risk occurring in 2020 through 2049: https://aspe.hhs.gov/sites/default/files/2021-07/hhs-guidelines-appendix-d-vsl-update.pdf. (132)
[22] Congressional Budget Office. "The 2021 Long-Term Budget Outlook." Table A-2. Average Annual Values for EconomicVariables That Underlie CBO's Extended Baseline Projections: Growth of Real Earnings per Worker, 2021-2051. https://www.cbo.gov/publication/57038. Accessed March 19, 2021. (128)

of the rule and the present discounted value of avoided deaths at both 3 percent and 7 percent using the midpoint VSL estimate of $11.8 million in the first year. Because we phase in avoided premature deaths as described earlier in this section, the VSL values are discounted by the number of years from the effective date of the final rule (e.g., in the third year after the rule goes into effect, the values are discounted three years, and in the fourth year they are discounted four years) as shown in the table. Table 9 presents the value of the benefits of the rule based on the 15 percent reduction in premature deaths.

Table 9. Present Discounted Value of Avoided Deaths over 40 Years from 2024 to 2063 for Exclusive Cigar Users Ceasing all Tobacco Use

Years after Effective Date of Rule (from 2024 to 2063)	Annual Deaths Avoided for Baseline Adults, Primary Estimate (Assumes Phase-in)[1]	Central Value of Statistical Life from 2024 to 2063 ($ Millions)	Present Discounted Value of Deaths Avoided at 3% ($ Billions)	Present Discounted Value of Deaths Avoided at 7% ($ Billions)
1	-	11.8	0.00	0.00
2	-	11.9	0.00	0.00
3	117	12.0	1.28	1.15
4	216	12.1	2.33	2.00
5	301	12.2	3.17	2.62
6	373	12.3	3.84	3.05
7	434	12.4	4.37	3.35
8	486	12.5	4.79	3.53
9	530	12.6	5.12	3.63
10	567	12.7	5.36	3.66
11	599	12.8	5.54	3.64
12	626	12.9	5.67	3.59
13	649	13.0	5.75	3.50
14	669	13.1	5.79	3.40
15	686	13.2	5.81	3.28
16	700	13.3	5.80	3.15
17	712	13.4	5.77	3.02
18	722	13.5	5.73	2.88
19	731	13.6	5.67	2.75
20	738	13.7	5.60	2.61

21	744	13.8	5.52	2.48
22	750	13.9	5.44	2.35
23	754	14.0	5.35	2.23
24	758	14.3	5.33	2.14
25	761	14.4	5.24	2.02
26	764	14.4	5.10	1.89
27	767	14.5	5.00	1.79
28	769	14.6	4.90	1.69
29	770	14.7	4.81	1.59
30	772	14.8	4.71	1.50
31	780	14.9	4.66	1.43
32	780	15.1	4.56	1.35
33	780	15.2	4.47	1.27
34	780	15.3	4.37	1.20
35	780	15.4	4.28	1.13
36	780	15.6	4.19	1.06
37	780	15.7	4.10	1.00
38	780	15.8	4.01	0.94
39	780	15.9	3.92	0.89
40	780	16.1	3.84	0.84
Total over 40 years	25,263		181.17	85.60

[1] Estimates are based on a first-year central VSL value of $11.8 million, and the VSL value then adjusts annually in accordance with the Department of Health and Human Services (HHS) Guidelines for Regulatory Impact Analysis (RIA) (52).VSL values for current adults are discounted by the number of years following the effective date of the final rule.

a. Estimated Monetized Benefits of Proposed Rule, Based on VSL

We summarize our full range of estimates of VSL values in Table 10. Over the 40-year time horizon of this analysis, we estimate that this rule would result in 25,263 avoided premature deaths among current users of flavored cigars. The present discounted value of total avoided deaths ranges from approximately $102 billion to $262 billion at a 3 percent discount rate, and approximately $48 billion to $124 billion at a 7 percent discount rate. Our primary estimates of the present discounted value of avoided deaths of current users equal approximately $181 billion at a 3 percent discount rate and $86 billion at a 7 percent discount rate. The annualized values of

the primary estimates equal approximately $8 billion at a 3 percent discount rate and $6 billion at a 7 percent discount rate.

Table 10. Present Discounted Value and Annualized Value of Quantified Mortality Reductions for Exclusive Cigar Users Ceasing Tobacco Use Applying a Central VSL Value, 40-year Period from 2024 to 2063 ($ Billions)

	Discount Rate	Low	Primary	High
Present Discounted Value of Averted Deaths	3%	$102.20	$181.17	$261.54
	7%	$48.29	$85.60	$123.57
Annualized Value of Averted Deaths	3%	$4.42	$7.84	$11.31
	7%	$3.62	$6.42	$9.27

Note: Based on a first-year VSL value of $11.8 million. The VSL value then adjusts annually in accordance with HHS guidelines (52).

b. Estimated Monetized Benefits Associated with Secondhand Smoke, Based on VSL

Reduced or averted use among current and future cigar users may lead to improved health outcomes among non-smokers. The Preamble provides detailed discussion on the health risks of exposure to secondhand smoke, such as premature death and disease in non-smoking youth and adults. The 2014 Surgeon General's report on smoking estimates that 41,280 deaths each year are due to secondhand smoke inhalation (11). Another 437,400 deaths are attributable to disease among smokers. Therefore, smoking-attributable mortality due to secondhand smoke is around 9.4 percent (= 100 * (41,280 secondhand deaths / 437,400 smoker deaths)). We account for averted mortality health benefits due to reduced secondhand smoke inhalation by multiplying total benefits in Table 10 by 9.4 percent.[23]

Table 11 shows that the present discounted value of reduced secondhand smoke inhalation ranges from approximately $10 billion to $25 billion at a 3 percent discount rate and approximately $5 billion to $12 billion at a 7 percent discount rate. The primary estimates of the

[23] We request comment on how to account for smoking restrictions, that exist in the baseline for many indoor public spaces, in extrapolating past second-hand smoke risk into the future.

present discounted value of reduced secondhand smoke inhalation equal approximately $17 billion at a 3 percent discount rate and $8 billion at a 7 percent discount rate. The annualized values of the primary estimates equal approximately $1 billion at both 3 and 7 percent discount rates.

Table 11. Present Discounted Value and Annualized Value of Quantified Reductions in Secondhand Smoke Inhalation Applying a Central VSL Value, 40-year Period from 2024 to 2063 ($ Billions)

	Discount Rate	Low	Primary	High
Present Discounted Value	3%	$9.61	$17.03	$24.58
	7%	$4.54	$8.05	$11.62
Annualized Value	3%	$0.42	$0.74	$1.06
	7%	$0.34	$0.60	$0.87

Note: Based on a first-year VSL value of $11.8 million. The VSL value then adjusts annually in accordance with HHS guidelines (52).

Table 12 totals the quantified benefits from averted mortality due to reduced exclusive cigar use and reduced secondhand smoke inhalation. The present discounted value of total benefits ranges from approximately $112 billion to $286 billion at a 3 percent discount rate and approximately $53 billion to $135 billion at a 7 percent discount rate. Our primary estimates of the present discounted value of avoided deaths equal approximately $198 billion at a 3 percent discount rate and $94 billion at a 7 percent discount rate. The annualized values of the primary estimates equal approximately $9 billion at a 3 percent discount rate and $7 billion at a 7 percent discount rate. These figures do not account for reduced morbidity from reduced second-hand smoke exposure, which provides additional benefits beyond those quantified here.

Table 12. Summary of Quantified Benefits—Including Present Discounted Value and Annualized Value of Mortality and Secondhand Smoke Reductions Applying a Central VSL Value, 40-year Period from 2024 to 2063 ($ Billions)

	Discount Rate	Low	Primary	High
Present Discounted Value of Benefits	3%	$111.81	$198.20	$286.12
	7%	$52.83	$93.65	$135.19

Annualized Value of Benefits	3%	$4.84	$8.57	$12.38
	7%	$3.96	$7.02	$10.14

iii. Qualitative Discussion of Other Benefits

We provide a qualitative discussion of other potential benefits of this proposed prohibition of characterizing flavors, except tobacco, in cigars.

1. Medical Cost Savings

Smokers use more medical services during their lifetimes than comparable non-smokers. A 2012 CBO report uses regression analysis on two large national surveys to estimate the impact of smoking on annual health care spending (53). The CBO estimates that current and former smokers have higher annual health care spending per capita than similar people who have never smoked: about $1,425 for 45–64-year-olds; about $1,568 for 65–74-year-olds; and about $1,853 for ages 75 and older. The difference in annual spending is around $285 for 18- to 24-year-olds, and around $570 for 25- to 44-year-olds.[24] The CBO finds that former smokers have higher medical costs than current smokers immediately after quitting, which is likely due to poor health leading smokers to quit, rather than a health disadvantage from quitting smoking.

Sloan et al. (54) estimate that cigarette smokers use more medical services over their life cycles than do comparable nonsmokers, with a specific net cost of $5,822 per female 24-year-old smoker and $4,056 per male 24-year-old smoker.[25] Regular cigar smokers are at increased risk for many of the same diseases as cigarette smokers, including oral, esophageal, laryngeal, and

[24] The CBO costs were updated from 2008 dollars to 2020 dollars using the most recent medical care Consumer Price Index data from the Bureau of Labor Statistics (http://www.bls.gov/cpi/cpid1312.pdf). (129)
[25] The Sloan et al. costs were updated to current dollars using the Bureau of Labor Statistics Consumer Price Index (http://data.bls.gov/cgi-bin/surveymost). The present value calculation used a 3 percent discount rate. (129)

lung cancer; cardiovascular diseases; and chronic obstructive pulmonary disease (COPD) (3), suggesting a similar cost burden for cigar smokers.

The Surgeon General has estimated that smoking-attributable costs include nearly $176 billion annually for direct medical care for adults (11). Smoking-attributable costs included nearly $156 billion in lost productivity due to premature death and exposure to secondhand smoke. More specifically, productivity losses due to secondhand smoke-attributable deaths are estimated to cost the U.S. $5.6 billion each year. The Surgeon General noted that, because these estimates do not include lost productivity due to illness, these costs significantly underestimate the full value of lost productivity costs due to smoking.

Xu et al. used data from the 2010-2014 Medical Expenditure Panel Survey and 2008-2013 National Health Interview Survey to estimate the portion of annual healthcare spending potentially attributable to cigarette smoking (55). Their results suggested that, during 2010 to 2014, 11.7 percent of U.S. healthcare spending each year was attributable to adult cigarette smoking, with health care spending by current smokers accounting for 6.0 percent and former smokers accounting for 5.7 percent (1.3 percent quit in the last five years + 4.4 percent quit more than 5 years = 5.7 percent). Translating this smoking-attributable fraction into dollars, the authors estimated that smoking may have accounted for more than $225 billion of total healthcare spending in 2014. Private insurance and out-of-pocket costs accounted for only $63.8 billion (12.3 percent) of these costs during 2010 to 2014.

Bolnick et al. used data from the 2017 Global Burden of Diseases, Injuries, and Risk Factors Study and the Disease Expenditure Project from the Institute for Health Metrics and Evaluation to estimate that healthcare spending attributable to tobacco smoking accounted for $130 billion dollars in 2016 in the U.S. (56). Tobacco smoke ranked fifth highest in terms of all

U.S. healthcare spending that could be attributed to modifiable risk factors, i.e., risk factors that may be mitigated through behavior. Cardiovascular disease (32.6 percent) and musculoskeletal disorders (21.4 percent) accounted for the largest portions of healthcare costs attributable to tobacco smoke.

Our main benefits estimates value mortality risk reductions using the VSL. As discussed in the HHS Guidelines for RIAs, the VSL may include costs borne by affected individuals, including the allocation of work and non-work time, and out-of-pocket costs.[26] Therefore, to avoid double-counting, we typically do not include medical cost-savings as part of mortality benefits estimates. We would include these cost-savings as benefits if third parties bear most of these costs in the absence of the rule. We request comment on what portion of these mortality-proximate medical cost-savings would be borne by third parties. While we do not separately estimate reductions in cigar smoking-attributable medical costs due to this product standard, we expect that these benefits would accrue to smokers who quit or reduced their cigar use, those that do not initiate, as well as those impacted by secondhand smoke exposure. We request comment, including data and research, that would assist in quantifying such benefits.

2. Productivity Losses and Impacts on Health-related Quality of Life

Reduced or averted cigar smoking and associated decreases in tobacco-related morbidity due to this proposed product standard, if finalized, are expected to reduce productivity losses associated with tobacco-related morbidity and improve health-related quality of life. Many smokers may suffer from more than one tobacco-related morbidity condition. Although we do not quantify the value of such changes in morbidity in this analysis, we expect that the proposed

[26] See also, this report: https://aspe.hhs.gov/reports/estimating-medical-costs-regulatory-benefit-cost-analysis-conceptual-framework-best-practices. (133)

cigar standard could reduce some of the lifetime productivity losses and pain and suffering. We expect that these benefits would accrue to smokers who quit or reduce their cigar use, those that do not initiate, as well as those impacted by secondhand smoke exposure. Quantifying these benefits would require more general information on the impact of cigar smoking on health-related quality of life. Additionally, as with the medical cost-savings above, some of these changes may be included in the value of statistical life estimates in our benefits analysis. While we do not separately estimate reductions in cigar smoking-attributable avoided productivity losses and improved health-related quality of life due to this product standard, we expect that these benefits would accrue to those impacted by secondhand smoke exposure. We request comment, including data and research, that would assist in quantifying such reductions.

3. Environmental Benefits

We do not estimate the impact of reduced cigar litter due to reductions in cigar smoking prevalence but note that this proposed product standard could reduce litter. Cigarette filters are a common source of litter (57) (58), and although we do not have empirical data on how flavored cigars contribute to litter, these cigars often include filter tips which may be discarded at the same rate as cigarette filters. Even without the filter, the tobacco itself can be harmful to the environment (59) (60) (61) (62) (63) (64).

The net effect of the potential environmental benefits will depend on the behavioral response of baseline flavored cigar consumers. The net environmental benefit associated with flavored cigar smokers who switch to non-flavored cigars (or other tobacco products) could be negligible. The environmental benefits would stem from those that stop or reduce tobacco use as estimated in the benefits section (see Section I.F), as well as from those who do not initiate. We

request comment on the environmental impact associated with baseline consumption of flavored cigars.

G. Costs of the Proposed Rule

This proposed standard, if finalized, would prohibit characterizing flavors, except for tobacco, in cigars. We expect this proposed rule to impose costs on industry to follow the product standard, on consumers impacted by the product standard, and on FDA to enforce this product standard. We request comment on all estimates in this section.

i. Costs to Industry

1. One-Time Friction Costs

We estimate one-time friction costs to manufacturers, as they may need to make adjustments to their productive resources. We do not estimate a friction cost to retailers, as this product standard is not likely to impact the use of their productive resources; however, we do estimate other costs for retailers. We request comment on the potential for friction costs to wholesalers.

Many manufacturers of flavored cigars also manufacture, or have the ability to manufacture, tobacco-flavored cigars or other tobacco products. Thus, we anticipate that manufacturers can use many of their production resources currently devoted to the manufacture of flavored cigars to manufacture other tobacco products. For some manufacturers, these costs will be small as they will either stop buying pre-blended flavored tobacco or use their equipment to manufacture cigars without characterizing flavors other than tobacco. We predict this product standard will cause a net reduction in cigar sales of 13.7 percent.[27] Therefore, not all productive resources could be switched to other tobacco products. This 13.7 percent reduction in revenue is not part of

[27] We estimate the lost revenue based on the Preamble's estimate of reduced consumption. The Preamble estimates a 71 percent (= 30% of the 42% of the number of cigars sold) reduction in unit sales. Flavored cigars make up 19.1 percent of dollar sales, so we estimate a 13.7 percent (= 71% * 19.1) reduction in revenue as a result of this rule.

the friction cost (see discussion in Section I.H.ii). We do not have data that would allow us to assess the potential impacts on employment and firm closures.

The cost of reallocating equipment used for flavored cigar production could be represented using capital expenditures. Using Annual Capital Survey Census Data from 2009-2019,[28] we estimate that capital expenditures account for between 0.28-0.44 percent of total annual revenues across the entire tobacco manufacturing industry, excluding electronic nicotine delivery systems (ENDS). However, we also expect manufacturers and their suppliers to incur some one-time adjustment costs, i.e., friction costs, as manufacturers reallocate resources to producing other tobacco products (which may include the preparation and submission of premarket applications for tobacco-flavored cigars) or reduce production capacity in response to the overall reduction in cigar consumption. We note the uncertainty associated with one-time costs to adjust production, such as potentially requiring additional labor, disposing of current equipment, or purchasing new equipment for the manufacture of tobacco products other than cigars with characterizing flavors. We present the full range of one-time adjustment costs, using 120 hours associated with planning and performing cigar production line reallocation and cleaning activities as the lower bound. FDA subject matter experts estimate it takes 2-4 hours to clean a production line between flavored and tobacco-flavored products. Additionally, firms would have to update their standard operating procedures. We estimate that these processes would take a total of 120 work hours. We request comment on this estimation. We use 1.5 percent of annual revenues from flavored cigars sold to adults (excluding excise taxes) as the upper bound. Note that we use a percent of revenue to estimate one-time friction costs, but the revenue itself is not the friction costs; rather, it provides a metric for the magnitude of potential friction costs. Lost revenue is discussed in

[28] Annual Capital Survey Census Data: https://www.census.gov/programs-surveys/aces.html. (130)

Section I.H.ii. We request comment on this measure of friction cost estimation. We expect that these costs would occur in the first year that the proposed rule, if finalized, takes effect.

Table 13 shows our steps for estimating primary and high friction costs. We subtract baseline total excise tax revenues from baseline cigar sales and multiply by the proportion of flavored products to obtain baseline producer revenues. Friction costs are then estimated to be 0.75 percent to 1.5 percent of this amount, or $21.5 million to $43.7 million.

Table 14 shows our steps for estimating the lower bound of friction costs. Although friction costs could include other categories of costs (including preparation and submission of premarket applications and reduced productive capacity) the lower bound estimate of friction costs only accounts for the potential labor costs associated with reallocating productive resources. To value the time to plan and implement reallocation procedures for those cigar product lines affected by the proposed rule, we use composite wages calculated from the 2020 Bureau of Labor Statistics' (BLS) national industry-specific occupational employment and mean wage estimates for the tobacco manufacturing industry (65). We assume a mix of 20 percent upper management occupations (occupation code 11-1000), 70 percent middle management occupations (occupation code 11-1021), and 10 percent administrative occupations (occupation code 43-0000). This mix yields a composite wage of $53.59 (0.2*($64.96) + 0.7*($54.82) + 0.1*($22.19) = $53.59). We double this to account for benefits and other indirect costs, yielding an hourly labor cost of $107.17. The lower bound estimate for each firm would be $12,860 (120 labor hours * $107.17 wage). As discussed in the Baseline section, there are 31 firms that manufacture flavored cigar products. Across all 31 firms, the lower bound cost would be equal to approximately $0.40 million. Overall, friction costs are estimated between $0.40 million and $43.7 million, with a primary estimate of $21.5 million.

Table 13. One-Time Friction Costs Primary and Upper Bounds ($ Millions, 2020)

	Primary	High
Baseline Annual Cigar Sales[1]	$16,666	$16,666
Baseline Federal and State Excise Tax Revenues[2]	$1,686	$1,436
Baseline Producer Revenues	$14,980	$15,230
Baseline Producer Revenues from Sales of Flavored Cigars	$2,868	$2,915
Friction Costs as a Proportion of Producer Revenues	0.75%	1.5%
Estimated Friction Costs	$21.5	$43.7

[1] Source: Table 3
[2] Source: Table 5

Table 14. One-Time Friction Costs Lower Bounds (2020 $)

	Lower-Bound
Total hours (2-4 hours per flavor, 30-60 production lines)	120
Wage ($ per hour)	$107.17
Cost per firm	$12,860
Number of entities (flavored)	31
Total cost in millions	$0.40

2. Effects on Producer Surplus

Producer surplus is the difference between the price a producer receives for their product and the minimum price it would accept. When the amount of product sold in a market falls, producers lose revenue, a portion of which is producer surplus. We can calculate producer surplus based on initial firm revenue, the elasticity of supply, and the percent change in quantity in the market.[29]

As a lower bound, we assume supply is perfectly elastic at the baseline market price. This is consistent with recent economics literature (66). A perfectly elastic supply curve implies that the quantity of cigars supplied to the market will adjust to any quantity demanded at the observed

[29] Producer surplus is the triangular area between the product price and the supply curve equal to one half the change in price times the change in quantity. Equivalently, producer surplus = $0.5 * (\text{Firm Revenue}_{\text{without rule}}) * \left(\frac{1}{supply\ elasticity}\right) * (\%\Delta Q)^2$. We request comment on this calculation.

market price. Because the supply curve overlaps the pre-tax market price, the baseline producer surplus equals $0 when the supply curve is perfectly elastic. However, depending on how the market is defined, the cigar industry could be considered concentrated, implying that the current pre-tax market price resides on an upward-sloping point of the supply curve. Previous empirical research has estimated the supply elasticity of tobacco at 7.0 (67).

Our primary estimate of producer surplus uses a supply elasticity of 7 and our estimated quantity change. [30] We are uncertain about the overall price change, which would depend on responses from both consumers and manufacturers.[31] We acknowledge that there could be more producer surplus loss, therefore we estimate the upper-bound loss as double the primary estimate to capture uncertainty about how prices may change with this product standard. We estimate producer surplus loss ranging from $0 to $175.1 million each year, with a primary estimate of $87.6 million annually.

A limitation of this analysis is that it relies on an estimate of supply elasticity which was estimated using data on tobacco growers in one state from 1950-1984. This estimate of supply elasticity may not generalize to other producers in the tobacco industry, including manufacturers, distributors, and retailers. More recent and regionally-diverse data on supply elasticity may also generate different results. We request comment on these assumptions and data on the elasticity of supply in the cigar market, market structure, and the resulting price impacts of this proposed standard. An additional limitation is that this analysis only assesses one point in the supply chain.

[30] Producer surplus = 0.5 * ($15.2 billion) * (1/7) * $(0.42)^2$ = $191.9 million. We adjust this quantity by a factor of 19.1/41.9 because flavored cigars make up 41.9% of cigar unit sales, but only 19.1% of cigar dollar sales.
[31] We note that the top four manufacturers/brand owners account for 91.8% of flavored cigar sales by volume and 88.3% of dollar sales in the United States (120). Historical evidence suggests that producer behavior in the cigarette market differs from the typical relationship between quantity, minimum price accepted, and market price, in part due to market consolidation. As observed in more recent studies, the prices for cigarette packs have continued to rise as the number of cigarette packs sold have decreased. However, cigarettes are a fairly uniform products while cigars encompass a larger variety of sizes and styles. Therefore, it is unclear if the cigar market will react in the same way as the cigarette market even if the markets are similarly concentrated.

There may be additional lost producer surplus at other points in the supply chain. The degree to which intermediaries in the market lose surplus depends on market structure and integration. We request comment on vertical integration and producer surplus in the cigar market.

3. Reading and Understanding the Rule

All entities affected by this proposed rule, if finalized, would spend time to read and understand the final rule, resulting in a one-time cost. The current Preamble and codified rule together contain approximately 60,000 words; we use this as a proxy for the length of the final rule. Consistent with HHS guidelines, we assume that industry reviewers read at the average adult reading speed of approximately 200 words to 250 words per minute, so the time to read and understand the regulation would range from 4 hours to 5 hours per person (52). We assume that one to four people would read the final rule at each entity manufacturing or importing cigar products, wholesalers, and retail firms.

To value the time associated with reading and understanding the rule if finalized, we use composite wages calculated from the 2020 BLS national industry-specific occupational employment and mean wage estimates for the tobacco manufacturing industry.[32] We use a mix of 50 percent management occupations (occupation code 11-0000) and 50 percent legal occupations (occupation code 23-0000). This mix yields a composite wage of $71.67 (65).[33] We double this to account for benefits and other indirect costs, yielding an hourly labor cost of $143.34.

[32] The BLS did not publish wage estimates for legal occupations within the tobacco manufacturing industry in 2020. We use instead, the legal occupation wage reported for the beverage and tobacco manufacturing industry (NAICS 312000).

[33] The management occupation average wage is listed at $64.99 per hour, and the legal occupation average wage is listed at $78.34 per hour. The calculation is 0.5*($64.99) + 0.5*($78.34) = $71.67.

We estimate the cost for one reviewer to read the rule if finalized to range from $573 to $717. Depending on the number of people who read the rule, these costs would range from $573 to $2,867 for each affected entity. As previously discussed, we estimate that the rule if finalized would affect 56 entities manufacturing or importing tobacco products and 139,404 retailer and wholesaler firms. The total costs for reading and understanding the rule then range from approximately $80.0 million to $399.8 million with a primary estimate of $239.3 million. Table 15 includes a summary of these costs.

Table 15. One-time Costs for Reading and Understanding the Rule ($, 2020)

	Low	**High**
Word Count	60,000	60,000
Average Reading Speed (words per minute)	250	200
Reading Time (Hours)	4	5
Composite Wage ($ per hour)	$143.34	$143.34
Cost per Reviewer	$573.36	$716.70
Number of People Reading Per Entity	1	4
Cost per Entity	$573.36	$2,867
Affected Entities	139,460	139,460
Total Cost ($)	**$80.0 million**	**$399.8 million**

ii. Costs to Consumers

1. One-Time Search Costs

Adult consumers who switch from a flavored cigar product to a substitute tobacco product or those who try other tobacco products before quitting or search for a nicotine replacement therapy will incur search costs to look for substitute products. Search costs may include the time it takes a former cigar smoker to research substitute products, including talking to other tobacco product or nicotine replacement therapy users, searching for reviews on the

internet and social media, reviewing tobacco product or nicotine replacement therapy packages in the store, and assessing the value of products that were purchased. We lack data to estimate the opportunity cost to search for alternative products. Thus, we assume all adult consumers would incur one-time search costs equal to between 0.5 and 1.5 hours of free time. We request comment on possible sources of data on potential search costs and on our assumption.

To monetize these impacts, we adopt a value of time based on after-tax wages. Our approach matches the default assumptions for valuing changes in time use for individuals undertaking administrative and other tasks on their own time, which are outlined in an ASPE report on "Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices."[34] We start with a measurement of the usual weekly earnings of wage and salary workers of $990. We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of $24.75.[35] We adjust this hourly rate downwards by an effective tax rate of about 17 percent, resulting in a post-tax hourly wage rate of $20.55.

For the number of adult users, we use the value discussed in the "Adult Use of Flavored Cigars in the United States" section of the preamble. The preamble uses data from the PATH survey that finds 3 million people 25 years and older currently use flavored cigar products. We recognize this could create an underestimate as it does not include flavored cigar smokers aged 21 to 24. We multiply the number of current adult smokers of flavored cigars, 3 million, by the estimated range for search time (range of 0.5 hour to 1.5 hours, 1 hour primary) and a $20.55 per

[34] The report can be found here: https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework. (131)

[35] As a sensitivity analysis, we assess the search cost with the augmented post-tax wage rate to account for non-wage benefits by doubling the wage. The search costs would be $61.7 million with a lower bound of $30.8 million and an upper bound of $92.5 million.

hour wage rate. We estimate that the proposed rule may result in approximately $61.7 million in consumer search costs with a lower and upper bound of $30.8 and $92.5 million.

2. *Utility Change for Consumers*

Regulations that reduce the demand for a product or that raise its market price may lead to reductions in consumer surplus or consumer utility. For fully-informed, rational consumers, consumer surplus reflects the difference between their willingness to pay for a product and the price they actually pay in the marketplace. A rational consumer is one whose choices maximize his or her utility, i.e., an individual who, when presented with a decision, chooses the option that maximizes their welfare. Circular A-4 states that regulatory impact analyses should consider including "gains or losses in consumers'…surpluses" as part of the economic analysis (68). This reduction or "loss" reflects consumers' diminished utility (i.e., a reduction in the sense of satisfaction or usefulness consumers obtain from using the good, above and beyond what they pay for it).

For cigar smokers, the concept of consumer surplus, or consumer utility, is premised on the assumptions that smokers are rational in their decision-making about smoking, fully informed about the associated risks associated with smoking, and derive benefit from smoking above the price they pay. There is a lack of consensus within the peer-reviewed economic literature regarding how to account for changes in consumer surplus when analyzing the effect of regulations on tobacco products, which are highly addictive and generally initiated before adulthood—considerations that bear on assumptions of consumer rationality.

Economic and scientific research has recognized significant challenges with modeling demand for tobacco and changes in utility. Characterizing flavors in cigars may raise additional challenges relating to demand and utility changes among consumers. These potential challenges include:

- the addictive nature of tobacco products and how characterizing flavors in cigars may impact the addictiveness of cigars;
- cigar initiation during adolescence when the brain is not yet fully developed and how characterizing flavors affect youth appeal;
- the developing nature of public awareness of information about the health harms of smoking;
- tobacco product demand based on demand for other perceived benefits of smoking (derived demand); and
- the regret expressed by current smokers, desire to quit, and flavors' impact on quitting.

It is difficult to disentangle the consumption driven by addiction from that which may be driven by demand for characterizing flavors in cigars. Thus, modeling consumers' willingness to pay for addictive products and, in particular, isolating the value consumers place on a key characteristic of an addictive product, such as characterizing flavors in cigars, is a source of uncertainty. These challenges are discussed in more detail in the following sections. We then discuss how the proposed rule could lead to utility changes for former smokers of flavored cigars who switch to tobacco flavored cigars and consumers who cease consumption of tobacco products altogether. In the Appendix, we provide a more detailed review of the literature and approaches to modeling tobacco product demand and associated changes in consumer surplus.

a. *Addictive Nature of Tobacco Products and the Role Flavors Play in Enhancing the Effects of Nicotine*

Tobacco use is the leading preventable cause of disease and death in the United States (11). Cigars, like other tobacco products, contain the highly addictive substance nicotine, and flavors have been shown to enhance the effects of nicotine. (See section V.C of the Preamble.) Summarizing years of research and analysis in the field of smoking and tobacco product use, the Surgeon General's Reports (SGR) from 1988 through 2020 have documented the many ways in which nicotine affects the brain and nicotine addiction drives smoking behavior. Three main reasons people smoke and use tobacco products were established by the 1988 SGR: "1) Cigarettes and other forms of tobacco are addicting; 2) [n]icotine is the drug in tobacco that causes addiction; and 3) [t]he pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine" (69). Speaking specifically to behavior and patterns of use, the report notes that "[p]atterns of tobacco use are regular and compulsive, and a withdrawal syndrome usually accompanies tobacco abstinence" [id.]. Most recently, the 2020 SGR discusses smoking cessation, asserting as a starting point that "[n]icotine addiction is now increasingly emphasized as a main driver of both the initiation and continuation of smoking" (12).

The National Institute on Drug Abuse (NIDA) includes tobacco and nicotine among commonly used drugs, stating that "nicotine acts in the brain by stimulating the adrenal glands to release the hormone epinephrine (adrenaline) and by increasing levels of the chemical messenger dopamine" and that "for many who use tobacco, brain changes brought on by continued nicotine exposure result in addiction" (70) (71). As DiFranza et al. discuss, the onset of nicotine dependence is "the point of experiencing loss of autonomy over tobacco use" (72). Multiple

studies have shown that symptoms of nicotine dependence can arise early after youth start smoking cigarettes, even among infrequent users (73) (74) (75).

If the demand for flavored cigar products, in part, stems from the demand for nicotine, substitutes for cigar products are readily available. Consumer derived value from other available tobacco products may meet or may exceed the value of some of the attributes of flavored cigars. With these additional complexities influencing demand, it is unclear what magnitude (if any) would accurately represent the loss to certain consumers.

As discussed in the Appendix, multiple economists have developed models of consumer surplus and addiction. Bernheim and Rangel argue that any regulation that helps eliminate cues that help sustain biased demand could also be welfare improving (76). The Bernheim and Rangel model proposes that the consumption of addictive goods is often a mistake triggered by environmental cues. They consider that any government actions that eliminate environmental cues would "unambiguously increase welfare" [id.] for dissuaded smokers. For example, if flavors serve as an environmental cue (i.e., as a type of sensorimotor stimuli), eliminating characterizing flavors in cigars will increase welfare (upon smoking dissuasion) by first reducing the reinforcing appeal of cigars for current flavored cigar smokers and encouraging current flavored cigar smokers to quit smoking. Further, Bernheim and Rangel note that "though individuals may have some ability to avoid problematic cues and create their own counter-cues, the government is arguably better positioned to do this" [id.]. Following the removal of characterizing flavors other than tobacco in cigars, current flavored cigar consumers could choose to cease all tobacco product use or switch to another product. For instance, they could seek flavors from other addictive or non-addictive products and/or continue to obtain nicotine from non-flavored cigars. As suggested by Bernheim and Rangel, cessation that occurs due to a

regulation that eliminates a cue (such as the characterizing flavors) will likely be welfare improving for individuals dissuaded from smoking [id.].

The research presented above shows that cigar smoking is driven primarily by nicotine addiction and its resulting drug-reinforced behavior, meaning that determining the point at which addiction overtakes the choice to continue to smoke cigars poses a significant challenge. Additional uncertainty stems from the ability of flavors to mask the harshness of tobacco smoke, particularly for those initiating tobacco use.

b. Cigar Smoking Initiation During Adolescence When the Brain is Not Yet Fully Developed and How Characterizing Flavors Affect Youth Appeal

Based on over 50 years of published and peer-reviewed scientific evidence and data, the 2014 SGR concluded that 87 percent of adult smokers start smoking before age 18 (11). Previous SGRs indicate that the percentage of smokers initiating tobacco products before the age of 18 has remained mostly constant. The 1994 and 2012 SGRs on smoking and health note that almost 90 percent of current adult regular smokers initiated smoking before age 18, and 99 percent initiated smoking before the age of 25, which is the approximate age at which the brain has completed development (13) (14). Smokers who begin before age 25, the approximate age at which the brain has completed development, are more vulnerable to developing nicotine dependence [id.]. The report further notes that adolescence and young adulthood represents a time of "immaturity in consequential thinking, impulsivity, and decision-making skills" [id.].

As with cigarettes, first cigar use often occurs before 18 years of age (77) (78). A study of almost 10,000 young adult college students who have ever used cigars reported that the mean age of first cigar use was 13.6 years (77). A longitudinal analysis of four waves of PATH Study data (2013-2017) found an increasing probability of initiating cigar use between ages 15 and 20 years (78). By age 20, 31 percent of youth in the PATH Study (2013-2017) had ever used a

cigarillo, filtered cigar, or traditional cigar, with the greatest increase in first use between 17 and 18 years of age (78). 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 (79), and that first use of flavored cigars is associated with continued use of these products (80) (81). As discussed further in the Preamble, due to the combined effects of nicotine and characterizing flavors in cigars, youth who smoke flavored cigars are particularly vulnerable to the effects of characterizing flavors on progression to regular use and dependence.

In the literature that discusses consumer welfare loss for individuals prevented from initiation, there is support for the position that consumer welfare losses for individuals prevented from initiating tobacco product use should not be considered within a welfare analysis (82) (83) (84). As summarized by Cutler et al. (2015), "because people deterred from starting to smoke never develop a special taste for tobacco products, they are able to get equal or better satisfactions from consuming other products, so a regulation that deters them from starting to smoke entails no utility loss" (82). In a later paper, Cutler et al. state:

> "... the strong 'taste' for cigarettes generally grows out of having become addicted to cigarettes. Thus, people who do not start consuming the good will not value it as highly as current users. If the average person deterred from starting to smoke finds a consumption bundle without cigarettes to be no less satisfying than one that includes them, a regulation that deters them from starting to smoke will cause no utility loss" (84).

Youth smokers are likely to enter adulthood with established nicotine dependence, compromising the ability of the vast majority of adult tobacco users to choose cigar smoking in the absence of addiction. As Chaloupka et al. state, "most smoking initiation takes place during adolescence or young adulthood among individuals who are often less than fully aware of the

health and economic consequences of smoking" (85). The authors conclude that "the decision to initiate smoking [among youth] is an irrational decision and any changes in their conventionally calculated consumer surplus resulting from changes in their tobacco use… should not be counted..." (85).

c. Developing Nature of Public Awareness of Information About the Health Harms of Smoking

Since the first SGR published in 1964, evidence of the negative health consequences of cigarette smoking and secondhand smoke has expanded dramatically, and it is difficult for individuals to be fully informed of all the potential risks they undertake when using these products. As noted in the 2010 SGR, 29 additional reports had been released in the 45 years between 1964-2010 documenting the "overwhelming and conclusive biologic, epidemiologic, behavioral, and pharmacologic evidence that tobacco use is deadly" (86). The health conditions established to be causally linked to cigarette smoking in the 2014 SGR are in addition to the more than 40 unique health consequences of cigarette smoking and exposure to secondhand smoke identified by earlier studies (11). As discussed in Section V.D of the Preamble, cigars produce toxic smoke containing the same harmful constituents as cigarette smoke, and cigar smoke may have even higher levels of several harmful compounds (11) (87) (4).

Many of the economists developing methods of analysis of consumer surplus effects have attempted to generate some proxy for assessing awareness of available information. As more information about the health harms of smoking enters public awareness, individuals are expected to be more informed. However, research has shown that being a member of a group with lower socioeconomic status is associated with having lower knowledge of the negative health consequences of smoking. (See 85 FR 15638 - Tobacco Products; Required Warnings for Cigarette Packages and Advertisements for a more detailed discussion.) How such ongoing

information development is assimilated by different individuals and incorporated into modeling results presents additional challenges and sources of uncertainty.

d. Tobacco Product Demand based on Demand for Other Perceived Benefits of Smoking (Derived Demand)

Often, the nature of tobacco product experimentation and progression into regular use, especially in adolescents, is based on demand for other perceived benefits of tobacco product use (such as peer acceptance) rather than demand for the tobacco product itself. This makes it difficult to model the demand for tobacco products separate from the demand for other perceived benefits of use. Evidence of this derived demand comes from surveys in which adolescents are asked about their motivations for initiating smoking.[36] Over time, the original derived demand rationale for tobacco product use may no longer be relevant, but users may be unable to stop due to the development of addiction. This suggests an additional explanation of derived demand: nicotine. In this case, smoking is the fastest way to deliver nicotine to the brain. In addition to the tobacco user's demand for nicotine, sensorimotor stimuli (e.g., smell/taste of smoke, inhaling/exhaling, airway sensations such as "throat hit") repeatedly occur during smoking tobacco products that contain nicotine (88). The sensory aspects of smoking, such as taste and sensations of smoking (e.g., throat hit), though initially unpleasant, become reinforcing because they have been paired repeatedly with nicotine exposure (89). These stimuli often act as secondary or conditioned reinforcers that contribute to the smoking "reward" and dependence (90; 88), and may also serve as another source of derived demand. Thus, it is difficult to disentangle the demand for cigars by adult smokers from the demand for other perceived benefits of smoking, demand for nicotine, demand for the addiction-associated sensorimotor stimuli, or

[36] (121) (123) (122)

demand for simply avoiding withdrawal. Availability of products that can replace this derived demand further contributes to the uncertainty in modeling consumer welfare changes.

e. Regret Expressed by Current Smokers and the Desire to Quit

The significant level of regret experienced by the vast majority of smokers who state that they regret ever having started smoking and wish to quit contributes to the challenges of estimating demand. In an analysis of 2015 National Health Interview Survey data, Babb et al. (2017) found that the majority of smokers (68%) stated that they wanted to quit smoking, and 56% of smokers made a serious attempt to quit, but only about 7% of smokers reported that they had recently quit (91). More recently, Pechacek et al. find that "more than 80% of current smokers report high (22.5%) or very high (59.8%) discontent due to inability to quit, perceived addiction and regret about having started to smoke" (92). The authors conclude that "the proportion of smokers who might be characterized as having a preference to continue smoking are greatly outnumbered by addicted, discontent and concerned smokers who want to quit and regret ever having started to smoke" [id.]. These smokers "could have a substantial net welfare gain if new regulations helped them escape their concerns about the health effects from continuing smoking" [id.]. These surveys of smokers consistently reflect that smoking preference and smoking behavior do not align, meaning empirical evidence shows that the decision utility of smokers is not aligned with their experience utility (terms that are now common in behavioral economics) and confirms the cognitive biases in the demand further complicating estimation of consumer surplus loss or gain.[37]

[37] Decision utility refers to an individual's perceived utility prior to experience, whereas experience utility is the realized utility after making the decision to consume a particular product.

3. Utility Change for Consumers who Continue to Smoke Cigars

This proposed standard may lead to a utility change for former smokers of flavored cigars who do not reduce overall cigar consumption and simply switch from flavored cigars to tobacco-flavored cigars. As discussed in Section I.E, we expect about half of the reduction in flavored cigar consumption would lead to consumers switching to tobacco-flavored products rather than quitting. These former smokers of flavored cigars would not experience the health benefits associated with reduced consumption. However, they would lose access to the flavor attribute that can activate the brain's reward circuit and produce rewarding effects. The magnitude of the utility change experienced by these consumers depends on how much they value (and may continue to value) cigars with characterizing flavors other than tobacco compared to tobacco-flavored cigars that continue to provide nicotine. Estimating this impact would require isolating what smokers of flavored cigars would be willing to pay for the flavored aspect of the product separately from the value they place on nicotine. When removing flavored products from the market, the utility change would be equal to the value that consumers placed on the flavored aspect of these products. Economists use an implicit price increase (higher search or acquisition costs) to estimate the amount consumers would need to spend to realize the same utility they acquired from smoking flavored cigars (83; 82). To incorporate the utility change for consumers who continue to smoke cigars into our regulatory impact analysis, we would need to consider and account for the uncertainties and challenges described previously and in the Appendix. We request comment on such approaches.

4. Utility Change for Cigar Users who Quit

This proposed standard may lead to a utility change for flavored cigar users who quit using tobacco products entirely. In addition to the loss of the flavored attribute described above, these

consumers would also experience the short-term costs of withdrawal associated with tobacco cessation. Although some studies have incorporated withdrawal as a proxy for utility impacts (82), to incorporate the holistic utility change from cessation we would need to consider and account for the uncertainties and challenges described previously and in the Appendix. We request comment on such approaches.

5. Summary of Costs to Consumers

FDA does not believe that any reasonable consideration of consumer utility change, even if such a change were negative, would change our E.O. 12866 determination that benefits associated with this rule justify the costs.[38] While FDA believes that consumer utility change is an appropriate impact to consider qualitatively for the proposed product standard, we decline to estimate the magnitude of any potential consumer utility changes due to the high level of uncertainty and challenges regarding approaches to consumer surplus estimation. This conclusion is driven by the findings noted above, including that: a) cigar smoking is driven primarily by nicotine addiction; b) the vast majority of adult smokers become addicted to nicotine at young ages, before the brain has completed development; c) many who smoke did not fully understand the information available about the health harms of smoking when they began smoking, and many still do not fully understand this information today; d) a smoker's original

[38] FDA reiterates that the benefits of this rule are expected to be very large. For example, the present discounted value of avoided premature deaths due to secondhand smoke exposure alone, for which estimating changes in consumer surplus would not apply under any scenario (since these benefits are to nonsmokers), is $17.03 billion (at a 3% discount rate) or $8.05 billion (at a 7% discount rate), while the present discounted value of total costs is $2.37 billion (at a 3% discount rate) or $1.5 billion (at a 7% discount rate). This is in addition to the value of all prevented premature deaths arising from firsthand smoking and all qualitative benefits to users and potential users of flavored cigars combined. As should be clear, while we are not able to quantify the value of any consumer utility changes, we do not believe that any reasonable consideration of such impacts would affect the determination that benefits associated with this rule justify the costs.

derived demand rationale for tobacco product use (such as peer acceptance) may no longer be relevant to an individual, and it is difficult to disentangle the demand for cigars from the demand for other perceived benefits of smoking, including simply avoiding withdrawal; e) evidence of regret shows that the decision utility of smokers is not aligned with their experience utility; and f) the role of flavorings specifically, including the possibility that switching products could increase utility for some due to status quo bias, and the existence of readily available substitute products.

Given the challenges outlined above and the breadth of literature and approaches discussed in the Appendix, this regulatory impact analysis qualitatively discusses, but does not estimate, changes in consumer surplus stemming from the proposed flavored cigar product standard. We request comment and/or data to assist in future application of potential modeling approaches.

iii. Government Enforcement Costs

With a new product standard, we expect some reallocation of CTP's resources to enforce the standard. Thus, we estimate the opportunity cost to reallocate these resources.

The cost of enforcement would include one-time tasks such as updating inspector training materials and websites to reflect the new product standard. In addition, there could be ongoing costs for detecting violations through in-person inspections of tobacco manufacturing establishments and retail distribution outlets, as well as additional monitoring of retail internet sites. CTP currently undertakes these inspection and monitoring activities while enforcing the Tobacco Control Act. We anticipate that CTP investigators may include additional criteria to monitor for flavored cigars during inspections and investigations. The enforcement of the proposed rule, if finalized, would also include investigating, drafting, and processing warning

letters, and taking other regulatory or enforcement actions as necessary, such as civil money penalties, criminal prosecution, seizure, and injunction.

CTP estimates that 2.5 to 5 full-time equivalent (FTE) employees would be required for the enforcement activities described above. We use the midpoint estimate of 3.75 FTEs for this analysis. We use an annual wage based on an Agency-wide estimate of the average cost for FTE employees to value this effort. The fully-loaded (inclusive of benefits and other indirect costs) cost per FTE in 2020 equals $263,646. Therefore, the annual cost of enforcement is estimated to range from $0.66 million to $1.32 million. However, this work could be conducted by existing staff and are considered as costs because we are shifting our resources to better serve the needs of the Agency. We note that these costs would not affect the total amount of user fees, overall FDA accounting costs, the size of the federal budget, or the amount of tobacco industry user fees. The TCA requires that industry user fees fully fund our regulation of tobacco products. Therefore, these costs represent an opportunity cost for Agency resources.

H. Transfers

i. Impacts on Federal, State, and Local Tobacco Excise Taxes

The reduction in quantity of cigars sold has a direct effect on the excise tax revenue collected by the federal government, states, and localities. The baseline scenario shown in Section I.D estimates that cigars contribute $1.56 billion in excise tax revenue. Federal excise tax revenue comprises approximately $0.62 billion of total excise taxes, while state excise taxes account for approximately $0.94 billion. As discussed in Section I.D, if the proposed standard is implemented, cigar sales are expected to decrease between 15 percent and 42 percent. The proposed product standard, if finalized, would result in an estimated reduction in excise taxes of

between 6.84 percent (=15%*(19.1/41.9)) and 19.15 percent (=42%*19.1/41.9)).[39] If cigar sales decline by 15 percent, we estimate that total excise tax revenues would fall to about $1.45 billion annually, which is a reduction of about $107 million per year. We estimate federal excise taxes would decrease by $42.4 million per year to $577.6 million, while state excise taxes would fall by $64.3 million per year to $875.7 million. If cigar sales decline by 42 percent, we estimate that total excise tax revenues would fall to about $1.26 billion, which is a reduction of about $299 million per year. We estimate federal excise taxes would decrease by $118.7 million per year to $501.3 million, while state excise taxes would fall by $180 million per year to $760 million.

Table 16. Impact on Federal and State Excise Taxes (in millions, 2020 $)

Estimated Reduction in Cigar Smoking	Estimated Reduction in Excise Taxes	Reduction in Excise Taxes ($ millions)		
		State	Federal	Total
15%	6.84%	$64.27	$42.39	$106.67
30%	13.68%	$128.55	$84.79	$213.34
42%	19.15%	$179.97	$118.70	$298.67

In addition to these changes in tax revenue, we request comment on other financial spillovers due to this standard that may impact net transfers. These other impacts may include ways in which non-smokers subsidize smokers.

ii. Tobacco Manufacturers, Distributors, and Growers

The proposed rule, if finalized, would eliminate the revenues that firms currently receive from the sale of flavored cigars. This revenue would transfer to consumers who could either save this money or spend it on other goods and services. We lack information that could be used to project which sectors might benefit from this spending shift.

[39] Flavored cigars make up 41.9 percent of cigar unit sales, but only 19.1 percent of cigar dollar sales. We use this ratio to adjust from the reduction in unit sales to the change in expected tax or revenue estimates, which are linked to dollar sales.

The distributional effects may not impact all sectors equally. For example, consumers who continue to use tobacco products might purchase products manufactured or offered for sale by the same entity that lost flavored cigar revenues. The extent to which those entities could obtain lost flavored cigar profits from other products would determine the magnitude of the distributional effect on those entities. Consumers who stop or reduce their use of tobacco products in response to a cigar flavors ban would reallocate their resources to non-tobacco industries. Of course, employees and owners of firms that currently produce those tobacco products will have less resources to spend elsewhere.

We estimate producer surplus above in Section I.G. However, we consider the remainder of the reduced firm revenue to be a distributional effect of the proposed rule. We estimate firm revenue to be $15.1 billion annually, based on market revenue minus excise taxes (=$16.67 billion - $1.56 billion). We estimate that quantity demanded would fall by 30 percent, or about 4.2 billion cigars (= 13.99 billion cigars * 0.30), because of the proposed product standard. This corresponds to a reduction in market revenue of about 13.69 percent (= 30% * (19.1/41.9), with significant uncertainty surrounding these estimates. Using the range of reduced consumption from 15 percent to 42 percent, we estimate reduction in firm revenue from 6.8 percent (= 15% * (19.1/41.9) to 19.1 percent (= 42% * (19.1/41.9). Therefore, we estimate a reduction in firm revenue between $1.03 billion and $2.89 billion, with a primary estimate of $2.06 billion. Subtracting the lost producer surplus, we get a range of $1.03 to $2.71 billion, with a primary estimate of $1.98 billion. We request comment on our assumptions and estimates of distributional effects.

This proposed rule may also have a distributional effect on tobacco farmers. We expect that this rule, if finalized, would correlate with an overall decrease in tobacco production and

consumption, and there may thus be slightly less demand for tobacco farmers' crops. Cigar tobacco accounted for less than 1 percent of the tobacco market in 2017 (93).

The proposed cigar flavor product standard is expected to impact demand for cigar products. In this section, we analyze the impacts on U.S. tobacco leaf growers due to an expected reduction in demand for cigar products:

Over the past five years, tobacco leaf production in the United States has decreased from 630 million pounds in 2016 to about 390 million pounds in 2020 a reduction of almost 40 percent (see Table 17) (93). Additionally, in 2017 (the most recent year with data) cigar type tobacco (Types 4-6) comprised approximately 0.61 percent of all tobacco leaf production in the US (see Table 18).

Table 17. U.S. Tobacco Leaf Production, 2016-2020, (1,000 lbs.)

States	2016	2017	2018	2019	2020	5-year average
Georgia	28,350	26,250	23,750	18,900	19,276	22,805
Kentucky	136,280	183,300	134,370	123,390	107,235	127,129
North Carolina	331,800	360,040	251,925	234,700	184,127	250,895
Pennsylvania	20,460	18,990	17,400	14,300	13,440	16,600
South Carolina	24,700	25,200	22,140	15,770	8,400	18,630
Tennessee	35,690	43,000	39,610	30,490	29,380	34,956
Virginia	51,440	53,381	44,046	30,406	27,555	39,499
United States	628,720	710,161	533,241	467,956	389,413	510,514

Source: U.S. Department of Agriculture, National Agricultural Service (93)

Table 18. US Tobacco and Cigar Tobacco Production, 2013-2017 (1,000 lbs.)

	2013	2014	2015	2016	2017
All Tobacco	724,266	876,689	719,563	628,720	710,161
Cigar Types (4-6)	8,573	9,313	8,718	3,840	4,320
Cigar Types as a Percent of All Tobacco	1.18%	1.06%	1.21%	0.61%	0.61%

Source: U.S. Department of Agriculture, National Agricultural Service (93)

Given that cigar type tobacco is a small portion of overall leaf tobacco production, we do not predict that the proposed rule will have a substantial impact on tobacco farmers. We request comment on any potential indirect impacts the proposed rule might have on farmers of cigar type tobacco.

iii. Tobacco Retailers

We expect that the proposed product standard prohibiting characterizing flavors, except tobacco, in cigar products would create transfers from retailers to consumers. Prior to the effective date of the proposed standard, retailers and related entities may continue to sell available stock of flavored cigar products. With many retailers under contract to provide dedicated shelf space for tobacco products, we expect that retailers will be stocked with other tobacco products to fill the shelf space previously reserved for flavored cigar products. We request comment on how this rule might impact renegotiations of these contracts. As consumers use money they were previously spending on flavored cigars on other products, including non-tobacco products, some retailers may see a reduction in sales while others experience an increase in sales. We do not separately estimate transfers from retailers and distributors to consumers as a result of this proposed product standard. We request comment on this approach.

iv. Impacts on FDA User Fees

FDA collects user fees each quarter from each manufacturer and importer of cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, or roll-your-own tobacco.[40] The total amount of user fees is set by statute, and neither the amount of user fees collected, nor overall FDA accounting costs, will change because of this rule. The total amount of user fees collected in

[40] See FD&C Act section 919.

fiscal year 2019 and each fiscal year that follows remain constant under the statute at $712 million. The amount of user fees paid by each tobacco product class is dependent upon federal excise taxes associated with the gross removal of tobacco products into domestic commerce, with the amount of user fees paid by each firm allocated according to the firm's market share within the tobacco product class.

Changes in tobacco product user fees are not a social cost; instead, reallocation of user fees between and within tobacco product classes represent a transfer between tobacco companies. Any decrease in market share and, thus, user fees collected from one tobacco product class results in a corresponding reallocation of user fees to manufacturers and importers of other tobacco product classes subject to user fees; similarly, any decrease in market share and, thus, user fees collected from manufacturers and importers within a tobacco product class subject to user fees results in a reallocation of user fees to other manufacturers and importers within that class. We expect this proposed standard to reduce cigar use and increase use of other tobacco products as some consumers switch from flavored cigar smoking. Therefore, we expect the amount of user fees paid by the flavored cigar manufacturers and importers to decline while the amount of user fees paid by manufacturers and importers of non-flavored cigars and other tobacco product classes may increase. As changes in market share among tobacco product classes under the proposed product standard are uncertain, we do not quantitatively estimate reallocation of user fees. We note that a single manufacturer may produce tobacco products across a range of tobacco product classes that are subject to user fees, resulting in net transfers of user fees within firms that are additionally uncertain. We request comment on the amount of user fees that may transfer between tobacco product classes under the proposed product standard and overall net changes in user fee allocation.

Although we cannot determine how the proposed rule, if finalized, will result in user fees being reallocated across tobacco product classes, we can estimate the magnitude of user fees that could be reallocated.[41] For fiscal year 2021, approximately 12 percent of the tobacco user fees were allocated to the cigar product class.[42]

I. Summary of Benefits and Costs

Table 19 presents the summary of the primary undiscounted stream of costs and benefits for this proposed rule. We evaluate the proposed rule over a 40-year time horizon from the effective date of the proposed rule, if finalized; however, because some costs of the proposed rule would happen prior to the effective date (i.e., in year zero), the 40-year time horizon includes 41 periods. We assume that this proposed rule, if finalized, would publish as a final rule in 2023, with an effective date in 2024.

Table 19. Stream of Benefits and Costs ($ Millions, Primary Estimate, 2020 $)

Year	Friction	Reading	Search	Producer Surplus	Enforcement	Avoided Mortality	Secondhand Smoke
	Cost	Cost	Cost	Cost	Cost	Benefit	Benefit
0	21.5	239.3					
1			61.7	87.6	1.0		
2				87.6	1.0		
3				87.6	1.0	1,403.1	131.9
4				87.6	1.0	2,617.4	246.0
5				87.6	1.0	3,669.9	345.0
6				87.6	1.0	4,583.5	430.8
7				87.6	1.0	5,377.9	505.5
8				87.6	1.0	6,070.2	570.6
9				87.6	1.0	6,674.7	627.4
10				87.6	1.0	7,204.1	677.2
11				87.6	1.0	7,669.1	720.9

[41] This reallocation of user fees would amount to a transfer from manufacturers and importers of flavored cigars to manufacturers and importers of other tobacco products subject to user fees. FDA assesses and collects tobacco user fees from domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigar, and pipe tobacco.

[42] See https://wayback.archive-it.org/7993/20201221035726/https://www.fda.gov/tobacco-products/manufacturing/tobacco-user-fee-assessment-formulation-product-class. (134)

12				87.6	1.0	8,078.7	759.4
13				87.6	1.0	8,440.9	793.4
14				87.6	1.0	8,762.5	823.7
15				87.6	1.0	9,049.2	850.6
16				87.6	1.0	9,306.1	874.8
17				87.6	1.0	9,537.3	896.5
18				87.6	1.0	9,746.6	916.2
19				87.6	1.0	9,937.1	934.1
20				87.6	1.0	10,111.5	950.5
21				87.6	1.0	10,272.1	965.6
22				87.6	1.0	10,420.8	979.6
23				87.6	1.0	10,559.3	992.6
24				87.6	1.0	10,840.8	1,019.0
25				87.6	1.0	10,963.9	1,030.6
26				87.6	1.0	11,004.1	1,034.4
27				87.6	1.0	11,098.4	1,043.2
28				87.6	1.0	11,216.6	1,054.4
29				87.6	1.0	11,331.5	1,065.2
30				87.6	1.0	11,443.8	1,075.7
31				87.6	1.0	11,658.9	1,095.9
32				87.6	1.0	11,752.2	1,104.7
33				87.6	1.0	11,846.2	1,113.5
34				87.6	1.0	11,941.0	1,122.4
35				87.6	1.0	12,036.5	1,131.4
36				87.6	1.0	12,132.8	1,140.5
37				87.6	1.0	12,229.8	1,149.6
38				87.6	1.0	12,327.7	1,158.8
39				87.6	1.0	12,426.3	1,168.1
40				87.6	1.0	12,525.7	1,177.4

Note: Note that costs to industry and enforcement costs would not affect the total amount of user fees or the size of the federal budget. The TCA requires that industry user fees fully fund our regulation of tobacco products. Therefore, these costs represent an opportunity cost for Agency resources. However, this work could be conducted by existing staff.

J. Analysis of Regulatory Alternatives

We analyze several alternatives to the proposed rule: extending the effective date, including pipe tobacco and waterpipe tobacco in the proposed standard, and prohibiting the intentional addition of flavorings, other than tobacco, in cigars. Table 20 summarizes our analysis of the alternatives of the proposed rule.

Table 20. Summary of Discounted Regulatory Alternatives Over a 40-year Time Horizon ($ Millions, 2020 $)

	Proposed Rule		24-Month Effective Date		Include Pipe Tobacco and Waterpipe Tobacco	
	3%	7%	3%	7%	3%	7%
Annualized Total Benefits	$8,574.7	$7,024.4	$8,325.0	$6,564.8	$9,403.1	$7,702.9
Annualized Total Costs	$102.5	$112.5	$99.5	$105.1	$112.4	$123.4
Annualized Net Benefits	$8,472.3	$6,911.9	$8,225.5	$6,459.7	$9,290.7	$7,579.6
Present Value Benefits	$198,203.2	$93,647.0	$192,430.2	$87,520.6	$217,349.9	$102,693.4
Present Value Total Costs	$2,368.3	$1,499.7	$2,299.4	$1,401.6	$2,597.1	$1,644.6
Present Value Net Benefits	$195,834.8	$92,147.3	$190,130.9	$86,119.0	$214,752.8	$101,048.9

i. *Change the Effective Date*

The proposed rule has a 12-month effective date. In this analysis, we consider an effective date of 24 months (see Table 21).[43] For the 24-month effective date we assume friction costs will be 1 percent of revenue of flavored cigar sales, the primary estimate of our friction cost estimate in Section I.G. We assume that the change in effective date does not have a substantial impact on the baseline. Specifically, in the 24-month effective date scenario, we assume for this analysis that there will be no tobacco regulation that would come out prior to this proposed rule that would cause major changes to the tobacco market.[44]

The 24-month effective date has a decrease in present value of the net benefits relative to the proposed 12-month effective date of $5,704 million at a 3 percent discount rate and $6,028 million at a 7 percent discount rate.

Table 21. Benefits, Costs and New Benefits Under the Alternative Effective date of 24-months ($ Millions, 2020 $)

	Benefits		Costs		Net Benefits	
	3%	7%	3%	7%	3%	7%
Benefits and Costs under Alternative Effective Date						
Present Value	$192,430	$87,521	$2,299	$1,402	$190,131	$86,119

[43] For the purpose of this analysis, we assume that if the effective date for this product standard is extended to 24 months, then the effective date for the menthol cigarettes product standard would also be extended to 24 months.
[44] This is not intended to be a prediction of forthcoming regulation; rather, this is a simplifying assumption.

Annualized	$8,325	$6,565	$99	$105	$8,226	$6,460
Difference between Proposed rule and Alternative Effective Date						
Present Value	($5,773)	($6,126)	($69)	($98)	($5,704)	($6,028)
Annualized	($280)	($400)	($15)	($34)	($265)	($366)

ii. Include Pipe Tobacco and Waterpipe Tobacco

We consider the alternative that would add a prohibition on characterizing flavors, other than tobacco, in pipe tobacco and waterpipe tobacco (also known as hookah tobacco or shisha), to the proposed rule. For simplicity, we assume the proportion of pipe tobacco and waterpipe tobacco that is flavored is the same as cigars. We request comment on this assumption. We use data from Euromonitor to characterize the baseline pipe tobacco and waterpipe tobacco market (23). The Euromonitor definition of pipe tobacco includes waterpipe tobacco. Euromonitor estimates pipe tobacco and waterpipe tobacco sales to be $1.61 billion in 2020. This means the pipe tobacco and waterpipe tobacco market is 9.66 percent (=1.61/16.67) of the size of the cigar market (23). This means that including pipe tobacco and waterpipe tobacco in the rule would increase the costs and benefits of the rule about 10 percent.

A summary of the costs and benefits under this alternative can be found in Table 22. The present value of net benefits is $214,753 million at a 3 percent discount rate and $101,049 million at a 7 percent discount rate. This is $19,147 million greater than the proposed rule at a 3 percent discount rate and $9,046 million more at a 7 percent discount rate.

Table 22. Summary of Benefits and Costs of the Alternative that Includes Pipe Tobacco and Waterpipe Tobacco in the Proposed Rule ($ Millions, 2020 $)

	Includes Pipe Tobacco and Waterpipe Tobacco		Proposed Rule		Difference	
Discount Rate	3%	7%	3%	7%	3%	7%
Annualized Total Benefits	$9,403	$7,703	$8,575	$7,024	$828	$679
Annualized Total Costs	$112	$123	$102	$112	$10	$11
Annualized Net Benefits	$9,291	$7,580	$8,472	$6,912	$818	$668

Present Value Benefits	$217,350	$102,693	$198,203	$93,647	$19,147	$9,046
Present Value Total Costs	$2,597	$1,645	$2,368	$1,500	$229	$145
Present Value Net Benefits	$214,753	$101,049	$195,835	$92,147	$18,918	$8,902

iii. Prohibit the Intentional Addition of Flavorings, Other than Tobacco, in Affected Products

This alternative considers a prohibition on intentionally adding flavorings, other than tobacco, of any quantity to cigars as part of the production or packaging process. This alternative contrasts with the current proposed product standard that provides that a cigar or any of its components or parts "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 . . . that is a characterizing flavor of the tobacco product or tobacco smoke." Under this alternative, a manufacturer of cigars would be prohibited from intentionally adding flavorings of any quantity, other than tobacco, during a cigar product's production or packaging.

If FDA pursued this regulatory option, the rule could potentially include more cigar manufacturers and cigar products. However, we are not able to estimate how many additional manufacturers and cigar products, if any, would be impacted by this alternative at this time. We request comment on any information that would help determine how many additional manufacturers and cigar products, if any, would be impacted by this alternative.

With this alternative, manufacturers would be required to develop and maintain purchase control records and production records to demonstrate that flavorings, other than tobacco, were not added at any stage in the production or packaging process, such that any detected level of flavorings, other than tobacco, in a commercial product would be unintentional. These records may create additional recordkeeping costs for those manufacturers that do not already create and

maintain similar information. Additionally, any changes in cigar additives that result in a new tobacco product would require a firm to submit for premarket review, creating additional costs.

The health benefits of this alternative are uncertain. As discussed in the Preamble of this proposed rule, flavor additives expose users to additional toxicants. It is unknown to what extent non-characterizing flavorings influence cigar smoking and, thus, we cannot estimate what additional effect prohibiting flavorings as an intentional additive in cigars would have on initiation and experimentation, nicotine dependence and addiction for cigars, and the likelihood of cessation among current cigar smokers. This alternative may reduce some government costs in comparison to the proposed product standard, as inspectors may be able to determine compliance by reviewing existing production and purchase control records. In addition to information reviewed during inspection, ingredient listing submissions required under Section 904(a)(1) of the Federal Food, Drug, and Cosmetic Act could also be used to confirm that flavorings (other than tobacco) were not intentionally added to cigars as part of the production or packaging process.

We request comment and data on the comparative costs and benefits that might be associated with prohibiting the intentional addition of flavorings, other than tobacco of any quantity to cigars as part of the production or packaging process.

K. Uncertainty and Sensitivity Analysis

i. Potential Impacts of a Proposed Menthol Cigarettes Product Standard

FDA is separately proposing a rule that would prohibit the use of menthol as a characterizing flavor in cigarettes.[45]

[45] https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers

In the analysis in Sections I.F and I.G, we estimate the impact of this proposed rule without considering the potential impacts, if any, of a menthol cigarettes product standard. However, if FDA issues a menthol cigarettes product standard that takes effect around the same time, some consumers who may have responded to this proposed rule by switching to menthol cigarettes if they were still available may quit tobacco use entirely or switch to non-combusted tobacco products, including ENDS, instead. In addition, some manufacturers may produce both flavored cigars and menthol cigarettes.

We request comment on the potential impacts of issuing these two rules.

ii. Illicit Trade

The analysis (in Sections I.F and I.G) of benefits and costs assumes full compliance with the proposed standard. In this section we discuss qualitatively how our analysis would change with the presence of illicit trade. It is estimated that illicit sales equal approximately 8.5 percent to 21 percent of the U.S. tobacco market (94). There is evidence that illicit markets respond to price changes in the legal market (95) and are expected to respond to tobacco product standards (96); therefore, we expect some illicit trade response to this proposed rule, if finalized.

An illicit market for flavored cigars would likely reduce the net benefits of the proposed rule as compared to the analysis in Sections I.F and I.G because more people would continue or initiate use of flavored cigars. As a result, consumers would experience both reduced health benefits and reduced consumer surplus losses relative to the estimates in Sections I.F and I.G. In addition, consumers would incur additional search and transaction costs, and government would incur additional administrative and enforcement costs relative to the estimates in Sections I.F and I.G. The sum of these impacts would likely reduce the net benefits of the proposed standard. How much net benefits would be impacted would depend on the size of any potential illicit

market for flavored cigars. We are uncertain about the size of any potential illicit market for flavored cigars and request comment. Additionally, we request comment on the magnitude of the impact of an illicit market on net benefits.

iii. Effect of the Policy with Other Tobacco Control Policies and Changes in Market Structure

In recent years, state and local tobacco control policies have proliferated. In this section, we summarize policies in three areas: increasing the minimum age for sale of tobacco products, banning characterizing flavors in various tobacco products, and implementing excise taxes on ENDS products.

The first policy trend noted above is increasing the minimum age for sale of tobacco products. As of July 2019, seventeen states and over 475 localities had increased the minimum age of sale to 21 (97). Then, in December 2019, the President signed a law making 21 the minimum age of sale at a national level. This increase in the minimum age of sale has been accounted for within the sensitivity analysis on deterred youth cigar initiation in Section I.K.ix.

The second recent policy trend has been for states and localities to ban flavors in tobacco products. These policies are less uniform than the increased age policies as some of them only apply to the location of retailers selling flavored tobacco products (98). Examples include:

- Bans on flavors or certain tobacco products
- Bans on sales by retailers located within a certain distance from schools
- Bans on sales by retailers in unincorporated areas of the county
- Bans on sales by certain types of retailers

As of July 2021, Maine and Massachusetts have the only state-wide restriction on the sale of flavored cigars.[46] Other localities have various flavor restrictions (99).

[46] The Maine law exempts "premium cigars" defined as a cigar that weighs more than 3 pounds per 1,000 cigars and

The third recent policy trend has been for states to collect excise taxes on ENDS products. As of March 2019, nine states and Washington DC have enacted excise tax legislation for ENDS products (100). This proposed rule, if finalized, may increase ENDS use and therefore generate additional tax revenue in these jurisdictions.

This complicated patchwork of rules makes it difficult to estimate the exact impact of this proposed rule given that the baseline set of tobacco control policies varies across jurisdictions and continues to evolve. Moreover, we anticipate that additional jurisdictions may enact rules that will limit access to cigars and other tobacco products prior to a cigar flavors final rule. This suggests that the proposed rule, if finalized, may have a smaller impact than we estimate if newly enacted state or local policies deter cigar consumption. We request comment on evaluating the overall impact of jurisdictional flavor restrictions.

However, while state and local policies are important, we note that they can potentially be avoided by simply making purchases outside of the locality with the tobacco control policy. A national rule provides a more uniform product standard, making compliance and enforcement approaches more consistent.

iv. Alternative Compliance Assumptions

The proposed rule states that multiple factors are relevant in determining whether a cigar has a characterizing flavor, other than tobacco. These factors include: the presence and amount of artificial or natural flavor additives, the multisensory experience of a flavor, flavor representations (including descriptors) on the labeling (including packaging) or advertising of the

is wrapped in whole tobacco leaf. It also exempts menthol, clove, coffee, nut, and pepper flavors. The Massachusetts law exempts products for sale in "smoking bars" defined as an establishment that exclusively occupies an enclosed indoor space and is primarily engaged in the retail sale of tobacco products for consumption by customers on the premises.

tobacco products, and any other means that impart flavor (see the Preamble of this proposed rule for a full description). However, data on all these factors are not readily available for cigars, so we limit our estimation of products potentially affected by the proposed rule to products that have flavor descriptors on the packaging. The proposed rule, if finalized, could apply to a larger set of flavored cigar products than those we include in our analysis. For example, there could be cigar products that do not have flavor descriptors on their packaging, but other factors could identify a characterizing flavor in the cigar product. In this case, the costs of the proposed rule might be higher than we have estimated if identifying these products and removing them from the market would require more resources from industry and FDA. Including additional products will also lead to higher benefits as these same products might not have been captured by the underlying studies used to estimate mortality impacts.

v. Health Effects from Switching and Switched Initiation

We do not estimate public health benefits resulting from switching or switched initiation in the analysis in Sections I.F and I.G because of the substantial uncertainty about the type of tobacco products users will adopt and the health risks of these substitute products. The lower bound of possible public health impacts includes switching and switched initiation that yields no change in health risks for users. In this case, users switch to a product with health risks that are like the risks of cigars. This implies no reduction in either incidence, morbidity, or fatal cases of disease relative to the baseline, and the ultimate public health impacts of the proposed rule will be identical to the analysis in Sections I.F and I.G.

In an upper bound scenario, all users who do not quit completely would switch to products with potentially lower health risks relative to cigars. Because the public health impacts of use of certain potentially lower health risk products remain highly uncertain, we request

comment on studies that would allow us to characterize the long-term risks and benefits associated with switching and switched initiation.

vi. Estimated Monetized Benefits of Proposed Rule Based on Life-Years

As recommended in HHS guidelines (52), the secondary method for estimating the value of avoided deaths uses a life-year approach.[47] We present this supplemental approach for valuing mortality reductions because the life extension associated with cigar-attributable mortality may be less than in the contexts (for example, hedonic wage studies using data on the general population) used to estimate VSL. The life-year approach accounts for these age differences by using only the expected increase in the number of life-years for those who prematurely die from cigar usage.

As discussed in the Preamble, cigar users who die from cigar use lose an average of 15.1 years of potential life, with a lower-bound of 12.0 years and an upper-bound of 16.7 years (4).[48] We use these measures to represent the life-years lost for cigar users that die prematurely of cigar-attributable causes. It is possible, however, that these estimates do not fully account for other individual characteristics related to smoking decisions that may influence mortality risk. We request comment on additional information regarding our assumptions about longevity gains for former cigar users. Table 23 presents the magnitude and timing of the reduction in adult life-years lost, calculated from multiplying the range of annual deaths prevented by the range of life-years lost.

Table 23. Estimates of the Magnitude and Timing of Reduction in Adult Life-Years Lost

[47] Like the VSL estimates discussed above, the value of a statistical life-year (VSLY) does not represent the dollar value of a person's life but instead represents the amount individuals are willing to pay for small reductions in morbidity or mortality risk. For more detail, please refer to page 17 of the guidelines cited above.

[48] For our estimates, we use a lower-bound of 12.0 years and an upper-bound of 16.7 years. We obtain this range from Nonnemaker et al.'s sensitivity analysis in their Table 4. Using the authors' formula for average lost life years per death, the lower estimate was produced using row 5 of Table 4 ("Including COPD (smoked ≥ 15 d in past 30 d)"), and the upper estimate was produced using row 2 ("Smoked cigars at least 1 day in past 30 d").

Years after Effective Date of Rule (from 2024 to 2063)	Baseline Annual Deaths	Policy Impact Phase-in	Annual Deaths Prevented Due to Proposed Standard			Reduction in Life-Years Lost Due to Proposed Standard		
			Low	Primary	High	Low	Primary	High
1	5,200	0.0%	0	0	0	0	0	0
2	5,200	0.0%	0	0	0	0	0	0
3	5,200	15.0%	66	117	169	791	1,766	2,819
4	5,200	27.7%	122	216	312	1,464	3,266	5,215
5	5,200	38.6%	170	301	434	2,036	4,542	7,252
6	5,200	47.8%	210	373	538	2,522	5,627	8,984
7	5,200	55.6%	245	434	626	2,936	6,549	10,456
8	5,200	62.3%	274	486	701	3,287	7,333	11,707
9	5,200	67.9%	299	530	765	3,586	7,999	12,771
10	5,200	72.7%	320	567	819	3,840	8,566	13,675
11	5,200	76.8%	338	599	865	4,056	9,047	14,444
12	5,200	80.3%	353	626	904	4,239	9,456	15,098
13	5,200	83.2%	366	649	937	4,395	9,804	15,653
14	5,200	85.8%	377	669	966	4,528	10,100	16,126
15	5,200	87.9%	387	686	990	4,641	10,352	16,527
16	5,200	89.7%	395	700	1,010	4,736	10,566	16,868
17	5,200	91.2%	401	712	1,027	4,818	10,747	17,159
18	5,200	92.6%	407	722	1,042	4,887	10,902	17,405
19	5,200	93.7%	412	731	1,055	4,946	11,033	17,615
20	5,200	94.6%	416	738	1,065	4,996	11,145	17,793
21	5,200	95.4%	420	744	1,075	5,039	11,240	17,945
22	5,200	96.1%	423	750	1,082	5,075	11,320	18,074
23	5,200	96.7%	425	754	1,089	5,106	11,389	18,183
24	5,200	97.2%	428	758	1,094	5,132	11,447	18,276
25	5,200	97.6%	429	761	1,099	5,154	11,497	18,355
26	5,200	98.0%	431	764	1,103	5,173	11,539	18,423
27	5,200	98.3%	432	767	1,107	5,189	11,575	18,480
28	5,200	98.5%	434	769	1,109	5,203	11,605	18,528
29	5,200	98.8%	435	770	1,112	5,214	11,631	18,570
30	5,200	98.9%	435	772	1,114	5,224	11,653	18,605
31	5,200	100.0%	440	780	1,126	5,280	11,778	18,804
32	5,200	100.0%	440	780	1,126	5,280	11,778	18,804
33	5,200	100.0%	440	780	1,126	5,280	11,778	18,804
34	5,200	100.0%	440	780	1,126	5,280	11,778	18,804
35	5,200	100.0%	440	780	1,126	5,280	11,778	18,804
36	5,200	100.0%	440	780	1,126	5,280	11,778	18,804
37	5,200	100.0%	440	780	1,126	5,280	11,778	18,804
38	5,200	100.0%	440	780	1,126	5,280	11,778	18,804

39	5,200	100.0%	440	780	1,126	5,280	11,778	18,804
40	5,200	100.0%	440	780	1,126	5,280	11,778	18,804
Total	208,000		14,251	25,263	36,470	171,014	381,477	609,048

We monetize these estimates by applying a central value per statistical life-year[49] at the effective date of the final rule (2024) of approximately $505,000 at a 3 percent discount rate and $855,000 at a 7 percent discount rate. For the 40-year period between 2024 and 2063, the life-year approach results in a present discounted value of reduced mortality that ranges from approximately $53 billion to $187 billion at a 3 percent discount rate, and approximately $42 billion to $149 billion at a 7 percent discount rate. Our primary estimates of the present discounted value of life-years saved are approximately $117 billion at a 3 percent discount rate and $94 billion at a 7 percent discount rate. The annualized values of the primary estimates are approximately $5 billion at a 3 percent discount rate and $7 billion at a 7 percent discount rate. Table 24 summarizes these estimates, which complement Table 9.

Table 24. Present Discounted Value and Annualized Value of Mortality Reductions for Exclusive Cigar Users Ceasing Tobacco Use Using the Life-Year Method, 40-year Period from 2024 to 2063

	Discount Rate	Low	Primary	High
Life-Years saved	Undiscounted	171,014	381,477	609,048
	3%	88,534	197,491	315,304
	7%	43,045	96,020	153,301
Value per Life-Year in 2024 ($ thousands)	3%	$505	$505	$505
	7%	$855	$855	$855
Present Discounted Value of Life-Years Saved ($ billions)	3%	$52.51	$117.13	$187.01
	7%	$41.98	$93.63	$149.49
Annualized Value of Life-Years Saved ($ billions)	3%	$2.27	$5.07	$8.09
	7%	$3.15	$7.02	$11.21

Note: Though this table presents rounded average life-year values, our calculations use unrounded values.

[49] We derive the value of a statistical life year by dividing the yearly VSL by the discounted expected number of life years remaining for the average 40-year-old.

vii. Estimated Monetized Benefits of Proposed Rule with VSL Range

In the analysis in Sections I.F and I.G, we report a range of health benefits that varies by all our inputs and use the central VSL to monetize these benefits. In Table 25, we include a sensitivity analysis of the total monetary value of health benefits using a range of VSL estimates. The present discounted value of total avoided deaths ranges from approximately $48 billion to $398 billion at a 3 percent discount rate, and approximately $22 billion to $188 billion at a 7 percent discount rate. Our primary estimates of the present discounted value of avoided deaths equal approximately $181 billion at a 3 percent discount rate and $86 billion at a 7 percent discount rate. The annualized values of the primary estimates equal approximately $8 billion at a 3 percent discount rate and $6 billion at a 7 percent discount rate.

Table 25. Present Discounted Value and Annualized Value of Quantified Mortality Reductions for Exclusive Cigar Users Ceasing Tobacco Use Applying a Range of VSL Values, 40-year Period from 2024 to 2063 ($ Billions)

	Discount Rate	Low	Primary	High
Present Discounted Value of Averted Deaths	3%	$47.54	$181.17	$397.80
	7%	$22.47	$85.60	$187.81
Annualized Value of Averted Deaths	3%	$2.06	$7.84	$17.21
	7%	$1.69	$6.42	$14.09

Note: Based on a first-year VSL value of $5.5 million (low), $11.8 million (primary), and $17.9 million (high). The VSL value then adjusts annually in accordance with HHS guidelines (52).

viii. Estimated Monetized Benefits of Proposed Rule with Alternative Baseline Cigar Attributable Deaths

As noted in the Preamble, we based our estimate of the annual mortality attributable to cigar smoking in the U.S. on a previously published analysis (4). 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. 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 approach will tend to underestimate the magnitude of benefits 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.

Due to the potential for averted mortality among dual users, we present an alternative set of estimates in this section that considers premature deaths from all regular cigar smokers (exclusive and dual users). To incorporate this alternative estimate of baseline deaths into our analysis, we multiply our main estimates by the ratio of 9,000 deaths to 5,200 deaths (1.73). We request comment on this approach for valuing the averted mortality of dual cigar users.

Table 26 presents these alternative estimates. The present discounted value of total avoided deaths ranges from approximately $177 billion to $453 billion at a 3 percent discount rate, and approximately $84 billion to $214 billion at a 7 percent discount rate. Our primary estimates of the present discounted value of avoided deaths equal approximately $314 billion at a 3 percent discount rate and $148 billion at a 7 percent discount rate. The annualized values of the primary estimates equal approximately $14 billion at a 3 percent discount rate and $11 billion at a 7 percent discount rate.

Table 26. Present Discounted Value and Annualized Value of Quantified Mortality Reductions for Exclusive Cigar Users Ceasing Tobacco Using Alternative Baseline Death Rate, 40-year Period from 2024 to 2063 ($ Billions)

	Discount Rate	Low	Primary	High
Present Discounted Value of Averted Deaths	3%	$176.88	$313.57	$452.66
	7%	$83.57	$148.15	$213.87

Annualized Value of Averted Deaths	3%	$7.65	$13.57	$19.58
	7%	$6.27	$11.11	$16.04

Note: Based on a first-year VSL value of $11.8 million (primary). The VSL value then adjusts annually in accordance with HHS guidelines (52).

Table 27 sums these new estimates with monetized benefits from secondhand smoke reductions. The present discounted value of total avoided deaths ranges from approximately $194 billion to $495 billion at a 3 percent discount rate, and approximately $91 billion to $234 billion at a 7 percent discount rate. Our primary estimates of the present discounted value of avoided deaths equal approximately $343 billion at a 3 percent discount rate and $162 billion at a 7 percent discount rate. The annualized values of the primary estimates equal approximately $15 billion at a 3 percent discount rate and $12 billion at a 7 percent discount rate.

Table 27. Present Discounted Value and Annualized Value of Quantified Mortality and Secondhand Smoke Reductions Using Alternative Baseline Death Rate, 40-year Period from 2024 to 2063 ($ Billions)

	Discount Rate	Low	Primary	High
Present Discounted Value of Averted Deaths	3%	$193.51	$343.04	$495.21
	7%	$91.43	$162.08	$233.98
Annualized Value of Averted Deaths	3%	$8.37	$14.84	$21.42
	7%	$6.86	$12.16	$17.55

Note: Based on a first-year VSL value of $11.8 million (primary). The VSL value then adjusts annually in accordance with HHS guidelines (52).

ix. Estimated Monetized Benefits of Reduced Mortality due to Deterred Youth Cigar Initiation

1. Estimating Lives Saved from Avoided Youth Initiation

While the analysis in Sections I.F and I.G monetized reduced mortality among baseline cigar smokers, this section studies benefits to non-users, particularly youth and young adults, who would start smoking cigars in the absence of regulation. In the Preamble, we discuss evidence that the availability of flavored cigars causes youth to increase experimentation with cigars, and that increased experimentation puts youth at risk of becoming regular cigar users—

avoidance of which is one of the principal purposes of the rule. We also describe the qualitative research and national studies that indicate that youths acknowledge that flavorings influence their initial cigar use, and that youths that initiate cigar use with flavored products are more likely to become regular cigar users. Relying on an analysis published by Rostron et al. (101) and updating it with more recent data, the Preamble estimates that roughly 106,000 18-year-olds who currently use cigars initiated with a flavored product, compared to 166,000 18-year-olds who self-reported every day or some day use of flavored or non-flavored (i.e., tobacco-flavored) cigars in 2019 (3.9 percent x 4.26 million 18-year-olds).[50] We use these estimates as our starting point to calculate the benefits of reduced youth initiation and progression to regular use.

First, following Rostron et al. (101), the Preamble estimates the proportion of current cigar users who would have initiated cigar smoking with non-flavored (i.e., tobacco-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 (i.e., tobacco-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, meaning that 32.5 percent of those currently initiating with flavored cigars would be deterred from trying cigars. We therefore estimate that 34,000 (106,000 * 32.5 percent) cigar smoking initiates would be prevented by the product standard.

Second, we also consider the possibility that flavored cigar initiates are more likely to continue cigar use than those who initiate with tobacco-flavored products. Without flavored

[50] Beginning with the 4.26 million 18-year-olds in 2019, the Preamble estimates 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. The Preamble also uses 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.

cigars, the chance that these youth would progress to regular cigar use decreases compared to their behavior in the absence of regulatory action. For this subgroup, we estimate the number who would initiate cigar use with a tobacco-flavored cigar with the proposed rule, but who would not continue to progress through the full initiation phase due to the absence of flavored cigars. PATH data from Waves 1 and 2 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 (i.e., tobacco flavored) cigars (adjusted prevalence ratio = 1.56, 95 percent confidence interval = 1.29, 1.87), controlling for other relevant factors related to cigar use (80). Similar estimates were obtained from analysis of Waves 2 to 4 data although results were presented separately for mint/menthol and other flavors (80). We therefore estimate that 26,000 (106,000 * (1 – 32.5%) * (1 – 1/1.56)) cigar smokers would be prevented from continuing to regular use.

Combining estimates of reduced youth initiation (34,000 smokers) and reduced progression to regular use (26,000 smokers) yields a total reduction of 60,000 current cigar smokers in each cohort of 18-year-olds due to the proposed product standard. This reduction represents roughly 35 percent of youth cigar smokers. Consistent with Rostron et al. (101), we accounted for the uncertainty inherent in estimating the impact of the proposed policy based on these data by conducting Monte Carlo simulations in @RISK statistical software to assess the effects of varying key data inputs. Using a triangular distribution for all parameters, 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 – 1/1.29) to 46.5 percent (1 – 1/1.87) 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.

These estimates represent between 25 and 45 percent of youth cigar smokers. Preamble Section VI.C.2 also reports these estimates.

Table 28. Derivation of the reduction in youth cigar initiation due to the proposed rule

Row	Description	Point Estimate and Distribution	Supporting Discussion or Calculation
1	Size of youth cohort that would have initiated cigar use with both flavored and non-flavored products available in the absence of regulation.	166,000	Section II.K.ix.1 and Preamble Section VI.C.2
2	Percent of youth cigar smokers whose first product was flavored	63.6%	Section II.K.ix.1 and Preamble Section VI.C.2
3	Number of youth cigar smokers whose first product was flavored	106,000	row 1 x row 2
4	Percent of flavored cigar initiators who would initiate with non-flavored cigars if flavored cigars were not available	67.5% [35, 100][a]	Section II.K.ix.1 and Preamble Section VI.C.2
5	Number of youths who would have initially tried flavored cigars, but are deterred from cigar initiation (will never try) due to the proposed rule	34,000	row 3 x (1 - row 4)
6	Percent reduction in progression from experimentation to regular cigar use for youth whose first product was flavored	35.9% [22.5, 46.5][b]	Section II.K.ix.1 and Preamble Section VI.C.2
7	Number of youth cigar initiators that would still initiate with non-flavored products, but would not continue progression to regular cigar use without flavored cigars due to the proposed rule	26,000	(row 3 - row 5) x row 6
8	Total number of youths deterred from cigars initiation due to the proposed rule	60,000	row 5 + row 7
9	Percent reduction in youth cigar use due to the proposed rule	36. 1% [25.3, 45.1][c]	row 8 / row 1

[a] These are the 5th and 95th percentiles generated from the mean value and standard error presented in the PATH study.

[b] These are the minimum and maximum values.
[c] These are the 5th and 95th percentile outcomes for this row.

As discussed earlier, cigar users who die from cigar use lose an average of 15.1 years of potential life (4).[51] We do not have precise data about the average age of death for cigar users who die of cigar-attributable mortality. Based on data from the SEER Cancer Statistics Review, 1975 – 2013 (from the National Cancer Institute), however, the median of the average ages at death of patients with oral and pharynx cancer, and cancers of the respiratory system was 69.5 years of age between 2009 and 2013. We use this measure as a proxy for the age at death of cigar users that die prematurely of cigar-attributable causes. In the case of youths who would initiate with flavored cigars, we use the difference between 69.5 years of age and age of 18 years[52], or 51.5 years, as the number of years into the future when premature cigar deaths of deterred youth initiations would be avoided.

Finally, we quantify the benefits of deterred youth initiation and progression to regular use from the reduction in cigar-attributable premature deaths for exclusive cigar smokers, assuming a 51.5-year lag. We assume that the estimated reduction in youth cigar use is directly proportional to the baseline number of annual cigar-attributable deaths. For the analysis in Sections I.F of adults, we used the percentage of cigar-attributable premature deaths for current adult cigar users (5,200 cigar-attributable deaths to exclusive cigar users). However, youth cigar use has decreased over time. To reflect this trend, we update the number of adult baseline cigar-attributable deaths with more recent population and prevalence data. Rostron et al. (101) reported that approximately 302,000 18-year-olds (7.2 percent) were every or some day cigar

[51] For our estimates, we use a lower bound of 12.0 years and an upper bound of 16.7 years. We obtain this range from Nonnemaker et al.'s sensitivity analysis in their Table 4. Using the authors' formula for average lost life years per death, the lower estimate was produced using row 5 of Table 4 ("Including COPD (smoked ≥ 15 d in past 30 d)"), and the upper estimate was produced using row 2 ("Smoked cigars at least 1 day in past 30 d").
[52] We assume that youth initiate by the age of 18 and therefore die 51.5 years later.

smokers. Based on 2019 Census data and PATH Wave 5 data as cited in the Preamble, the population of 18-year-old some or everyday cigar smokers decreased to approximately 166,000 18-year-olds (3.9 percent) by 2019. This amounts to a 45 percent decrease in youth cigar smoking ((302,000 – 166,000)/302,000). Assuming that this decrease in use is directly proportional to the number of cigar attributable deaths, we estimate baseline cigar deaths to be roughly 2,900 annually (5,200 – (5,200 * 45 percent)). As it is not clear how recent changes in youth cigar use will influence long-term adult mortality, we use the adjusted 2,900 deaths as a lower bound and the unadjusted 5,200 deaths as an upper bound, with the mean of approximately 4,000 as our primary estimate.

We note that the data we use predate the 2019 Tobacco 21 law (Tobacco 21), which raised the federal minimum age for sale of tobacco products from 18 to 21 years. We expect this law to contribute to further reductions in baseline youth cigar-attributable mortality. To incorporate the potential effects of Tobacco 21 on baseline mortality, we rely on simulations conducted by the Institute of Medicine (IOM). In a 2015 report, IOM simulated forecasts of cigarette smoking prevalence and the health consequences of cigarette use under policy scenarios that raise the minimum age of legal access to tobacco products (MLA) nationwide to 19, 21, and 25 (102). IOM simulated the effect of reduced cigarette smoking initiation under three MLA standards that would have been effective in 2015, tracking outcomes from 2015 to 2100 compared to effects from status quo projections of cigarette smoking initiation. Table 8-1 of the IOM report[53] presents estimates of lifetime deaths prevented by birth cohort under a national MLA 21 policy. According to these estimates, a national MLA 21 policy could reduce lifetime smoking-attributable deaths by 11 percent compared to the status quo. IOM acknowledges

[53] This table is on page 221 of the report.

limitations to its simulations, including the lack of empirical literature based on existing MLA 21 laws underlying the simulation inputs.[54] Furthermore, IOM assumes, as noted in Tables 7-2 and 7-3, that raising the minimum tobacco purchase age to 21 would have several times the effect on initiation by minors as raising it to 19; however, many 15- to 17-year-olds attend high school with 18-year-olds, thus facilitating the sharing of cigarettes in a manner that is not as obviously available between minors and twenty-somethings. However, despite these limitations, we believe that this report, combined with our own adjustments described in greater detail below, represents a reasonable source for forecasting the effects of the Tobacco 21 law.

We make three further adjustments to the IOM report's estimates. First, the report assumed a 2015 policy change, though the Tobacco 21 law went into effect in late 2019. We therefore shift cohorts by five years to account for this timing difference and identify the cohorts that fall within our time horizon. Second, to incorporate potential reductions in mortality due to existing MLA laws, we attribute half of the predicted reductions in adult smoking prevalence to existing state and local MLA laws and half to Tobacco 21. We adjust the estimated effect of Tobacco 21 downward by 50 percent (with lower and upper bounds of 40 and 60 percent respectively) to reflect state and local MLA laws that were not in effect at the time of the IOM report. Finally, IOM based its baseline forecast of adult smoking prevalence on the NHIS data from 1965 to 2012, which does not capture additional reductions in prevalence observed from 2012 to 2019. Compared to NHIS data from this more recent period, we estimate that baseline IOM forecasts may overstate smoking prevalence by 14 percent. We therefore reduce the effect of the Tobacco 21 law by 14 percent to reflect the observed reduction in tobacco prevalence beyond what was predicted in the report. To combine these adjustments, using the example of

[54] This discussion appears in the chapter "Other Considerations for Policymakers," beginning on page 241.

the youngest birth cohort, we multiply the IOM report's estimated 10.3 percent reduction in deaths by 50 percent (1 – 50 percent) and 86 percent (1 – 14 percent), yielding an estimated reduction in deaths of 4.4 percent due to the Tobacco 21 law. We then reduce our pre-Tobacco 21 baseline cigar-attributable deaths, ranging from roughly 2,900 to 5,200, by the estimated Tobacco 21 impact. Using the youngest cohort as an example, we multiply the pre-Tobacco 21 range by roughly 96 percent (1 – 4.4 percent). Table 29 summarizes IOM's mortality reduction estimates, originally presented in Table 8-1, alongside our adjusted estimates of baseline cigar-attributable deaths. We request comment on this approach, including about how to refine it to incorporate emerging literature as it is peer reviewed and published (such as Bryan et al. (103)), into our assumptions.

Table 29. Estimated Youth Baseline Cigar-Attributable Deaths, Incorporating the Effects of the Tobacco 21 Law

IOM		With Adjustments			
Birth cohort	Percent Reduction in Deaths Under MLA 21	Birth cohort	Cigar-Attributable Premature Deaths		
			Lower	Primary	Upper
2000-2019	10.3%	2006-2019	2,756	3,851	4,925
2020-2039	10.9%	2020-2039	2,750	3,840	4,909
2040-2059	10.9%	2040-2045	2,750	3,840	4,909

With both the pre- and post-Tobacco 21 adjustments incorporated, the primary number of avoided deaths due to the proposed product standard equals roughly 3,800 cigar-attributable premature deaths per year times the 36.1 percent reduction from Table 28, or roughly 1,400 fewer deaths annually. Table 30 presents estimates for both the number and timing of avoided deaths of deterred youth cigar users due to this rule, using the mean estimate of affected products.

2. Estimated Magnitude of Benefits from Avoided Initiation

As in the analysis in Sections I.F, we quantify the benefits associated to these averted deaths using a VSL approach. These VSL values are multiplied by the corresponding estimated number of avoided premature deaths for youths. We do not phase in the avoided deaths for deterred youth as we did for adults. Instead, we apply the 36.1 percent reduction from Table 28 to baseline cigar-attributable deaths for each year. We also account for the timing of youth impacts differently from adults. For adults, we assume that averted deaths begin to occur immediately following the effective date of the final rule. For youth, as described earlier, we assume that initiation occurs by the age of 18, followed by a cigar-attributable death 51.5 years later (based on the 69.5 median of the average ages at death of patients with oral and pharynx cancer and cancers of the respiratory system). For the first cohort of 18-year-olds exposed to the final rule, who would have otherwise initiated cigar use by 2024, averted deaths therefore begin to accrue 51.5 years in the future. For the subsequent cohort of 18-year-olds, who would have otherwise initiated by 2025, averted deaths begin to accrue 52.5 years in the future – and so on. As a result of this timing, the VSL values for youths are discounted by 51.5 years in the first year following the effective date of the final rule, and in each succeeding year following the effective date, the VSL values are discounted by one additional year. We use this approach because, when risk change occurs with a delay (such as future premature mortality resulting from current cigar smoking), the VSL should represent an individual's value at the time of the risk change (i.e., their future VSL). To compare this future value to the present, it must be discounted back to the year when costs first occur (52) (104). We request comment on this approach for valuing future avoided deaths of deterred youth initiators. Table 30 shows the number of avoided deaths each year over the first 40 years of the rule and the present discounted value of avoided deaths using the midpoint VSL estimate of $11.8 million in the first year.

Table 30. Estimates of the Magnitude, Timing, and Value of Avoided Deaths of Deterred Youth Initiators over 40 years from 2024 to 2063 ($ Billions)

Years after Effective Date of Rule[1]	Avoided Deaths	Cumulative Avoided Deaths	Timing of Avoided Deaths (Years in the Future)	Present Discounted Value of Deaths Avoided at 3% ($ billion)	Present Discounted Value of Deaths Avoided at 7% ($ billion)
1	1,391	1,391	52	$3.58	$0.50
2	1,391	2,782	53	$3.51	$0.47
3	1,391	4,173	54	$3.43	$0.45
4	1,391	5,564	55	$3.36	$0.42
5	1,391	6,955	56	$3.29	$0.40
6	1,391	8,346	57	$3.22	$0.37
7	1,391	9,737	58	$3.15	$0.35
8	1,391	11,128	59	$3.09	$0.33
9	1,391	12,519	60	$3.02	$0.31
10	1,391	13,910	61	$2.95	$0.29
11	1,391	15,301	62	$2.89	$0.28
12	1,391	16,692	63	$2.83	$0.26
13	1,391	18,083	64	$2.77	$0.25
14	1,391	19,474	65	$2.71	$0.23
15	1,387	20,861	66	$2.64	$0.22
16	1,387	22,248	67	$2.58	$0.21
17	1,387	23,635	68	$2.53	$0.19
18	1,387	25,022	69	$2.47	$0.18
19	1,387	26,409	70	$2.42	$0.17
20	1,387	27,796	71	$2.36	$0.16
21	1,387	29,183	72	$2.31	$0.15
22	1,387	30,570	73	$2.26	$0.14
23	1,387	31,957	74	$2.21	$0.13
24	1,387	33,344	75	$2.19	$0.13
25	1,387	34,731	76	$2.14	$0.12
26	1,387	36,118	77	$2.08	$0.11
27	1,387	37,505	78	$2.03	$0.11
28	1,387	38,892	79	$1.99	$0.10
29	1,387	40,279	80	$1.95	$0.09
30	1,387	41,666	81	$1.90	$0.09
31	1,387	43,053	82	$1.86	$0.08
32	1,387	44,440	83	$1.82	$0.08
33	1,387	45,827	84	$1.79	$0.07
34	1,387	47,214	85	$1.75	$0.07
35	1,387	48,601	86	$1.71	$0.07
36	1,387	49,988	87	$1.67	$0.06

37	1,387	51,375	88	$1.64	$0.06
38	1,387	52,762	89	$1.60	$0.06
39	1,387	54,149	90	$1.57	$0.05
40	1,387	55,536	91	$1.53	$0.05
Total over 40 years				$96.83	$7.89

[1] For this benefits analysis, we include the avoided deaths of the deterred youth initiators over 40 years, which is the time horizon used in the analysis in Section I.F. Differences between the sum of avoided deaths and cumulative avoided deaths are due to rounding. Estimates are based on a first-year central VSL value of $11.8 million, and the VSL value then adjusts annually in accordance with HHS guidelines (52).

We summarize our full range of estimates of VSL values in Table 31. The present discounted value of total avoided deaths from averted youth initiation ranges from approximately $49 billion to $155 billion at a 3 percent discount rate, and approximately $4 billion to $13 billion at a 7 percent discount rate. Our primary estimates of the present discounted value of avoided deaths equal approximately $97 billion at a 3 percent discount rate and $8 billion at a 7 percent discount rate. The annualized values of the primary estimates equal approximately $4 billion at a 3 percent discount rate and $1 billion at a 7 percent discount rate.

Table 31. Present Discounted Value and Annualized Value of Quantified Mortality Reductions for Averted Youth Initiation, 40-year Period from 2024 to 2063 ($ Billions)

	Discount Rate	Low	Primary	High
Present Discounted Value of Averted Deaths	3%	$48.52	$96.83	$154.72
	7%	$3.95	$7.89	$12.60
Annualized Value of Averted Deaths	3%	$2.10	$4.19	$6.69
	7%	$0.30	$0.59	$0.95

Note: Based on a first-year VSL value of $11.8 million. The VSL value then adjusts annually in accordance with HHS guidelines (52).

x. Alternative Youth Averted Initiation Estimate that Excludes Dual Users

Because our baseline rate of adult cigar-attributable deaths does not include dual users, we present an alternative set of estimates below. As discussed previously, the analysis in Section I.F uses a baseline of 5,200 annual cigar-attributable deaths associated with exclusive cigar users.

As a result, that analysis does not consider the potential health benefits of cigar cessation to dual users. If we consider both exclusive and dual cigar users, cigar-attributable deaths are estimated at 9,000 per year (4). For our alternative estimates, we thus use 9,000 cigar-attributable deaths as an upper bound. As in the previous section, we adjust this number for pre- and post-Tobacco 21 decreases in youth cigar use which provides a baseline range of about 3,900 to 8,500 annual cigar-attributable deaths.

We use this new range to replicate our analysis and summarize the resulting estimates in Table 32. The present discounted value of total avoided deaths ranges from approximately $69 billion to $268 billion at a 3 percent discount rate, and approximately $6 billion to $22 billion at a 7 percent discount rate. Our primary estimates of the present discounted value of avoided deaths equal approximately $157 billion at a 3 percent discount rate and $13 billion at a 7 percent discount rate. The annualized values of the primary estimates equal approximately $7 billion at a 3 percent discount rate and $1 billion at a 7 percent discount rate.

Table 32. Present Discounted Value and Annualized Value of Quantified Mortality Reductions for Averted Youth Initiation Using Alternative Baseline Death Rate, 40-year Period from 2024 to 2063 ($ Billions)

	Discount Rate	Low	Primary	High
Present Discounted Value of Averted Deaths	3%	$68.88	$156.92	$267.82
	7%	$5.61	$12.78	$21.81
Annualized Value of Averted Deaths	3%	$2.98	$6.79	$11.59
	7%	$0.42	$0.96	$1.64

Note: Based on a first-year VSL value of $11.8 million (primary). The VSL value then adjusts annually in accordance with HHS guidelines (52).

L. International Effects

We expect that the proposed rule would have the same impact on foreign firms as domestic firms. We use data from Euromonitor cigars and cigarillos report to evaluate cigar

imports. We find imports of about 8,167 million units in 2020, or about 58 percent of the value of all cigars sold in the United States. Of the total imports about 3,142 million sticks of flavored cigars are imported which accounts for 53.5 percent of all flavored cigars sold in the US.

Since the Euromonitor report only provides import information on units sold we evaluate the Tobacco Import data from 2017[55] for import data by dollar sales. Cigars account for about 43 percent of total tobacco imports in the United States by dollar sales. Most cigar imports come from North America and Central America with about 70 percent of imported cigars from the Dominican Republic and 18 percent from Nicaragua. However, the import data does not provide information on the origin of flavored cigars.

With the proposed rule, if finalized, any imports of flavored cigars manufactured by foreign firms would end as manufacturers, importers, wholesalers, and retailers stop offering flavored cigars for sale in the United States. Therefore, these firms would face the same costs as domestic firms for the portion of their products being sold to the United States.

The proposed rule, if finalized, would not prohibit the export of flavored cigars manufactured domestically to other countries that allow the sale of these products. Exports of flavored cigars could increase if demand for these products exists in other countries and domestic manufacturers continue to produce flavored cigars for export. We do not have data on flavored cigars currently being exported out of the US. However, we find no evidence that tobacco exporting companies continued to export any flavored cigarettes after the TCA banned flavored cigarettes, except menthol (105). Based on industry reaction to the cigarette flavors ban, we anticipate that any domestic manufacturers currently exporting flavored cigars would stop all

[55] Prepared by U.S. Food & Drug Administration – Import Compliance Systems Branch – Minneapolis District Office, prepared on March 26th, 2018.

domestic production of flavored cigars, including flavored cigars for export. We request comment on the potential impacts of the proposed rule on trade.

We acknowledge that this proposed rule, if finalized, could have budgetary and producer surplus impacts to international firms similar to those of domestic firms.

M. Distributional Effects

i. Vulnerable Populations

Data indicate that all age groups smoke cigars, but the patterns of cigar use differ markedly by age group, race and ethnicity, household income, education level, and among other vulnerable groups such as individuals who identify as LGBTQ+ and persons with disabilities. While evidence from national surveys has suggested that, like cigarettes, cigar use has been on the decline among U.S. youth in recent years, in 2020, cigars were the most commonly reported combusted tobacco product used by youth (106) (107) (5). Nationwide, in 2020, nearly one million youth had smoked a cigar on at least one day during the past 30 days (6). 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 (6). The most recent NYTS data also found that, of those youth who use cigars, the largest proportion use cigarillos (44.1 percent), followed by traditional cigars (33.1 percent), and little cigars (22.6 percent) (6).

While there has been an overall downward trend in cigar use among youth in general, this decrease has not been equitably experienced as the popularity of cigar use remains disproportionately high among non-Hispanic Black youth, posing public health concerns. The

2020 NYTS data show that the popularity of cigars is especially high—equal to or greater than cigarettes—among non-Hispanic Black high school students (5). Additionally, the findings show that cigars were significantly more popular than cigarettes among these youth in 2020, with 9.2 percent of non-Hispanic Black high schoolers reporting having smoked cigars during the past 30 days, compared with 2.8 percent reporting having smoked cigarettes (5). These rates of past 30-day cigar use by non-Hispanic Black high school students were twice as high as their White counterparts (5). A study by Cantrell (2021) 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 six months relative to non-Hispanic Whites (108). Also, within six months of initiation, the average frequency of use, days per month used, was higher for non-Hispanic African Americans compared to non-Hispanic Whites (108).

As discussed in the Preamble, disparities in tobacco use contribute to tobacco-related disparities in morbidity and mortality. The Preamble also includes a discussion of the disproportionate burden of cigar use observed for racial and ethnic subpopulations, those with lower household income and educational attainment, individuals who identify as LGBTQ+, and those with pre-existing health conditions. The disparities observed in tobacco product and cigar use likely contribute to the disproportionate tobacco-related disparities in morbidity and mortality experienced by these population groups. Given these existing disparities in tobacco use as well as tobacco-related morbidity and mortality, vulnerable populations could be expected to experience a disproportionate impact of this rule. We request comment and data on the assumption that vulnerable populations could expect to experience disproportionate impacts of this rule.

ii. Impacts on Tribal Governments

The proposed product standard applies to all cigars and cigar manufacturers, including those manufacturers that are tribally-affiliated or operating on tribal land. Under Section 905 of the FD&C Act, owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products are required to register with FDA and to list their products. However, FDA does not require information on tribal affiliation or tribal ownership as part of our tobacco registration and listing data. Under Section 704 of the FD&C Act, FDA inspects such establishments registered under Section 905 of the FD&C Act, to evaluate whether the establishment, including those that are tribally-affiliated and/or operating on tribal land, is in compliance with the FD&C Act and FDA's implementing regulations. Therefore, because persons submitting registration and listing data to FDA under Section 905 of the FD&C Act do not designate whether they are tribally affiliated and/or operating on tribal land, FDA's estimate is based on the addresses of registered establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products; its determination of whether the address is on tribal land; and inspection history.[56]

Of the count of domestic manufacturers potentially affected by the proposed product standard, FDA estimates that there are 13 tobacco product manufacturers that are tribally-affiliated and/or operate on tribal land. However, we are not aware that any of these 13 manufacturers manufacture flavored cigars. We request comment on our estimates of the

[56] FDA's Registration and Product Listing database may provide an over- or underestimate of the number of domestic establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products operating on tribal land. Information in the database is confirmed upon inspection, at which time FDA may request that the person who registers under Section 905 of the FD&C Act update registration and/or product listing information. As an example of how the registration information may provide an overestimate, some firms may have registered establishments not engaged in the manufacture, preparation, compounding, or processing of tobacco products, such as certain warehouses, due to confusion.

potential impacts of the proposed product standard on manufacturers, including those that are tribally-affiliated or operating on tribal land.

III. Initial Small Entity Analysis

We have examined the economic implications of this proposed rule for small entities as required by the Regulatory Flexibility Act. If a proposed rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the proposed rule on small entities. Consequently, this analysis, together with other relevant sections of this document and the Preamble of the proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

Initial Regulatory Flexibility Analysis Elements:

1. Reasons action is being considered and object of the rule (see section I.A - I.C) and legal basis for the rule (see section I.C of the preamble to this proposed rule)
2. Estimate of the small entities impacted (see section I.D and this section)
3. Compliance requirements (see section I.G and this section for small business specific estimates)
4. Significant alternatives considered (see section I.J and this section)
5. Duplicative overlapping and conflicting rules (see section I.K.iii)

A. Description and Number of Affected Small Entities

i. Cigar Manufacturers

The data on affected entities comes from CTP's Tobacco Registration and Listing Module data and D&B firm data. From the TRLM data we identify firms that produce flavored and tobacco-flavored cigar products. We merge this data with D&B firm data to identify firm-level characteristics. According to the Small Business Administration (SBA), a small tobacco manufacturer is any firm with under 1,500 employees (109).[57] Because the tobacco manufacturing firms do not all have tobacco manufacturing as their primary business in the D&B data and different lines of business have varying standards to determine small businesses, we determine the number of small businesses by relying on the D&B created small business indicator which D&B determines using the SBA definitions and primary business for each firm. For firms that had missing data for the small business indicator but did have data on the number of employees at the establishment that data was used to make the determination.

At baseline there are 57 cigar firms of which 50 are small, 2 are large and 5 did not have available data to make a determination, as summarized in Table 33. There are 26 firms that produce only tobacco-flavored cigars, of which 23 are small businesses. There are 5 firms that only produce flavored cigars, of which all 5 are small. Finally, 26 firms produce both flavored and tobacco-flavored cigars, of which 22 are small businesses. We note that this may be a lower bound number of entities as the TTB data report 74 cigar manufacturers and 114 cigar importers. However, TRLM and TTB have slightly varying definitions of manufacturers which likely accounts for the difference. We use the TRLM data in the analysis as the TTB data does not

[57] Under section 900(16) of the FD&C Act, tobacco product manufacturers (and importers) are considered small if they employ "fewer than 350 employees." Note that, "For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer." However, the Small Business Administration's definition of small is applicable to the small entity analysis required under the Regulatory Flexibility Act.

provide the data needed to determine if the businesses are small businesses and if they produce flavored cigars, tobacco-flavored cigars, or both.

Table 33. Firms by Cigar Product Type

	Total Firms	Small Firms
Total Number of Firms	57	50
Only Flavored Firms	5	5
Only Tobacco-flavored Firms	26	23
Both Flavored and Tobacco-flavored	26	22

The distribution of the size of small firms is presented in Table 34. Most small firms (28 of 50) have fewer than 10 employees.

Table 34. Distribution of Small Tobacco Manufacturers by Employee Size from Dun & Bradstreet Data

Number of Employees	Number of firms	Average revenue per firm
0-4	15	$353,746
5-9	13	$833,336
10-19	5	$3,725,664
20-49	8	$15,813,718
50-99	4	$80,332,297
100-249	3	$74,579,220
250-1500	2	$167,104,955

Note: Two of the firms considered small by D&B did not have revenue data available. This table summarizes the available data.

ii. Retailers and Wholesalers

To estimate the number of small wholesale and retail entities that may be affected by the proposed product standard, we use the estimated number of tobacco-selling wholesale and retail firms and their associated SBA size thresholds by NAICS code from Section I.D.iv. Incorporating 2017 SUSB employment data for tobacco wholesalers and 2017 Economic Census data on firm and establishment counts by size of sales, value of shipments, or revenue for retailers, we match SBA size thresholds to Census thresholds and estimate the percentage of firms that may be small for each wholesale or retail NAICS code (25) (93). For each wholesaler

and retailer NAICS code, we note that the closest Census size threshold is below the SBA size threshold for identifying small businesses. For this reason, our estimate of the percentage of small firms in each category likely represents an underestimate. These calculations can be found in Table 35.

Table 35. SBA Size Standards and Census Size Categories for Wholesale and Retail Categories 2017

NAICS	Description of NAICS Category	SBA Standard (employees or $million)	Census Size Category, (employees or $million)	Total Number of Firms	Total Number of Estab.	Firms Below Census Standard	% Small Firms
424940	Tobacco and Tobacco Product Merchant Wholesalers	250	200	1,285	1,513	1,240	96.5%
445110	Supermarkets and Other Grocery (except Convenience) Stores	$35.0	$25.0	40,981	65,141	30,123	73.5%
445120	Convenience Stores	$32.0	$25.0	25,844	28,460	18,095	70.0%
445300	Beer, Wine, and Liquor Stores[a]	$8.0	$5.0	30,313	34,440	25,380	83.7%
446110	Pharmacies and Drug Stores	$30.0	$25.0	19,259	45,358	17,939	93.1%
447110	Gasoline Stations with Convenience Stores	$32.0	$25.0	56,926	98,788	52,553	92.3%
447190	Other gasoline stations	$16.5	$10.0	10,084	16,581	8,521	84.5%
452311	Warehouse Clubs and Supercenters	$32.0	$25.0	9	8,202	0	0.0%
452319	All other general merchandise stores	$35.0	$25.0	7,857	41,241	6,596	84.0%
453991	Tobacco Stores	$8.0	$5.0	8,286	10,415	6,143	74.1%

[a] Small Business Administration size threshold available for 445310 NAICS code, which is the only detailed code under the aggregate 445300 code.

In Table 36 we apply the percentage of firms that may be small from the 2017 data to our estimates of firms that sell tobacco products in 2019 and estimate that about 116,000 small wholesale and retail firms may be impacted by the proposed product standard.

Table 36. Estimate of Small Wholesale and Retail Establishments with Tobacco Sales in 2019

NAICS	NAICS Description	2019 Count of Firms with Tobacco Sales	Estimated % of Small Firms	Estimated Count of Small Firms with Tobacco Sales in 2019

42494	Tobacco and Tobacco Product Merchant Wholesalers	1,308	96.5%	1,262
44511	Supermarkets and Other Grocery (except Convenience) Stores	18,332	73.5%	13,475
44512	Convenience Stores	24,854	70.0%	17,402
44530	Beer, Wine, and Liquor Stores	16,578	83.7%	13,880
44611	Pharmacies and Drug Stores	8,269	93.1%	7,702
44711	Gasoline Stations with Convenience Stores	52,390	92.3%	48,366
44719	Other gasoline stations	2,140	84.5%	1,808
452311	Warehouse Clubs and Supercenters	28	0.0%	0
452319	All other general merchandise stores	5,839	84.0%	4,902
453991	Tobacco Stores	9,667	74.1%	7,167
	Total	139,404		115,963

B. Description of the Potential Impacts of the Rule on Small Entities

i. Cigar Manufacturers

Small entities would be subject to the costs to firms as described in the cost section (see Section I.G.i). This includes the cost of reading and understanding the proposed rule and the one-time friction cost to reallocate productive resources to compliant tobacco products.

We discuss the one-time friction cost in Section I.G.i.1. Friction costs come from manufacturers moving production away from flavored cigars to compliant tobacco products. We estimate this cost equals between 120 labor hours and 1.5 percent of annual revenue of sales of flavored products. While this proposed rule, if finalized, could create more of a burden for firms with a higher proportion of products affected by this rule, we calculate the effect on an average firm. Based on data from D&B, the average small firm has revenue of $14.9 million. Therefore, we estimate the friction costs for the average small firm equal between $12,860 (= 120 hours*$107.17 wage)) and $224,280 (= 14.9 million * 0.015) (110). See Section II.G.i.1 One-Time Friction costs for details on these estimates.

We expect that some small firms may experience long term changes to their revenue due to the proposed product standard. This lost revenue consists of both the lost producer surplus and the lost transfers from firms to consumers. For the purpose of the small entity analysis, we consider all lost revenue to be a cost to the firms. We estimate the lost revenue based on the Preamble's estimate of reduced consumption. The Preamble estimates a 71 percent (= 30% of the 42% of the number of cigars sold) reduction in unit sales. Flavored cigars make up 19.1 percent of dollar sales, so we estimate a 13.7 percent (= 71% * 19.1) reduction in revenue as a result of this rule. A 13.7 percent reduction of the average small business revenue is $2,048,000. We note that this estimate is for the average small business. The revenue reduction for each individual firm will depend on firm size, what percent of revenue comes from flavored products, and the extent to which consumers who switch products stay within brand when switching.

We discuss the cost to read and understand the proposed rule in Section I.G.i. We estimate a one-time cost of reading and understanding the rule between $573 to $2,867 per affected entity. Table 37presents the average costs per small entity and Table 38 presents the undiscounted flow of costs for the average small business. We request comment on the potential revenue, employment, and firm exit impacts for manufacturers.

Table 37. Estimated Average Cost per Small Entity over a 40-year time horizon (2020 $)

Discount Rate	Annualized Costs	Present Value Costs
3%	$1,966,744	$46,824,654
7%	$1,912,383	$27,280,003

Table 38. Stream of Undiscounted Costs for the Average Small Manufacturer ($ thousands, 2020 $)

Year	Friction Cost	Reading Cost	Lost Revenue Cost
0	$118	$2	
1			$2,048
2			$2,048

3			$2,048
4			$2,048
5 to 40			$2,048

ii. Retailers and Wholesalers

As estimated in Section II.G.i, we expect small retailers and wholesalers to face one-time costs of reading and understanding the rule of between $573 and $2,867 per firm. Additionally, retailers and wholesalers could face lost revenue, although that lost revenue could in part be offset with revenue from whatever the consumer purchases with money previously spent on flavored cigars. We request comment on the potential revenue, employment, and firm exit impact for retailers and wholesalers.

C. Alternatives to Minimize the Burden on Small Entities

One alternative that could reduce the impact to small entities would be a delayed effective date for all entities as discussed in Section I.J.i. With a 24-month effective date, manufacturers would have lower one-time friction cost because they would have more time to switch over productive resources. We estimate the cost would equal an average of $149,000 per small manufacturer. All other costs would be unimpacted by the longer effective date, except that the costs would not begin for an additional year. For small retailers and wholesalers this alternative would also delay the cost of reading and understanding the rule and delay the potential loss in revenues caused by this rule.

Table 39 presents the discounted cost per small manufacturer under the alternative effective date and the difference from the 12-month effective date proposed in the rule. While extending the effective date to 24 months decreases the burden on small business, it also decreases the benefits of this proposed rule by delaying the benefits for an additional 12 months.

Table 39. Costs of the Proposed Rule per Small Manufacturer in Dollars

Discount Rate	3%	7%

Cost per firm under 24-Month Effective Date		
Present Value	$45,460,830	$25,495,330
Annualized	$1,885,186	$1,778,946
Difference Between Proposed Rule and 24-Month Effective Date		
Present Value	($1,363,825)	($1,784,673)
Annualized	($81,558)	($133,437)

IV. References

The following references have been placed on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen 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 in the Division of Dockets Management. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document is published.

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V. Appendix

A. Consumer Surplus

Regulations that reduce the demand for a product or that raise its market price may lead to reductions in consumer surplus or consumer utility. We include a discussion of this topic in Section I.G.ii . This appendix provides additional background and explores the challenges of addressing potential gains and losses in consumer surplus from this proposed flavored cigar product standard. At a higher level, our purpose is to discuss the uncertainty and practical challenges surrounding consumer demand estimation, which complicates the ability to provide a quantified analysis. To do so, we provide a comprehensive review of available literature on the topic of demand and consumer surplus estimation for tobacco products and outline some of the open questions for consideration.

For fully-informed, rational consumers, consumer surplus reflects the difference between their maximum willingness to pay for a product and the price they pay in the marketplace. A rational consumer is one whose choices maximize his or her utility, i.e., an individual who, when presented with a decision, chooses the option that maximizes their welfare. Circular A-4 states that regulatory impact analyses should consider including "gains or losses in consumers'...surpluses" as part of the economic analysis (68).

As with other tobacco products, consumer behavior in the market for flavored cigars is distorted by addiction, imperfect information, and internalities. The Preamble[58] and Section II.B. of this preliminary regulatory impact analysis describe the internalities that influence demand for flavored cigars, including how characterizing flavors further enhance cigars' addictiveness and youth appeal. These complexities and other challenges are briefly described in this appendix.

[58] See the Preamble Section IV on how characterizing flavors impact cigar use, particularly among youth and young adults, and Section V on how cigar use is common, addictive, and harmful.

The focus of this appendix is to provide additional background, especially on relevant literature on the approaches to modeling demand and associated consumer surplus for tobacco products, which are highly addictive and generally initiated before adulthood. A review of the literature highlights the lack of consensus regarding how to account for lost consumer surplus in analyzing the effect of regulations on tobacco products

i. Summary Literature Review: Consumer Surplus in Tobacco Product Use

Early economic modelers of cigarette consumption noted that cigarette demand decreased as price increased, similar to other products on the market, and attempted to fit a model of rational addiction to cigarette use (111). Applied more generally, these models simplified demand for addictive products, such as cigars, in ways that allowed application of classic economic theory and concepts, such as consumer preference, demand, and willingness to pay. Under this rational addiction approach, cigar users derive a surplus from smoking equal to the difference between the price they were willing to pay for cigars and the shadow, or full, price of cigars. For harmful addictive goods, the shadow price includes both the market price and the present value of future costs resulting from current consumption. Thus, any reduction in cigar use caused by regulation would create a loss in surplus, seen as a cost to the consumer once these future costs are incorporated.

However, because consumers face the internality problems discussed above, it is difficult to disentangle consumption driven by addiction from that which may be driven by rational demand. For this reason, there is a lack of consensus about how to consider forgone consumer surplus in tobacco regulatory impact analyses (66). In contrast to the rational addiction approach above, some argue that most consumers do not experience losses from reduced use because they derive little to no pleasure from consumption (112). Under this framework, forgone consumption

would not be a cost to consumers in welfare analysis. Others argue that some consumers who reduce their cigar use do experience some disutility [e.g., (113), (82), (114)].

Even among those who conclude that some consumer surplus loss exists, there is a lack of consensus about how to meaningfully incorporate it into welfare analysis (66). As H. Levy et al. (2018) note, there is an open question of how best to quantitatively assess welfare and lost consumer surplus when consumers are not fully informed and rational. One approach is to offset health gains by some factor intended to represent consumer surplus loss. This approach has been used in the past since data and methods did not allow for direct estimation of the consumer surplus change due to specific tobacco regulations. However, this approach has proven controversial, especially when offsets are not estimated directly from consumer demand. For example, Pechacek et al. (2018) note that "the underlying logic of assessing tobacco regulations using methods grounded in rational choice theory still remains a controversial issue." Pechacek et al. also note that "there are limited cohort data showing that subjective well-being increased among smokers who quit; however, ex-smokers do report being happier" (92). As a result, studies have increasingly aimed to identify utility losses by comparing the demand of consumers with and without internality problems, though doing so creates additional challenges.

In contrast, H. Levy et al. asserts that the "correct approach to evaluating the economic impact of regulation is to calculate changes in the welfare of a rational and fully informed consumer, rather than first calculating the value of health gains and then offsetting them by some amount" (66). The paper identifies three main questions framing the assessment of welfare[59] and lost consumer surplus:

[59] We note that H. Levy et al. uses the economic meaning of the term "welfare." For purposes of this discussion, we define welfare to be overall well-being, including economic, health, and social well-being. Although text in this appendix may refer to the welfare of cigar smokers specifically, social welfare analysis in tobacco regulations encompasses overall well-being of both cigar smokers and non-smokers.

- "First, under the assumption that consumers are fully informed and rational, what is the appropriate framework for welfare analysis of government regulations that yield both health gains and potentially large losses in consumer surplus?"
- "Second, *are* consumers fully informed and rational?" [emphasis added]
- "Third, what is the appropriate framework for welfare analysis if consumers are *not* fully informed and rational?"

In response to the second question, the authors note that "to date no research has developed an empirical test that distinguishes clearly between rational and quasi-rational models of smoking behavior." In response to the third question, the authors propose a model for performing a welfare analysis when consumers are not rational, arguing that "even if consumers are not rational, the correct response from an economic perspective is not to abandon welfare analysis in favor of policies that maximize health." Instead, H. Levy et al. outline further research for refining the methods for performing a "welfare analysis when consumers are not rational" but note that they do not "claim to have solved the practical question of how the FDA should carry out regulatory impact analysis of anti-smoking policies." The next section discusses these approaches in the context of this proposed rule.

ii. Approaches to Modeling Demand for Tobacco Products

Several studies consider how to measure unbiased demand that reflects a rational and fully informed consumer, as compared with biased demand based on current consumption. As H. Levy et al. note, bias increases demand above and beyond unbiased demand levels, which could be due to many factors such as "…they do not know how bad it is for them, do not realize how hard it will be to quit down the road, or simply cannot control themselves" (66). The driving idea

behind these models is that any regulation that moves consumer demand closer to an unbiased demand curve would be welfare improving from the consumer's perspective. We discuss these studies to present a range of approaches. We conclude with the most recent model by H. Levy, et al. (2018) because using an unbiased demand curve appears to be an improvement over models that do not consider the bias in tobacco product demand caused by nicotine addiction, noting that some of the questions posed by H. Levy et al. would first need to be resolved before a model could be constructed.

In the context of addictive products, a white paper drafted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S. Department of Health and Human Services (83) and Cutler et al. (84) (82) outline an approach for analyzing utility, or consumer surplus, offsets to health benefits of smoking regulations based on the identification of a subset of smokers most likely to be rational – i.e., fully informed to choose their consumption levels in ways that rationally weigh benefits, costs, and risks – and whose impacts should be assessed separately and differently from non-rational smokers. Cutler et al. use several proxies for rationality, including smokers who self-report not smoking within 30 minutes of waking[60] and smokers aged 30-45 with a college degree, regardless of age of initiation. The authors assume that the 30-45 age cohort would have initiated well after the health risks of smoking became well-publicized and use a college degree as a proxy for awareness of public information (82). [61] Individuals aged 30 or below were excluded from the analysis as their education levels had not yet been established [id.]. However, the authors acknowledge that their estimated "rational"

[60] "A widely used measure of nicotine addiction is whether the person has their first cigarette within one-half hour of waking…" (Cutler et al., citing (11)]. Smoking within 30 minutes of waking (time to first cigarette) is a widely used measure of nicotine dependence (124).

[61] The 30-45 age cohort analyzed by Cutler et al. using data from the 2010-11 Tobacco Use Supplement to the Current Population Survey from the U.S. Census Bureau would have likely reached adulthood during the 1990s. It is unclear what public information would have been most salient to this population at time of initiation.

smoking rate is likely too high as "some well-educated young smokers probably initiated 'accidentally' in their teens and now would prefer to quit" [id.]. Cutler et al. (2015) uses withdrawal costs as a proxy for utility impacts for the population of "rational" smokers. By considering these short run withdrawal costs relative to the lifetime health benefits of quitting, they conclude that, for most regulations, "a population-level estimate of the offset ratio will be closer to 5%" (82).

In Jin et al. (2015), the authors acknowledge that an individual's initiation decisions are likely mistaken and that "individual failures stem from some combination of poor information about the health consequences of smoking, other decision-making errors that lead to imperfect optimization, and bounded self-control" (18). In response to irrational initiation, the authors adopt a framework that attempts to eliminate internalities that lead to smoking initiation by considering an individual's decision-making process *post* initiation [id.] (emphasis added). Simulations in Jin et al. are predicated on the assumption that past cigarette consumption is a determinate of future demand, regardless of whether past consumption decisions were rational [id.]. However, the authors also admit that "rational demand might be mainly driven by the value of cigarettes as a means to reduce the utility losses from withdrawal" [id.]. While Jin et al. conclude—in an addendum that segments into gross and net results their primary reduced-form estimates— that "about 94% of the gross health benefits from past anti-smoking policies are offset by losses of consumer surplus in the cigarette market," the authors calculate that about 33 percent of estimated health benefits from future, hypothetical tobacco regulations would be offset by losses in consumer surplus from reduced cigarette use (18).

With respect to tobacco product cessation, these studies and others identify a subset of smokers that may be considered rational and present a wide array of potential values for

consumer surplus estimates that offset public health benefits: ranging from 5 percent to 99 percent [(82); (18); (113)]. Chaloupka et al. (2015) identify only a "small fraction" of smokers that "made what might be interpreted as a rational decision" to smoke (the authors provide an estimate of 8.8 percent of the smoking population who may experience consumer surplus loss), without offering an estimate of the potential size of this lost consumer surplus (85). Chaloupka, Gruber, and Warner (2015), however, conclude "that the 'lost pleasure' from tobacco use, as represented by conventionally measured consumer surplus, should not be included as a cost in FDA economic impact analyses of tobacco regulations" (112). Previous regulatory impact analyses evaluating rules regulating the use of tobacco products have estimated potential consumer surplus loss for those who quit as a percentage of the health benefits attributable to the rule. For example, based on their analysis of recent literature, the Department of Housing and Urban Development's regulatory impact analysis of the Smoke-Free Public Housing Final Rule, considered potential offsets totaling 5 percent to 33 percent of the health benefits attributable to the rule as the consumer surplus loss associated with the rule.[62] This broad range of values for consumer surplus estimates that offset public health benefits from cessation demonstrate the uncertainty with an offset approach, and later sections of this appendix discuss additional uncertainty with an offset approach in the context of flavored tobacco products.

[62] The literature cited in the HUD RIA includes: Levy, Helen, Edward C. Norton and Jeffrey A. Smith (2016). "Tobacco Regulation and Cost-Benefit Analysis: How Should We Value Foregone Consumer Surplus?" NBER Working Paper No. 22471. http://www.nber.org/papers/w22471; DeCicca, Philip, Donald S. Kenkel, Feng Liu and Hua Wang (2016). "Behavioral Welfare Economics and FDA Tobacco Regulations." NBER Working Paper No. 22718. http://www.nber.org/papers/w22718; Cutler, D. et al. (2015); Valuing Regulations Affecting Addictive or Habitual Goods. Journal of Benefit-Cost Analysis 6 (2): 247-280, and; Jin, L., et al. (2015). Retrospective and prospective benefit-cost analyses of U.S. anti-smoking policies. Journal of Benefit-Cost Analysis 6(1): 154-186. The utility-loss estimate of 33 percent of health benefits is based on a hypothetical prospective regulation that cuts the smoking initiation rate in half, increases the smoking cessation rate by one-third and reduces the average quantity of cigarettes smoked by one-third. HUD's rule is not expected to have an identical impact on smoking activity and thus the loss in consumer utility may be different than 33 percent of health benefits.

DeCicca et al. (2016) developed a two-period model based on internalities, or the long-term costs to oneself resulting from consumption of a harmful good, to estimate the impact of tobacco control policies on social welfare, assuming that smoking only creates adverse health consequences in the second period, and that if smokers quit by the end of the first period, which studies have shown to be around age 40, most of the excess mortality risk of smoking is avoided (114). The authors argue that "[m]ortality risks are valued so much more heavily than morbidity risks that they dominate consumer decision-making and social welfare calculations. Ultimately, DeCicca et al. attempt to correct for some of the flaws in previous rational addiction modeling by allowing for the existence of internalities, moving the best practice in consumer surplus evaluation of tobacco policy away from the offset approach to directly modeling the utility in the market.

In furthering this discussion, H. Levy et al. identify the main questions that would need to be answered in order to create an "unbiased" demand curve that represents demand for a fully informed and rational consumer (66). These questions include what framework to use in building an "unbiased" demand curve (i.e., the demand of tobacco product users who are fully informed of the health effects to tobacco product use and rational in deciding to use these products); whether tobacco product usage can be considered fully informed and rational; and how to evaluate welfare when consumers are not fully informed and rational [id.]. The authors conclude that moving consumers closer to the unbiased demand curve can be welfare improving, while also noting the limitations of the model due to empirical challenges estimating unbiased demand [id.].

We note that while Cutler et al. and Jin et al. perform their analyses on the cigarette market, these methodologies would be analytically similar to possible evaluations of dissuasion

effects in the flavored cigar market. However, H. Levy et al. note challenges with these approaches, explaining that characteristics like age and education may not properly capture differences in bias because they are related to other characteristics, like discount rates accounting for time-inconsistency, that likely affect smoking. This same challenge would apply to an analysis of dissuasion from consumption of flavored cigars.

While H. Levy et al. present theoretical demand curves, significant uncertainty remains regarding what unbiased demand curves for tobacco products might look like and how they could be estimated. The peer-reviewed literature provides a wide range of price elasticity estimates for *market* (biased) demand curves, and unbiased estimates are even more uncertain. For example, Massin and Miéra discuss an additional source of uncertainty with models like the ones suggested by H. Levy et. al. (2018) (115).[63] Such models construct biased and unbiased demand curves using the same price elasticity of demand, or slope. This slope (i.e., how steep or flat the demand curve is) represents the rate of change in the quantity of tobacco products purchased in reaction to a change in price. Addicted and non-addicted consumers may not have the same reaction to a change in price; an unbiased demand curve for a tobacco product may have a much flatter slope than the biased demand curve, reflecting the behavior of the more price-conscious, non-addicted user. Thus, assuming the same elasticity of demand for addicted and non-addicted consumers is likely to overestimate consumer surplus (115).

Peer-reviewed models of biased and unbiased demand for tobacco products, although an improvement on previous approaches, have yet to address such challenges. They also make simplifying assumptions that do not fully capture the complexity of tobacco demand and

[63] Massin and Miéra appear to exclude Jin et al. from the list of papers that suffer from the problems mentioned here. However, we request comment on this interpretation.

challenges specific to a flavored cigar product standard, including the continued availability of potential tobacco product substitutes.

Given these challenges and differing potential analytic approaches for modeling consumer surplus for cigars generally, and flavored cigars specifically, there is significant uncertainty regarding how consumer surplus impacts should be valued in tobacco product regulations. To conduct an analysis of biased versus unbiased demand for flavored cigars, we would need, among other things, to estimate current market unbiased demand, the magnitude of internalities facing consumers, and the expected demand under the proposed flavor prohibition. We request comment on relevant data that could inform such an approach or an alternative approach.

The proposed product standard prohibiting the use of characterizing flavors, other than tobacco, in cigar products presents additional complicating questions in the discussion of consumer surplus loss from tobacco product regulations. As discussed in the Preamble of this proposed rule, characterizing flavors may impact the effects of nicotine. In particular, characterizing flavors can activate the brain's reward circuit, producing rewarding effects that, when added to tobacco products, can reinforce the effects of nicotine (116) (117). For example, the use of sweet/candy and other characterizing flavors popular to youth produces a robust reinforcing effect in young populations (116) (117). One animal study found that flavors can enhance the reinforcing effects of low nicotine doses in rodents (118). 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 (117), these findings suggest that flavors and nicotine can interact to enhance the reinforcing effects of nicotine (119) (116) (118). The proposed flavored cigar product standard only impacts one

attribute of the product—flavor—making it even more challenging to consider welfare effects. Section II.G.ii.2 of the main analysis describes this issue in more detail.

iii. Challenges with Estimating Consumer Surplus for Cigars Generally, and Flavored Cigars in Particular

Recent advances in behavioral economics are moving the field towards more reliable estimation of consumer surplus, recognizing that significant challenges remain with modeling demand for cigars. Characterizing flavors in cigars raise additional challenges relating to demand and consumer surplus. These challenges include the role flavors play in enhancing addictive effects of nicotine, the role of characterizing flavors in affecting appeal to youth during brain development, the developing nature of information on health harms of smoking, perceived benefits of smoking rather than product attributes themselves, regret expressed by most smokers and inability to quit, and availability of other products to replace the derived demand for flavored cigars. These issues are described in more detail in Section II.G.ii.2.

iv. Conclusions

Given the concerns outlined in this Appendix, including the complexity of modeling a hypothetical rational demand curve for a good with an internality and cognitive bias problems, this regulatory impact analysis does not estimate changes in consumer surplus stemming from the proposed flavored cigar product standard. This applies both to non-smokers who are dissuaded from initiating the use of cigars, current smokers who quit in response to the standard, and current smokers who switch to other combustible products as a result of this ban. Although consumer surplus loss among quitters or switchers may not be zero, there are a number of challenges and a lack of consensus surrounding the tools used to measure demand for tobacco products. As a result, we discuss consumer surplus qualitatively and request comment and/or data to assist in a future application of potential modeling approaches.

Over the last ten years there has been a growing movement of peer reviewed literature looking at approaches to modeling the impact of tobacco policy on consumer surplus. The literature has largely moved away from the utility offset method and instead has made significant strides towards directly modeling biased and unbiased demand curves. While we believe there will be an approach that can be used in regulatory impact analyses, there are currently still several technical issues that need to be solved, including:

- How do addiction, imperfect information, and internalities influence the magnitude of biased demand for these products?
- What role does the significant regret voiced by the majority of current tobacco users play in welfare analysis of addictive goods?
- How should we estimate an unbiased, non-addictive demand curve?
- Given that estimating consumer surplus does not necessarily include a direct estimate of health benefits, how can an analysis of consumer surplus present health benefits clearly and transparently to the public?

Additional questions surrounding demand for tobacco products and associated consumer surplus stem from the nature of the proposed product standard under consideration, which prohibits characterizing flavor, other than tobacco, in cigars:

- How do characterizing flavors in cigars impact the valuation of consumer utility and surplus?
- How does the consumer utility provided by substitute goods (both tobacco and non-tobacco) compare to consumer utility provided by flavored cigar products?

We request comment on this discussion and the questions raised; the application of consumer surplus analysis in the context of a product standard prohibiting the use of

characterizing flavors, other than tobacco, in cigar products; and potential methods for developing and comparing biased and unbiased demand curves for tobacco products.