DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products

Docket No. FDA-2016-N-2527

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

Economics Staff
Office of Planning
Office of Policy, Planning, Legislation, and Analysis
Office of the Commissioner
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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 have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. We believe that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many smokeless tobacco products may need to be reformulated, and reformulation represents the main driver of the costs of the rule, 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 $146 million, using the most current (2015) Implicit Price Deflator for the Gross

Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

B. Summary

The proposed rule would establish a product standard for all finished smokeless tobacco products. Specifically, the proposed rule would require that all finished smokeless tobacco products comply with a limit for N-nitrosonornicotine (NNN) in such products in order to be marketed and distributed for sale in the United States. This proposed product standard would require that the mean level of NNN in any batch of finished smokeless tobacco products not exceed 1.0 microgram (µg) of NNN per gram of tobacco on a dry weight basis at any time through the product's labeled expiration date as determined by product testing. The proposed standard also includes requirements on the sale and distribution of smokeless tobacco products, product testing, labeling, and recordkeeping.[1]

The costs of the proposed rule, when finalized, will be due to affected entities ensuring that the smokeless tobacco products comply with the proposed product standard. We have estimated that the annualized costs associated with the proposed rule over 20 years to be between $17.91 million and $42.72 million using a 3 percent discount rate, with a primary value of $30.31 million, and between $20.11 million and $50.57 million, with a primary value of $35.34 million using a 7 percent discount rate. The primary estimate for the present value of total

[1] The proposed product standard includes a number of requirements in addition to the actual NNN limit, including requirements related to product testing, recordkeeping, and sale and distribution restrictions. However, generally, this analysis uses the term product standard as shorthand for the NNN limit requirement. Similarly when we discuss anticipated compliance status and compliant versus noncompliant products, we generally refer to compliance with the NNN limit requirement.

quantified costs over 20 years is approximately $450.97 million at a 3 percent discount rate and $374.36 million at a 7 percent discount rate.

NNN is a carcinogenic agent found in smokeless tobacco products. As described in the preamble of the proposed rule, on the basis of the available scientific evidence, FDA has determined that NNN is the predominant driver of excess oral cancer risk among smokeless tobacco users. This determination is based on multiple, consistent lines of evidence. First, several reviews have concluded smokeless tobacco products, including those currently marketed in the United States, cause cancer (International Agency for Research on Cancer [IARC], 2007; International Agency for Reseach on Cancer [IARC], 2012; European Commission, Scientific Committee on Emerging and Newly Identified Health Risks, 2008; National Cancer Institute, 2014). Second, NNN is a potent carcinogenic agent found in smokeless tobacco and, along with NNK, another tobacco-specific nitrosamine (TSNA), is labeled as Group 1 (known human carcinogen) by IARC (International Agency for Research on Cancer [IARC], 2007; International Agency for Reseach on Cancer [IARC], 2012). Third, substantial recent evidence supports site-specific concordance of the carcinogenic effects of NNN in animal and human epidemiologic studies. In particular, oral and esophageal tissues have been identified as targets for NNN-induced carcinogenicity (Balbo, et al., 2013; Stoner & Adams, 1998; Zhang, et al., 2013; Zhang, Wang, Villalta, Lao, & Hecht, 2009), with observation of tumors in the oral cavity and esophagus following oral exposure to NNN in experimental animals ((Hecht, Young, & Maeura, 1983; Balbo, et al., 2013; Stoner & Adams, 1998; Castonguay, Rivenson, Trushin, Reinhardt, Weiss, & Hecht, 1984; Hoffmann, Raineri, Hecht, Maronpot, & Wynder, 1975; Singer & Taylor, 1976)). These animal studies suggest a degree of concordance with effects observed at these sites in epidemiologic studies (Yuan, Knezevich, Wang, Gao, Hecht, & Stepanov, 2011; Khariwala, et

al., 2013). Finally, reviews have observed differences in the magnitude of cancer risks due to smokeless tobacco use across regions of the world, which have been found to correlate highly with variation in the levels of tobacco specific nitrosamines in smokeless products (International Agency for Research on Cancer [IARC], 2007; Khariwala, et al., 2013).

We quantify benefits associated with the proposed rule in the form of reduced oral cancer morbidity and mortality attributable to smokeless tobacco. As described in Section V.A.3 of the preamble of the proposed rule, we also expect the standard to reduce the risk of esophageal cancer and it may reduce the risks of other cancers such as pancreatic, laryngeal, prostate, and lung cancer. However, there is more limited information to directly quantify these health benefits. As such, we only consider reductions in oral cancer as the quantified benefit of the proposed product standard.

Most of the estimated benefits arise from quality life-years gains gained from reduced oral cancer mortality. The annualized value over 20 years of quality adjusted life-years gained from reduced oral cancer mortality ranges from $228.66 million to $2.46 billion at a 3 percent discount rate, with a primary value of $858.46 million. Using a 7 percent discount rate, the annualized value of quality life-years gained from averted deaths ranges from $182.01 million to $1.96 billion, with a primary value of $683.34 million. The primary estimate of the present value of mortality reductions quantified over 20 years is $12.77 billion at a 3 percent discount rate and $7.24 billion at a 7 percent discount rate. The annualized value over 20 years of quality adjusted life-years gained from reduced oral cancer mortality and morbidity ranges from approximately $283.95 million to $3.05 billion at a 3 percent discount rate, with a primary value of $1.06 billion, and approximately $246.40 million to $2.65 billion, with a primary value of $0.92 billion at a 7 percent discount rate. The primary estimate of the present value of total quantified benefits

over 20 years is approximately $15.86 billion at a 3 percent discount rate and $9.80 billion at a 7 percent discount rate for reductions in oral cancer alone. These values are likely an underestimate of the benefits associated with the proposed rule, as we do not quantify reductions in mortality and morbidity from cancers other than oral cancer. Costs and benefits are summarized in Table 1.

Table 1.- Summary of Benefits, Costs and Distributional Effects of Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized millions/year	$924.91	$246.40	$2,647.21	2015	7%	20 years	Most of the health benefits included in the totals would be realized more than 20 years after publication of the final rule, but the risk reductions associated with these benefits occur during the 20-year period beginning at publication of the final rule.
		$1,065.92	$ 283.95	$3,051.09	2015	3%	20 years	

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Quantified					7%	20 years	
						3%	20 years	
	Qualitative							Potential cost savings from net life-time reduction in medical care utilization; additional health benefits from reduction in other toxicants correlated with NNN; reduction in cancers, other than oral cancers
Costs	Annualized	$35.34	$20.11	$50.57	2015	7%	20 years	
	Monetized millions/year	$30.31	$17.91	$42.72	2015	3%	20 years	
	Annualized					7%	20 years	
	Quantified					3%	20 years	
	Qualitative							
Transfers	Federal Annualized					7%	20 years	
	Monetized $millions/year					3%	20 years	
		From:			To:			
	Other Annualized					7%	20 years	
	Monetized $millions/year					3%	20 years	
		From:			To:			

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Effects	State, Local or Tribal Government: None estimated							
	Small Business: The average cost per small entity is largest in Year 1 and range between $2.67 million and $7.97 million. Reformulation costs and stability testing represent the largest proportion of costs—up to 60 percent of average sales for entities with fewer than 50 employees and up to 13 percent of average sales for entities with 50-100 employees.							
	Wages: None estimated							
	Growth: None estimated							

II. Preliminary Regulatory Impact Analysis

A. Need for Proposed Rule

The proposed rule would, if finalized, designate a standard for N-nitrosonornicotine (NNN) in any batch of finished smokeless tobacco products. Specifically, the rule would require that the mean level of NNN in any batch of finished smokeless tobacco products not exceed 1.0 µg of NNN per gram of tobacco on a dry weight basis at any time through the product's labeled expiration date as determined by product testing.

As with other tobacco products, smokeless tobacco is addictive and can cause serious health problems. Smokeless tobacco causes oral, esophageal, and pancreatic cancers (International Agency for Research on Cancer [IARC], 2007; International Agency for Reseach on Cancer [IARC], 2012). In addition, cancer survivors can experience substantial loss of function and disfigurement as a result of treatment (Chandu, Smith, & Rogers, 2006) (See Preamble Section V.A.3.). The tobacco-specific nitrosamine (TSNA) NNN is a recognized carcinogen (International Agency for Research on Cancer [IARC], 2007; International Agency

for Reseach on Cancer [IARC], 2012) that has been demonstrated to be a main factor affecting these health outcomes among smokeless tobacco product users. This is due both to NNN being present in high levels in smokeless tobacco and its potent carcinogenic potential (International Agency for Reseach on Cancer [IARC], 2012; National Cancer Institute, 2014). FDA is proposing this standard because NNN is a potent carcinogenic agent found in smokeless tobacco products, experimental animal evidence suggests that NNN is a major contributor to the elevated cancer risks associated with smokeless tobacco use, products with higher NNN levels pose higher risks of cancer, and many smokeless tobacco products currently exceed the proposed standard. The proposed product standard is expected to reduce tobacco-related harms by requiring lower levels of NNN in smokeless tobacco products sold in the United States, thereby reducing the risk of oral and possibly other types of cancer in smokeless tobacco product users. FDA finds that the proposed standard is appropriate for the protection of the public health and believes it is technologically achievable.

Manufacturers should be aware of the NNN content in their products because they are currently required to report that information to FDA under section 904 of the Tobacco Control Act. Manufacturer awareness of the NNN content in their products is evidenced by some manufacturers adopting voluntary industry quality standards that directly limit quantities of carcinogens (including NNN) in Sweden, such as Swedish Match's GothiaTek standard. This standard was first established in 1981. Furthermore, there exists research and internal memos from authors directly employed by tobacco product manufacturers discussing NNN content in smokeless tobacco products (Borgerding, Bodnar, Curtin, & Swauger, 2012; Dufresne, 1993; Finster & Kausch, 1986; Marmor, 1985; Perini, 1985; Risner, Reece, & Morgan, 2001).

Users of smokeless tobacco, however, are likely to be unaware of the NNN content in these products and of the relationship between NNN and cancer. There is a limited body of published data about awareness of tobacco constituents, particularly in smokeless tobacco. However, in a survey measuring beliefs regarding tobacco constituents, Hall et al. (2014) found that only 4 percent of smokers and nonsmokers were even aware of NNN when presented with a list of 20 tobacco constituents. In addition, no one in the sample was able to spontaneously mention NNN as a tobacco constituent. NNN levels vary considerably across different smokeless tobacco products and brands.[2] Even if consumers are aware of the general health risks of smokeless tobacco use, consumers may not understand the specific toxicants associated with these risks and the fact that the health risks of using smokeless tobacco vary with the distribution of NNN in these products.

Market failure derived from inadequate information about product characteristics leads to non-optimal levels of consumption and corresponding reductions of social welfare. Moreover, even if consumers had access to information on NNN levels in specific smokeless products, it is unclear how this would affect behavior. As noted in the preamble, smokeless tobacco initiation among youth has been shown to be associated with social influences such as actual or perceived peer use to a greater extent than perceptions of the long-term health effects (Boyle, Claxton, & Forster, 1997; Nemeth, Liu, Klein, Ferketich, Kwan, & Wewers, 2012). Furthermore, most users or potential users may have difficulty in understanding the implications of information about NNN levels in smokeless tobacco products for health risks, meaning that

[3] Based on comments provided by the Alcohol and Tobacco Tax and Trade Bureau (TTB), we understand that under the Internal Revenue Code, the manufacture of tobacco products requires a permit as a manufacturer of tobacco products from TTB. As we understand TTB's permitting requirements, entities lacking a manufacturer permit, including importers, may not engage in manufacturing activities. We also understand that certain provisions of the Internal Revenue Code prohibit importers of tobacco products from repackaging tobacco products after such products are released from customs custody.

the provision of more information alone would be unlikely to spur appreciable shifts in consumption across smokeless products that would result in a demand that could drive the high NNN-products off the market. Thus, even if more information were provided, consumers may not understand that cancer risk varies with NNN content well enough to demand lower NNN smokeless tobacco products. They would remain unable to make fully informed decisions given the difficulty of evaluating complex information about smokeless tobacco products. Likewise, because social influence is such a significant factor in youth usage, they may not act on such information. In the absence of regulation, this market failure is unlikely to be resolved as private market incentives are insufficient for smokeless tobacco manufacturers to lower the NNN content of their products. We also note that there are regulatory restrictions for tobacco products that affect the incentives of manufacturers to compete on improvements in safety.

In addition to problems of information, the addictiveness of smokeless tobacco would be expected to generate inefficiencies in the market for these products. In their model of addictive behavior, Gruber and Koszegi (2001) identify intrapersonal market failures, or internalities, stemming from time inconsistent preferences. Time inconsistency exists when consumers use lower rates of discount for consequences far in the future than for consequences close to the present. Smokeless tobacco users with time inconsistent preferences may find that they are unable to quit using tobacco despite having a preference to do so. Market failure arising from incomplete and asymmetric information is compounded when consumption of smokeless tobacco, an addictive good, is also characterized by intrapersonal market failures. As information about the relationship between the level of NNN and the associated health risks is unlikely to be a salient factor in smokeless tobacco consumption decisions, we would expect that even if the

information failures could be addressed these other types of market failures would pose additional barriers to bringing about a lower NNN level without regulation.

This rule would mitigate the public health impacts from consumption of smokeless tobacco products resulting from information failures and addiction. Either of the market failures identified above results in exposure to a level of NNN that is likely to be greater than would otherwise occur. The reduction in NNN proposed by this rulemaking brings the level of NNN for smokeless tobacco products closer to the exposure level that would occur with full information and time consistent preferences.

B. Background and Baseline Conditions

1. Baseline Market for Smokeless Tobacco Products

According to Nielsen Inc., sales of smokeless tobacco products (STP) in 2015 reached nearly $5.5 billion up from $2.61 billion in 2009 (US Federal Trade Commission, 2015). Based on submitted data to FDA's Center for Tobacco Products, smokeless tobacco products are currently manufactured in 23 different manufacturing establishments based in the United States which are owned or operated by 18 different firms.[3] Based on Euromonitor International and other proprietary industry market reports, we find that the industry is highly concentrated, with two firms sharing 78-90 percent of the domestic market, a third firm holding about 9-14 percent, and the rest being shared by the other 15 firms.

[3] Based on comments provided by the Alcohol and Tobacco Tax and Trade Bureau (TTB), we understand that under the Internal Revenue Code, the manufacture of tobacco products requires a permit as a manufacturer of tobacco products from TTB. As we understand TTB's permitting requirements, entities lacking a manufacturer permit, including importers, may not engage in manufacturing activities. We also understand that certain provisions of the Internal Revenue Code prohibit importers of tobacco products from repackaging tobacco products after such products are released from customs custody.

Smokeless tobacco products vary in form and method of use. These include moist snuff, snus, dry snuff, chewing tobacco, and some dissolvables.[4] Chewing tobacco comes in the form of a loose leaf, plug, or twist that is placed between the cheek and gum and requires spitting. Snuff and snus are finely ground tobacco that can be dry, moist, or packaged in pouches that is sniffed or inhaled into the nose or placed in the mouth. Dry and moist snuff products require spitting, but snus products do not. Dissolvable smokeless tobacco products as the name implies dissolve in the mouth and come in the form of lozenges, small mints (orbs), sticks (toothpick-like appearance), or strips (thin sheets that resemble breath or medication strips) (Centers for Disease Control and Prevention, 2014).

According to FDA Registration and Listing data, there are approximately 800 smokeless tobacco products available in the market--including more than 500 moist snuff products, about 50 snus products, more than 60 dry snuff products, and over 120 chewing tobacco products (US Food and Drug Administration, 2016a).[5] Retail scanner data of U.S. sales by Nielsen Inc. showed that in 2015, moist snuff accounted for most of the sales (67 percent), followed by snus (27 percent), chewing tobacco (5 percent), dry snuff and dissolvables (less than 1 percent). Although there is variation in the types of products available, there is also market segmentation among brands. For instance, in 2014 three brands accounted for almost two-thirds of the U.S. market share in terms of overall retail volume.

The most recently available data from the National Survey on Drug Use and Health (NSDUH) indicate that 3 in every 100 people 12 years and older (or 9 million individuals)

[4] Dissolvable products that do not meet the definition of smokeless tobacco products are not covered by the proposed rule.

[5] Unless otherwise indicated, for purposes of this analysis, we estimate the number of products based on the number of individual listings in FDA's Registration and Listing data. However, we note that this is an estimate and may not accurately reflect the actual number of products.

reported using smokeless tobacco at least one time in the month preceding the 2014 survey, and that prevalence of use varies by gender, ethnicity, age, educational attainment, and employment status (Centers for Disease Control and Prevention, 2015; Center for Behavioral Health Statistics and Quality, 2015b). According to the NSDUH, 6.4 percent of males reported being users of smokeless tobacco, compared to 0.3 percent of women. Among ethnic groups, American Indians/Alaska Natives reported the highest rate of smokeless tobacco product use at 7.0 percent, followed by non-Hispanic Whites (4.5 percent), Native Hawaiian/Pacific Islanders (3.1 percent), non-Hispanic African Americans (1.1 percent), Hispanics (0.9 percent), and non-Hispanic Asians (0.5 percent).

There are differences in use by age groups, with the highest prevalence among young adults. Two percent of 12-17 year-olds reported being current users of smokeless tobacco, compared to 5.6 percent and 3.0 percent, respectively, of 18-25 year-olds and 26 years and older. A separate survey, 2011-2015 National Youth Tobacco Survey, which covers US middle and high school students indicate there is also variation in smokeless tobacco use among young adults. Six percent of US high school students (representing 900,000 students) reported using smokeless tobacco products at least one time in the thirty days preceding the survey. The prevalence among middle school students is 1.8 percent (or 210,000 students) (Singh et al, 2016).

Results of the NSDUH suggest that prevalence of smokeless tobacco use reportedly decreases with educational attainment. Among 18-25 year-olds—7.2 percent of individuals ages 18-25 and with less than a high school education reported using smokeless tobacco compared to 6.3 percent of high school graduates, 5.2 percent of those with some college education and 3.8 percent of those with a college degree in the same age category. Smokeless tobacco use is

highest among individuals working full time (4.6 percent of those 18 and older), followed by those unemployed (3.4 percent) and part-time workers (2.1 percent of those 18 and older). Estimates of current smokeless tobacco use among adults were shown to be relatively constant across most years between 2002 and 2014 (Center for Behavioral Health Statistics and Quality, 2015b). The same data show that in 2013 and 2014, about 1 million individuals aged 12-49 began to use smokeless tobacco products in the year preceding the survey. The mean age at first use among these initiators was 18 in 2014, which was similar to the 2013 estimate. (See Preamble Section III.B)

We note that these estimates are based on survey data where "current smokeless tobacco use" captures chewing tobacco or snuff, and that dissolvable tobacco, snus and other smokeless tobacco products were not specifically asked about and as such these estimates should be interpreted as a lower bound. We also note that these estimates are based on survey data where "current use" is defined as any use, even one time, in the past 30 days and as such these estimates could be capturing intermittent use of smokeless tobacco products.

2. TSNA (NNN and NNK) Content of Currently Marketed Smokeless Tobacco Products

NNN is a TSNA found in varying concentrations in smokeless tobacco products (Lawler, 2013, p. 384). Levels of NNN in tobacco plants can also vary from year to year, intra-year, and farm-to-farm (Fisher, et al., 2012). In addition, factors such as the tobacco type, growing conditions, curing techniques, production process, and storage conditions can affect the NNN levels found in the finished product (International Agency for Research on Cancer [IARC], 2007, p. 57; National Cancer Institute, 2014, p. 99)

Several studies confirm that the levels of NNN in smokeless tobacco products on the U.S. market can vary across product subcategories and within product subcategories. We conducted a review of the literature that reports NNN levels (in dry weight) in products marketed in the US. Using the brand information provided by the studies and information from company and online searches, we categorized the products into smokeless tobacco product subcategories (moist snuff, snus, dissolvable, dry snuff) consistent with those defined by FDA's Registration and Listing information. Review of these studies[6] resulted in a sample of 161 products. Some products appear in multiple studies but availability of products varies by the period of time during which the product was purchased or analyzed. In this sample, the average level of NNN was found to be highest in dry snuff, followed by moist snuff, chewing tobacco, snus, and dissolvable products (see Table 2). However, Table 2 shows that there is variation in terms of the levels of NNN found across and within product subcategories.

Table 2.- NNN Levels in Marketed Smokeless Tobacco Products Drawn from a Convenience Sample

Description	Smokeless Tobacco Product By Subcategory					All Smokeless Tobacco Products
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	
Mean NNN Level ((µg/g), dry weight)	1.83	0.93	9.05	4.59	1.16	2.65
Standard Deviation	1.24	1.06	4.13	2.01	0.83	2.57
Minimum	0.66	0.00	3.86	0.85	0.00	0.00

[6] We initially selected 11 studies published between 2004 and 2015 that included product and NNN level information. We limited the analysis to 9 studies that provided NNN level on a dry-weight basis only. These studies are:(Hatsukami, et al., 2015; Hecht, Stepanov, & Hatsukami, 2011; Osterdahl, Jansson, & Paccou, 2004; Borgerding, Bodnar, Curtin, & Swauger, 2012; Richter, Hodge, Stanfill, Zhang, & Watson, 2008; Stepanov, Jensen, Hatsukami, & Hecht, 2006; Stepanov, Jensen, & Hecht, 2008; Stepanov, Knezevich, Zhang, Watson, Hatsukami, & Hecht, 2012; Stephanov, Yershova, Carmella, Upadhyaya, & Hecht, 2013).

Maximum	5.05	2.66	14.42	12.77	5.30	14.42
Sample Size (N)	13	23	6	55	64	161

We note however, that the estimates in Table 2 are based on a convenience sample of 161 observations, representing approximately 21 percent of all 800 products registered in the current market. For this reason, to determine the percentage of products that would exceed the proposed NNN standard, we present estimates based on industry reports submitted under Section 904 of the Tobacco Control Act (Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke), which are intended to cover all marketed products (see Table 3). Table 3 lists the percent of products that are estimated to be compliant (Panel A) and noncompliant (Panel B). It also shows the distribution of products by product subcategory and by whether the estimated NNN levels fall above or below the proposed threshold (Panel B). The number of entities affected (18) represent the number of firms, some of which are associated with multiple registered establishments (23). A firm can manufacture products across multiple product subcategories. Thus, it is possible for a firm to manufacture products with varying levels of NNN across product subcategories. Analysis of the data shows results that are qualitatively consistent with the findings from the literature review discussed above. Namely, snus and dissolvables have the highest percentage of products that would meet the proposed NNN level, while chewing tobacco and dry snuff products have the lowest percentage of products meeting the proposed standard. For this analysis we use the results on the estimated compliance rate by product subcategory and the list of firms from the data reported under Section 904. We supplement the available data with product information collected from FDA's Registration and Listing, and firm revenue from Dun & Bradstreet. We also conducted online searches and field research to gather product specific information such as labeling and storage information.

Table 3.- Entities and Products Affected by the Proposed Rule

Panel A. Estimated Compliance Rate

Description	Smokeless Tobacco Product By Subcategory					All Smokeless Tobacco Products
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	
Percent of products meeting the proposed standard (mean NNN level is lower or equal to 1.0 microgram per gram of tobacco by dry weight)[a]	27%	100%	0%	30%	67%	38%

Panel B. Estimated Noncompliance Rate

Description	Smokeless Tobacco Product By Subcategory					All Smokeless Tobacco Products
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	
Percent of products exceeding the proposed NNN standard (mean NNN level is greater than 1.0 microgram per gram of tobacco by dry weight)[a]	73%	0%	100%	70%	33%	63%
Percent of products nearly compliant[b] (mean NNN level is less than or equal to 2x standard but exceeds standard)	19%	0%	3%	59%	33%	40%
Percent of products not nearly compliant[a] (mean NNN level is greater than 2x standard)	54%	0%	97%	12%	0%	23%

Panel B. Entities and Products Affected

Description	Smokeless Tobacco Product By Subcategory					All Smokeless Tobacco Products
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	
Number of firms affected[b]	12	1	6	8	12	18
Number of products[c]	117	6	28	534	99	784
Number of products exceeding proposed NNN limit	86	0	28	376	33	523
Number of products anticipated to be meet the proposed NNN limit	31	6	0	158	66	261

Notes: a. Based on FDA TCA Section 904 reports, "nearly compliant" is defined as having a mean NNN level greater than the proposed standard but less than or equal to twice the proposed standard, "not nearly compliant" is defined as mean NNN levels greater than twice the proposed NNN standard. b. Total count based on entities submitting Section 904 reports; total may not add up across product subcategories because an entity may produce products in multiple product sub-categories. c. Number of products from FDA Registration and Listing database (as of March 1, 2016).

C. Benefits of the Proposed Rule

1. Health Gains from Reduction in NNN Exposure

Estimates of the proposed rule's public health impact are based on a comparison of oral cancer risks between the average NNN level found in baseline smokeless tobacco and an average of NNN of 1.0 µg per gram, which is the maximum mean NNN level allowed in any batch of finished smokeless tobacco products under the proposed standard. As discussed in the preamble, FDA has estimated the number of incident (i.e. new) and fatal cases of oral cancer that would be prevented in the US each year after the introduction of a smokeless tobacco product standard for NNN set at 1.0 µg/g of tobacco (on a dry weight basis). To do so, FDA first estimated the number of incident and fatal cases of oral cancer that are attributable to smokeless tobacco use in the US on an annual basis using standard population attributable risk (PAR) calculations. These

calculations use smokeless tobacco use prevalence, relative risks for oral cancer for smokeless tobacco use compared with never use, and number of incident and fatal cases of oral cancer in the US by year. FDA then estimated the number of these cases that would be prevented if the excess oral cancer risk for US smokeless tobacco users were reduced by 65%, consistent with the estimated reduction in excess cancer risk that will be achieved by the product standard. The difference between the number of oral cancer cases and deaths attributable to smokeless tobacco use across the baseline and proposed rule scenarios forms the basis of the benefits estimates in this section.

Because of the uncertainty in these estimates, FDA uses a range of relative risks from studies that estimate the relationship between oral cancer and the use of smokeless tobacco. These relative risks are based on meta-analyses conducted by Boffetta, Hecht, Gray, Gupta, & Straif (2008) and Lee & Hamling (2009). As described in the preamble to the proposed rule, FDA uses the Boffetta et al. (2008) relative risk estimate, adjusted by removing two estimates that did not account for cigarette smoking (Stockwell & Lyman, 1986), which yields 2.16 (95% CI: 1.55-3.02) as the summary relative risk for oral cancer among smokes tobacco users in the US in the absence of the proposed standard. Estimates of smoking- adjusted oral cancer relative risks (RR=1.65, 95% CI: 1.22-2.25) and never smoker oral cancer relative risks (RR=3.33, 95% CI: 1.76-6.32) for U.S. smokeless tobacco users from Lee and Hamling (2009) are used as the lower and upper bound relative risk estimates in the absence of the proposed rule. The use of these relative risks in the PAR calculation results in a range of benefit estimates, which we denote as either “Low”, “Primary”, or “High”.

FDA’s Center for Tobacco Products (CTP) reports projections of avoided oral cancer cases and deaths in the preamble. These projections assume that the full public health impact of

the final rule will accumulate over a period of 10 years, but the timing in which the benefits from avoided cancer cases and avoided deaths accrue differs. As described in the preamble, this assumption is based on studies of cigarette smoking cessation that generally find higher risks for oral cancer for former smokers during the first 10 years after smoking cessation compared to never smokers, but not necessarily thereafter. The reduction in oral cancer cases would begin on the effective date of the final rule, which is 3 years after the publication date. For avoided oral cancer deaths, the reduction would begin 3 years after the effective date of the final rule, or 6 years after the publication date. Throughout both periods, we assume benefits accrue in increments of 10 percentage points each year until the full benefit level is reached. The full benefit level corresponds to approximately 823 avoided oral cancer cases and 178 avoided deaths each year. Table 4 and Table 5 summarize the timing and magnitude of avoided oral cancer cases and deaths over the 20 year period following publication of the rule.[7]

Table 4.- Estimates of the Timing and Magnitude of Avoided Smokeless Tobacco Attributable Oral Cancer Cases

Years after publication of rule	Benefits phase-in	Low cancer risk reduction	Primary cancer risk reduction	High cancer risk reduction	Cumulative reduction in cases*
1	0%	0	0	0	0
2	0%	0	0	0	0
3	0%	0	0	0	0
4	10%	47	82	155	82
5	20%	95	165	311	247
6	30%	142	247	466	494
7	40%	190	329	621	823
8	50%	237	412	776	1,235
9	60%	285	494	932	1,729

7 We note that the total number of cases and deaths presented in the preamble are determined using a 20 year-evaluation period following implementation of the proposed product standard, but those underlying the estimated benefits are calculated using a 20 year-evaluation period following publication of the final rule.

Years after publication of rule	Benefits phase-in	Low cancer risk reduction	Primary cancer risk reduction	High cancer risk reduction	Cumulative reduction in cases*
10	70%	332	576	1,087	2,305
11	80%	380	659	1,242	2,964
12	90%	427	741	1,397	3,705
13	100%	475	823	1,553	4,528
14	100%	475	823	1,553	5,351
15	100%	475	823	1,553	6,175
16	100%	475	823	1,553	6,998
17	100%	475	823	1,553	7,821
18	100%	475	823	1,553	8,645
19	100%	475	823	1,553	9,468
20	100%	475	823	1,553	10,291

Notes: *These estimates are based on the primary risk reduction estimates. The cumulative number of avoided cancer cases in the 20 year period after rule publication for the low and high risk reduction estimates are 5,932 and 19,408, respectively.

Table 5.- Estimates of the Timing and Magnitude of Avoided Smokeless Tobacco Attributable Oral Cancer Deaths

Years after publication of rule	Benefits phase-in	Low cancer risk reduction	Primary cancer risk reduction	High cancer risk reduction	Cumulative reduction in deaths*
1	0%	0	0	0	0
2	0%	0	0	0	0
3	0%	0	0	0	0
4	0%	0	0	0	0
5	0%	0	0	0	0
6	0%	0	0	0	0
7	10%	10	18	34	18
8	20%	20	36	67	53
9	30%	31	53	101	107
10	40%	41	71	134	178
11	50%	51	89	168	266
12	60%	61	107	201	373
13	70%	72	124	235	497
14	80%	82	142	268	639
15	90%	92	160	302	799
16	100%	102	178	335	977

Years after publication of rule	Benefits phase-in	Low cancer risk reduction	Primary cancer risk reduction	High cancer risk reduction	Cumulative reduction in deaths*
17	100%	102	178	335	1,154
18	100%	102	178	335	1,332
19	100%	102	178	335	1,510
20	100%	102	178	335	1,687

Notes: *These estimates are based on the primary risk reduction estimates. The cumulative number of avoided cancer deaths in the 20 year period after rule publication for the low and high risk reduction estimates are 972 and 3,186, respectively.

For purposes of this analysis, we assume that the prevalence of smokeless tobacco use and the population of the United States remain constant over time.[8] The projected impacts of the proposed rule are based on 2010 data of smokeless prevalence and oral cancer incidence reported by CTP in the preamble. FDA does not expect consumers to respond to the reduced NNN levels with increased initiation or decreased cessation in a manner that would offset the expected public health benefits of the rule. If initiation increases or cessation decreases then prevalence of smokeless tobacco use may increase as a result of the rule. It is unclear what effect an increase in prevalence would have on the expected benefits of the rule. If it is primarily driven by initiation from current cigarette smokers seeking to limit or quit the use of cigarettes or other combustible forms of tobacco by switching to smokeless products because the perceived risks of these products decline, then the expected benefits associated with the rule would increase. Alternatively, initiation from non-tobacco users and decreased cessation from current smokeless users would lower expected benefits relative to our estimates, although users would be using a product with lower NNN levels than current smokeless products. We estimate the possible

[8] Results from 2014 National Survey on Drug Use and Health suggest that recent trends in smokeless tobacco prevalence are stable (Center for Behavioral Health Statistics and Quality, 2015b). The percentage of people 12 years and older reporting smokeless tobacco use in the past month was 3.3% in both 2002 and 2014. In the case where the population of smokeless tobacco users is expected to increase over time, then the benefits estimated for this rule should grow as a greater number of cancer cases and deaths are avoided.

impacts from an increase in smokeless tobacco prevalence on the public health benefits associated with this rule in the Uncertainty and Sensitivity Analysis, section II.G, below. We request comment and data relating to these assumptions and calculations.

Finally, we quantify only benefits stemming from reductions in NNN and related reductions in oral cancer incidence. We do not quantify additional public health impacts related to reductions in other toxicants (that may occur as a result of or concomitantly with the reduction of NNN) or types of cancer. The preamble outlines some of the additional benefits associated with the proposed rule, including health benefits from reduced levels of NNK and decreased incidence of esophageal and pancreatic cancer. FDA expects reducing NNN levels to reduce the risk of esophageal and pancreatic cancer as well; however, the limitations with the data do not allow the estimation of the health impact and, thus, we do not quantify these benefits here. The rule may also lead to reductions in risk of other cancers. Accounting for these impacts would likely increase estimates of the overall benefits of this rule. For these reasons, our quantified estimates potentially underestimate the eventual public health impacts of the proposed rule (see preamble section V.).

2. Value of Health Gains

a. Reduced Cancer Mortality

We value avoided oral cancer deaths using two different methods. The primary method is a value per statistical life (VSL) approach, which uses a range of VSL estimates to measure the value of reduced cancer mortality. VSL estimates do not represent the dollar value of a person's life, but a statistic that represents the amount society would be willing to pay to reduce the probability of one death. We use VSL estimates which are based on a review of published

studies by Robinson and Hammitt(2016). The estimates of VSL in the first year after publication of the rule range from $4.4 million to $14.3 million, with a mid-point value of $9.5 million.[9] We note that, based on two meta-analyses, OMB Circular A-4 recommends a VSL range of $1 to $10 million in 2001 dollars, which would represent $1.3 to $13.1 million using the GDP deflator. We request comment on whether the methodology used by Robinson and Hammitt is sufficiently similar to the approaches in the VSL literature cited by Circular A-4 to justify the use of VSL estimates greater than $13.1 million.

These estimates are presented in 2015 dollars using 2015 values of the Consumer Price Index (US Bureau of Labor Statistics, 2015).[10] VSL values in future years are adjusted for projected real income growth. The Congressional Budget Office (CBO) projects real income growth at 1.6 percent per year through 2025, and 1.4 percent in each year after 2025 (Congressional Budget Office [CBO], 2015).[11] We note that the income growth adjustment may not accurately forecast future income growth for the demographic that traditionally uses smokeless tobacco products.

These VSL values are multiplied by the corresponding estimated number of averted deaths for each year, summarized in Table 5. We apply 3 and 7 percent discount rates to

[9] Throughout this analysis, we present "Low", "Primary", and "High" estimates of benefits. Unless indicated otherwise, these descriptions are meant to indicate the range of relative risk estimates and the range of VSL estimates. Estimates denoted as "Low", for instance, are calculated with both the lower bound relative risk ratio and lower bound VSL estimate.

[10] Much of the VSL literature uses the Consumer Price Index (CPI) to calculate real results but does not provide thorough information about such calculations, thus creating difficulty for analysts attempting to combine VSL estimates with other measures of inflation. A prominent alternative measure is the Gross Domestic Product implicit price deflator (GDP deflator), which OMB Circular A-4 states should be used for inflation adjustment in regulatory impact analyses. In light of the resulting tension between internal analytic consistency and compliance with Circular A-4, we request comment on how to adjust VSL estimates calculated with the CPI so as to instead reflect the GDP deflator.

[11] The estimated VSL values reflect adjustments for both inflation and real income growth. We request comment on the appropriateness of adjusting the VSL to reflect real income growth over time when data limitations prevent analogous adjustments for other goods and services whose values are used as inputs in the regulatory impact analysis. More specifically, we request comment on whether empirical estimates of the social discount rate sufficiently capture the effects of real income growth, at least as an average across goods and services.

estimate the present discounted value of the averted deaths in each year. The values for each year are summed across the 20 year period beginning with the publication date of the rule.

Over the 20 year period beginning with publication of the rule, we estimate that the rule will result in 1,687 averted deaths. The present discounted value of averted deaths ranges from approximately $3.4 to $36.6 billion at a 3 percent discount rate, and approximately $1.9 to $20.7 billion at a 7 percent discount rate. Our primary estimates of the present discounted value of averted deaths are approximately $12.8 billion at a 3 percent discount rate and $7.2 billion at a 7 percent discount rate. The annualized values of the primary estimates are approximately $858 million at a 3 percent discount rate and $683 million at a 7 percent discount rate. Table 6 summarizes the present discounted value of averted oral cancer deaths associated with the rule.

Table 6.- Present Discounted Value of Mortality Reductions Using the VSL Method, 20 Year Period after Publication

	Discount Rate	Low	Primary	High
Present Discounted Value of Averted Deaths	3%	$3,401.86	$12,771.73	$36,567.70
	7%	$1,928.25	$7,239.28	$20,727.34
Annualized Value of Averted Deaths	3%	$228.66	$858.46	$2,457.92
	7%	$182.01	$683.34	$1,956.51

Note: Values are shown in millions of dollars, using 2015 dollar values

As recommended in draft HHS guidance, the secondary method for estimating the value of avoided oral cancer deaths uses a quality-adjusted life years (QALY) approach. We present this supplemental approach for valuing mortality reductions because the age distribution of oral cancer patients is older than in the general population on which the VSL values are based. The QALY approach accounts for these age differences by estimating the expected value of future quality-adjusted life years for an age distribution specific to oral cancer patients. To generate

these estimates, we calculate the present discounted value of quality-adjusted life years remaining for an individual at the median age of diagnosis for oral cancer. Cancer Statistics Review data, published by the National Cancer Institute, show that median age of oral cancer diagnosis between 2008 and 2012 was 62 (Howlader, et al., 2015). For each year of life, we assign an age specific health-related quality of life weight, survival probability, and apply a discount rate of either 3 or 7 percent.[12] We multiply these measures together, and then sum the result across each year of life beginning at the age of 62 and ending at 100. These final values, one each for the 3 and 7 percent discount rates, reflect the discounted quality-adjusted life years gained for an individual that would have died at the age of 62.

To monetize these estimated gains in QALYs for premature deaths averted, we construct measures of the value per QALY. These are derived from the VSL estimates discussed above. The VSL estimates are divided by the present discounted quality-adjusted life years remaining for an individual 40 years in age and averaged across gender. The result is a value per QALY estimate for each of the 20 years after publication of the final rule. These estimates are summarized in the first two rows of Table 7. Notably, the upper half of the resulting range is well above the value-per-QALY ranges used in earlier regulatory impact analyses or appearing in the peer-reviewed literature (see, for example, Aldy and Viscusi (2008), Cutler (2008), and Murphy and Topel (2006)). In light of this divergence from past publications, we request comments on these estimates and approach.

Next, we multiply the estimates for quality-adjusted life years gained from an avoided death at the age of 62, the value per QALY, and the overall number of avoided deaths in each

[12] Estimates for the health-related quality of life are measured using EuroQol-5D (EQ-5D) health index scores found in Hanmer, Lawrence, Anderson, Kaplan, & Fryback (2006). We use their estimates for males, and assume that the EQ-5D scores for 80 to 89 year olds apply to older ages. Survival probabilities are constructed using United States Life Table information from 2011 (Arias, 2015).

year following publication of the final rule. Finally, the result is adjusted for 3 and 7 percent rates of discount and summed across each year of the 20 year period.

For the 20 year period after publication of the rule, the QALY approach results in a present discounted value of reduced oral cancer mortality that ranges from approximately $2.1 to $22.7 billion at a 3 percent discount rate, and approximately $1.4 to $15.4 billion at a 7 percent discount rate. Our primary estimates of the present discounted value of averted deaths are approximately $7.9 billion at a 3 percent discount rate and $5.4 billion at a 7 percent discount rate. The annualized values of the primary estimates are approximately $533 million at a 3 percent discount rate and $507million at a 7 percent discount rate. Table 7 summarizes these estimates.

Table 7.- Present Discounted Value of Mortality Reductions Using the QALY Method, 20 Year Period after Publication

	Discount Rate	Low	Primary	High
Value per QALY in first year after publication (shown in dollars)	3%	$230,458	$498,432	$755,688
	7%	$382,854	$828,032	$1,255,404
Present Discounted Value of Quality Adjusted Life-Years Saved	3%	$2,111.45	$7,927.07	$22,696.60
	7%	$1,430.32	$5,369.89	$15,374.93
Annualized Value of Quality Adjusted Life-Years Saved	3%	$141.92	$532.82	$1,525.57
	7%	$135.01	$506.88	$1,451.28

Note: Unless indicated otherwise, values are shown in millions of dollars using 2015 dollar values

b. Reduced Cancer Morbidity

In addition to lower cancer mortality, the rule would lead to a reduction in time spent suffering from cancer and its effects. These effects include the health costs of oral cancer and

any physical or mental impacts associated with having or surviving cancer. We use a QALY approach to quantify and value these costs. In order to estimate the present discounted value of quality-adjusted life years gained associated with reduced morbidity, we make several assumptions on the timing and duration of the different health costs associated with oral cancer. We assume that, upon diagnosis, the health costs of cancer are incurred for an entire year. To this period we assign a health-related quality of life weight of 0.68, a value first estimated in Downer et al. (1997) to describe late stage oral cancer and used by Dedhia et al. (2011) to evaluate the cost-effectiveness of oral cancer screening.[13] Next, we assume that an individual with cancer is at risk of recurrence at any point within five years of the initial diagnosis. For this period we assign a health weight of 0.68 and a yearly recurrence probability of 19.1% from Ermer et al. (2015). Finally, we assume that cancer patients who are treated and remain cancer-free for five years incur a reduction to their health-related quality of life. In each year after the diagnosis we assign a health-related quality of life weight of 0.75, estimated by Rogers et al. (2006). We also assign a five year survival probability based on data published in the Cancer Statistics Review (Howlader, et al., 2015). All health-related quality of life weights used in this part are based on a scale ranging from 0 to 1.

This information is used to determine the incremental impact of cancer on the health-related quality of life of an individual 62 years in age, the median age of a newly diagnosed oral cancer patient. As in the mortality analysis, we assign an age specific health-related quality of life weight in each year of life between the age of 62 and 100: 0.840 for ages 62 to 69, 0.802 for ages 70 to 79, and 0.782 for ages 80 and above. This is the baseline quality of life weight for

[13] Recent Cancer Statistics Review data for 2008-2012 show that 62% of cancer diagnoses are classified as either regional or distant, suggesting that a majority of cancer cases have spread beyond their initial location by the time of diagnosis (Howlader, et al., 2015). For this reason, we assign the late stage oral cancer weight of 0.68 estimated by Downer et al. (1997).

individuals without cancer. We measure the incremental health costs of cancer by subtracting the quality of life weight associated with late stage cancer (0.68) or survival (0.75) from the baseline health-related quality of life weight. This is multiplied by the baseline survival probabilities associated with each age, and either the probability of recurrence or the probability of five year survival.[14] We apply a discount rate of either 3 or 7 percent, and sum the result across each year of life. The final values reflect the present discounted quality-adjusted life years gained by each individual that avoids incurring the health and survival costs associated with oral cancer.

Gains in estimated QALYs due to morbidity risk reduction attributable to the rule are monetized using measures of the value per QALY, constructed as in the mortality analysis, and are presented in Table 8. In each of the 20 years following publication of the final rule, we multiply the QALY estimates by the value per QALY and the number of avoided oral cancer cases. The result is adjusted for 3 and 7 percent rates of discount and summed across each year of the 20 year period. We estimate a present discounted value of reduced oral cancer morbidity that ranges from approximately $823 million to $8.8 billion at a 3 percent discount rate, and approximately $682 million to $7.3 billion at a 7 percent discount rate. Our primary estimates are approximately $3.1 billion at a 3 percent discount rate and $2.6 billion at a 7 percent discount rate. The annualized values of the primary estimates are approximately $207.5 million at a 3 percent discount rate and $241.6 million at a 7 percent discount rate. Table 8 summarizes these estimates.

[14] Between the second and fifth years following the diagnosis year, our assumptions imply that oral cancer patients may incur both the costs of cancer recurrence and survival. After the fifth year, these individuals experience only the costs of cancer survival.

Table 8.- Present Discounted Value of Morbidity Reductions, 20 Year Period after Publication

	Discount Rate	Low	Primary	High
Value per QALY in first year after publication (shown in dollars)	3%	$230,458	$498,432	$755,688
	7%	$382,854	$828,032	$1,255,404
Present Discounted Value of Quality Adjusted Life-Years Saved	3%	$822.62	$3,086.45	$8,824.82
	7%	$682.09	$2,559.18	$7,317.26
Annualized Value of Quality Adjusted Life-Years Saved	3%	$55.29	$207.46	$593.17
	7%	$64.38	$241.57	$690.70

Note: Unless indicated otherwise, values are shown in millions of dollars using 2015 dollar values

c. Effects on the Utilization of Medical Services

We do not quantify the net effect of the rule on the use of medical services. This is because we lack sufficient information to quantify the medical utilization of smokeless tobacco users relative to non-users. While smokeless tobacco users who die prematurely from oral cancer are likely to incur high levels of medical spending due to cancer and other illnesses, this also implies that they forgo the value of medical spending typically experienced by non-users later in life. However, we do not have data or information to quantify these two opposing effects. Existing estimates of lifetime spending differences focus on cigarette smokers. The CBO reports that current and former smokers who are at least 45 years in age experience annual per capita medical spending that is between $1,101 and $1,431 higher than similar non-smokers (Congressional Budget Office [CBO], 2012).[15] Users of smokeless tobacco products may also incur higher levels of medical spending. However, the magnitude of these spending differences

[15] These estimates were adjusted for inflation and presented in 2015 dollars using Consumer Price Index data from the Bureau of Labor Statistics (U.S. Bureau of Labor Statistics, 2015). The specific estimates from the CBO, in terms of 2015 dollars, are: $1,101 for 45-64 year-olds, $1,211 for 65-74 year-olds, and $1,431 for 75 year-olds and older.

depends on the health effects associated with smokeless tobacco. Without information specific to smokeless tobacco, it is difficult to estimate the net reduction in medical spending associated with the proposed rule. We request comment and data relating to medical utilization.

3. Summary of Benefits

Panel A of Table 9 summarizes the combined mortality and morbidity benefits associated with the rule. The mortality estimates in this panel are based on estimates calculated using the VSL approach, shown in Table 6. For the 20 year period after publication of the rule, the annualized value of quality adjusted life-years gained from reduced mortality and morbidity ranges from approximately $284.0 million to $3.1 billion at a 3 percent discount rate, and approximately $246.4 million to $2.6 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $1.1 billion at a 3 percent discount rate, and $924.9 million at a 7 percent discount rate.

In Panel B of Table 9 we summarize combined mortality and morbidity benefits based solely on the QALY approach. The mortality estimates in this table are based on estimates shown in Table 7. For the 20 year period after publication of the rule, the annualized value of quality adjusted life-years gained from reduced mortality and morbidity ranges from approximately $197.2 million to $2.1 billion at a 3 percent discount rate, and approximately $199.4 million to $2.1 billion at a 7 percent discount rate. Our primary annualized estimate is $740.3 million at a 3 percent discount rate and $748.5 million at a 7 percent discount rate.

Table 9.- Present Discounted Value of Health Benefits, 20 Year Period After Publication

Panel A: Combined Morbidity and VSL Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$4,224.49	$15,858.18	$45,392.52
	7%	$2,610.34	$9,798.47	$28,044.60
Annualized Value of All Benefits	3%	$283.95	$1,065.92	$3,051.09
	7%	$246.40	$924.91	$2,647.21

Panel B: Combined Morbidity and QALY Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$2,934.07	$11,013.52	$31,521.42
	7%	$2,112.41	$7,929.07	$22,692.19
Annualized Value of All Benefits	3%	$197.22	$740.28	$2,118.73
	7%	$199.40	$748.45	$2,141.98

Note: Values are shown in millions of dollars, using 2015 dollar values

D. Costs of the Proposed Rule

In this section, we estimate the costs to industry and government due to the rule. Each of these cost categories are discussed in further detail and summarized in subsequent sections.

Some of the costs initially borne by industry may be passed through to consumers via price increases (especially if there is market exit of certain products), and there are other types of costs that may be experienced directly by consumers but depend on actions taken by industry. For example, if a smokeless tobacco producer performs a limited and relatively inexpensive reformulation, consumers may experience welfare loss if there is a significant change in product characteristics or lack of product availability when climatic conditions yield a crop of tobacco that is too high in NNN to be compliant with the standard. On the other hand, consumers are less likely to experience such harms if smokeless tobacco producers perform more thorough, and thus

more costly, reformulations. We request comment on how to model these types of interactions between different categories of costs.

1. Industry Costs

We have identified the following costs to industry associated with the proposed rule: product batch and stability testing, reformulation costs, package labeling costs, and record-keeping costs. In addition, we anticipate costs associated with investigations, reworking or disposing of nonconforming products. Finally, we anticipate costs associated with submission of substantial equivalence applications.

a) Reformulation Cost and Time Cost of Responding to the Rule

The physical differences and application of use across smokeless tobacco product subcategories also reflect variation in the underlying manufacturing processes. The preamble provides a simplified version of the major processing steps involved in each of the smokeless tobacco product subcategories. It is reported that certain processing methods help limit the levels of NNN formed during production (National Cancer Institute, 2014, p. 99; International Agency for Research on Cancer [IARC], 2007, p. 57). Some of these include changing the amount of fertilizer, using low conversion seeds, and modifying the curing heat-treatment methods. Thus, based on the technical knowledge of CTP experts about the manufacturing process, FDA anticipates that in order to meet the proposed NNN standard manufacturers would respond by changing their processing methods or by changing a major ingredient. Such changes could include alterations to growing conditions, selectively breeding low-NNN tobacco types,

changing their processing methods (e.g., curing, pasteurization), or changing their storage conditions (US Food Drug Administration, 2016c).

FDA lacks data specific to the activities and resources that would be associated with reformulation of smokeless tobacco or tobacco products. Given this limitation, we estimate the costs of reformulating non-conforming smokeless tobacco products using estimates from the FDA Reformulation Cost Model developed by RTI International (RTI International, 2015a). This model was initially developed to support food safety and nutrition regulations that require reformulation of affected products or induce manufacturers to reformulate because of changes in labeling requirements. The model provides cost estimates for different types of reformulation activities and compliance periods that take into account the complexity of the product and the company size at the product formulation level (i.e. one formula may be used to produce multiple products). In the model, the complexity of the product is determined by several product characteristics that facilitate or complicate reformulations processes such as number of ingredients, shelf stability, or storage condition. We recognize that food and tobacco products are not perfectly interchangeable in terms of production; below we describe how we use and adapt the model in the context of smokeless tobacco products as well as limitations. FDA seeks comments or data to support alternative assumptions or estimates.

The reformulation cost estimates generated by FDA's Food Reformulation Model are largely driven by activities that are good proxies for what we expect to be incurred by smokeless tobacco product manufacturers in response to the rule. The original model included ten activities that food safety experts identified as key to the reformulation process. CTP experts identified three activities as either not related to the anticipated reformulation activities in the context of smokeless tobacco products or that were included elsewhere in the analysis. Specifically, we

excluded packaging assessment and development and product and package performance testing. Thus, the activities that we included in the analysis were: determining response to regulation, project management, product reformulation, production scale-up testing, recordkeeping, analytic tests and consumer tests (see Appendix Table 1**)**. Given the variation in the product complexity and manufacturing steps for each smokeless tobacco product subcategory, we find that the underlying activity cost estimates produced by the FDA Food Reformulation Model are the best available proxies for related costs that may arise for smokeless tobacco manufacturers affected by the proposed rule and request comment supported by data on our estimates.

To estimate the costs of reformulation in the FDA's Food Reformulation Model, RTI International worked with experts to determine the typical resources (types and quantity) required for labor, materials and utilities, analytical testing, and marketing testing, if applicable, for each of the activities and level of reformulation complexity that were identified. RTI International developed the estimates of market testing using information provided by three companies that conducted studies for manufacturers. Estimates of analytical testing costs were based on published prices from testing laboratories, and estimated market testing costs were based on information provided by vendors. Using the estimated labor hours, wage rates, and related testing costs, the model calculates per-formula reformulation costs for each reformulation activity. In addition, RTI International used the simulation model @Risk to generate the 5^{th}, mean and 95^{th} percentile for each of the activities. More details can be found in the model's documentation (RTI International, 2015a, pp. 2-5 to 2-7, 3-29 to 3-45).

FDA's tobacco product scientists have identified multiple factors which influence the NNN content of finished smokeless tobacco products, including tobacco variety, fertilizers, curing method, storage conditions, tobacco plant part used, tobacco moisture, and microbial

control additives. FDA's tobacco subject matter experts have noted that no cost effective technologies currently exist to reduce NNN levels at the finished smokeless tobacco product stage, so we believe that compliance activities will follow techniques for controlling NNN levels earlier in the production process, with the most likely method being the purchase of tobacco varieties and blends which have lower NNN levels. Preventing NNN levels from increasing during production is possible through changes in farming, harvesting and curing methods, though these changes are not directly required by this rule. We expect that manufacturer interest in purchasing tobacco blends with lower NNN content will result in growers making such changes in response to regular market forces. As we expect many manufacturers to comply with this rule through changes in purchasing practices, we use the food reformulation model's description of "major ingredient or process change" to capture the associated burden.[16]

We recognize that food and tobacco products are not perfectly interchangeable in terms of production; however, the reformulation costs model was developed with current best industrial manufacturing practices in mind. Although the total estimates produced by the model, which include inputs like size and structure of the food processing industry, would not be applicable to this rulemaking, the costs of individual activities, such as process modification, product performance testing, and project management could be applicable to any industrialized production of a consumable good. Thus, as discussed above, we apply only individual activity costs, which FDA's tobacco subject matter experts believe are applicable, adjusted by

[16] In the Reformulation model a "major ingredient" is defined as one that is used at high levels with functional performance effect, food safety effect, or both types of effects (e.g., it is a macro component or it represents more than 2 percent by weight). In the model, a change in the production process cannot happen without a change in ingredient also occurring, but a major change in ingredient can occur without there being a change in process. A functional performance effect includes changes to the product related to sensory characteristics observable by the consumer. A food safety effect includes changes that can alter the product's safety such as shelf stability.

complexity of the tobacco product and size of the operation, to the industry covered by this rulemaking.

We adapt the model by using CTP's estimates on the number of smokeless tobacco product formulations that would need to be reformulated for compliance with the proposed NNN standard. CTP experts assume that each entity that manufactures a smokeless tobacco product subcategory, on average, utilizes four different core blends. A "core blend" represents a mixture of tobacco to which different ingredients and processes are applied to produce a unique finished smokeless tobacco product. We use the number of core blends as the number of formulations that would have to be modified to comply with the proposed NNN standard. A key assumption is that once a "core blend" has been reformulated to comply with the NNN standard any subsequent processing of the "core blend" to produce a unique finished smokeless tobacco product for a particular product line or brand by that manufacturer would not need to change (US Food Drug Administration, 2016c). In other words, some manufacturers could use the same "core blend" that has been reformulated to comply with the NNN standard for multiple smokeless tobacco product lines without having to develop a different reformulation method for each unique finished smokeless tobacco product, assuming that subsequent processing methods do not alter NNN. Because the NNN level is primarily determined by the variety of tobacco used, CTP considers a "core blend" to be an adequate proxy for the number of formulations that would be affected to meet the proposed standard within each product subcategory. We also use the FDA Reformulation Model, along with other data sources, to differentiate reformulation costs by company size, product attributes, and anticipated core blend compliance status (with the proposed NNN limit). The use of core blends is likely to overestimate the reformulation costs if manufacturers can address NNN levels through changes in farming and curing practices prior to

blending. Alternatively, the use of core blends is likely to underestimate the reformulation costs if subsequent processing of the product can alter NNN levels. In Section II.G.a. (Reformulation Costs under Alternative Definitions of Formulations and Reformulation Complexity) we present reformulation costs under various definitions of what a formula represents in the context of the reformulation model. We request comment and data relating to these assumptions, including those in the document "Informing the NNN Product Standard RIA" (US Food Drug Administration, 2016c).

We note, however, that a given firm can be selling both products that would be compliant given their existing characteristics and products whose characteristics would need to be adjusted to achieve compliance with the rule if it is finalized as proposed (for convenience, we refer in this RIA to such products as "non-compliant"), and we incorporate this fact into the analysis as follows. First, using data at the product level we estimate the distribution of products within each product subcategory that is currently compliant and noncompliant (Table 3 Panel B). Next, because the reformulation costs are primarily driven by the number of core blends that each firm produces we determine how many firms produce products that are compliant and noncompliant. We do this by first determining how many firms are represented within each of the product subcategories and by firm size (Panel A of Table 10), and then disaggregating these counts further by compliance status, and degree of noncompliance (Panel B of Table 10).

In this analysis, we estimate the number of products based on the number of individual listings in FDA's Registration and Listing data. However, we note that this is an estimate and may not accurately reflect the actual number of products. For purposes of this analysis, "small companies" as defined by the reformulation model, are those with annual sales under $1 million, "medium-size companies" are those with annual sales between $1 and $500 million, and "large

companies" are those with annual sales greater than $500 million. Per-formulation costs vary by company size to account for the fact that larger companies have and could allocate more resources into reformulation than smaller companies. We emphasize that for purposes of this analysis only, the definition of firm size does not correspond to the definitions established in the Tobacco Control Act or by the Small Business Administration, and the firm size definition is used to mimic the setting in which the expert elicitation was conducted for purposes of the FDA Food Reformulation Model. The names of companies included in the Section 904 data were supplemented with other FDA registration and listing information and then matched to company revenue information from Dunn & Bradstreet and other online sources in order to categorize the size of the entities according to the revenue definition described above.

Table 10.- Estimated Number of Smokeless Tobacco Entities Producing Smokeless Tobacco Products that are Estimated to be Compliant and Noncompliant by Firm Size

Panel A. Estimated Number of Entities Producing Products that are Compliant and Noncompliant

Compliance Status	Firm Size	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus
All	Large	5	1	3	4	4
	Medium	6	0	3	2	6
	Small	1	0	0	2	2
	Total	**12**	**1**	**6**	**8**	**12**
Compliant (mean NNN level is less than or equal to proposed standard)	Large	1	1	0	1	3
	Medium	2	0	0	1	4
	Small	0	0	0	1	1
	Total	**3**	**1**	**0**	**3**	**8**
Noncompliant (mean NNN level is greater than proposed standard)	Large	4	0	3	3	1
	Medium	4	0	3	1	2
	Small	1	0	0	1	1
	Total	**9**	**0**	**6**	**5**	**4**

Panel B. Estimated Number of Entities Producing Products that are Noncompliant by Noncompliant Subcategories

Compliance Status	Firm Size	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus
Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	Large	0	0	0	2	1
	Medium	1	0	0	1	1
	Small	0	0	0	1	0
	Total	**1**	**0**	**0**	**4**	**2**
Not Nearly Compliant **(**mean NNN level is greater than 2x standard)	Large	4	0	3	1	0
	Medium	3	0	3	0	1
	Small	1	0	0	0	1
	Total	**8**	**0**	**6**	**1**	**2**

Notes: The number of entities by firm size is estimated based on FDA Registration and Listing data matched to Dunn & Bradstreet Inc. firm revenue information. In the reformulation model, "small companies" include firms with annual sales under $1 million, "medium-size companies" are those with annual sales between $1 and $500 million, and "large companies" are those with annual sales greater than $500 million. The number of products was then multiplied by the estimated compliance percentage determined by data submitted in Section 904 reports. Totals may not add up due to rounding. Totals in Panel B represent the number of entities producing noncompliant products only.

Table 11 presents the distribution of formulations by firm size and anticipated compliance status, derived from the following steps. We begin by first calculating the total number of core blends across product subcategories. This is determined by taking the total number of firms manufacturing products in each product subcategory (total of 18 firms), and then multiplying them by four---the assumed average number of core blends per firm per product subcategory (US Food Drug Administration, 2016c). FDA does not have specific data on the number of core blends used by each company; however, based on collected inspection and site visit data, CTP believes that four blends per smokeless tobacco product subcategory per manufacturer is a reasonable estimate of the average number of core blends for purposes of estimating reformulation costs. FDA asks for comments or data supporting other estimates or assumptions.

Table 3 above showed that there are 12, 1, 6, 8, and 12 firms manufacturing smokeless tobacco products in chewing tobacco, dissolvables, dry snuff, moist snuff, and snus, respectively.

Thus, we estimate that there are a total of 48, 4, 24, 32, and 48 core blends in each of the smokeless tobacco product subcategories, respectively. To the extent that some manufacturers purchase pre-blended tobacco or use fewer than four core blends, these estimates overstate the economic impact of this rule to the industry. Alternatively, to the extent that some manufacturers use more than four core blends, these estimates understate the economic impact of this rule to the industry. For example, in the case of snus manufacturers with only one product brand with different flavoring, the average number of core blends may not represent the number of formulations that need to be reformulated to comply with the rule as we are using an average. To obtain the number of core blends by firm size, we then apply the estimated distribution of firm size for each of the product subcategories based on product counts presented in Panel B of Table 10. We note that for purposes of this analysis we estimate the number of products based on the number of individual listings in FDA's Registration and Listing database, which is a proxy for the number of products likely to be affected by this rule. The estimated number of core blends for each subcategory and company size is presented in Table 11, We assume that distribution of firm size is the same for each compliance category (i.e. those that are "not compliant, as well as those that are "nearly compliant" and "not nearly compliant"). For example, to obtain the estimate of twelve core blends produced by medium-size companies that are "not nearly compliant" in the chewing tobacco subcategory, we multiply the total number of entities in this subcategory by the estimated percent of blends that are "not nearly compliant" and the estimated percent of products that are produced by medium-sized firms (12=6 entities*54% not nearly compliant*4 blends per entity). The rest of the estimated formulation counts are estimated in a similar fashion.

Table 11.- Number of Core Blends by Estimated Compliance Status

Panel A. Number of Formulations: All, Compliant and Noncompliant

Anticipated Compliance Status	Firm Size	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus
All	Large	20	4	12	16	16
	Medium	24	0	12	8	24
	Small	4	0	0	8	8
	Total[a]	**48**	**4**	**24**	**32**	**48**
Compliant (mean NNN level is less than or equal to proposed standard)	Large	4	4	0	4	12
	Medium	8	0	0	4	16
	Small	0	0	0	4	4
	Total	**12**	**4**	**0**	**12**	**32**
Noncompliant (mean NNN level is greater than proposed standard)	Large	16	0	12	12	4
	Medium	16	0	12	4	8
	Small	4	0	0	4	4
	Total[b]	**36**	**0**	**24**	**20**	**16**

Panel B. Number of Formulations

Anticipated Compliance Status	Firm Size	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus
Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	Large	0	0	0	8	4
	Medium	4	0	0	4	4
	Small	0	0	0	4	0
	Total[c]	**4**	**0**	**0**	**16**	**8**
Not Nearly Compliant (mean NNN level is greater than 2x standard)	Large	16	0	12	4	0
	Medium	12	0	12	0	4
	Small	4	0	0	0	4
	Total[d]	**32**	**0**	**24**	**4**	**8**

Notes: a. Total number of core blends is based on the number of entities producing products in each product subcategory and assuming that each entity has four core blends in each product subcategory, this includes 12, 1, 6, 8, and 12 entities in chewing tobacco, dissolvable products, dry snuff, moist snuff, and snus, respectively. b. Noncompliant includes “Nearly compliant” and “Not nearly compliant”. c. “Nearly Compliant” includes core blends that are assumed to have mean NNN levels less than or equal to 2x standard but exceeds standard. d. “Not Nearly Compliant” includes core blends that are assumed to have mean NNN levels greater than 2. e. Totals may not add up due to rounding. In the reformulation model, “small companies” include firms with annual sales under $1 million, “medium-size companies” are those with annual sales between $1 and $500 million, and “large companies” are those with annual sales greater than $500 million.

As mentioned before, costs estimates developed in the FDA Food Reformulation model also vary by the complexity of reformulation for each product subcategory to account for the fact that some products are more easily reformulated than others. First, for purposes of this analysis we assumed that all smokeless tobacco products may be considered “low”, “medium”, or “high” complexity products in the context of the reformulation model (Appendix Table 1). The complexity level is determined based on the number of ingredients that interact with other ingredients, and whether or not the manufacturing process is technologically challenging. Low complexity, in this context, is akin to products where the manufacturing process is well understood and one major ingredient is involved. For example, milk, cheese, packaged tea bags and low-calorie carbonated beverages are considered low complexity products because their finished product involves a manufacturing process that is predetermined, well understood and involves mainly one ingredient. Products where the manufacturing process is more complex and involves few ingredients—such as regular (non-low-calorie) gum, dried fruit, chocolate and non-chocolate candy, powdered milk or noncarbonated beverages—are considered medium complexity products. On the other hand, low-calorie gum, refrigerated flavored milk or yogurt shakes are considered high complexity products because their manufacturing involves many ingredients and highly complex processes. The reformulation cost model categorizes food products by acidity levels, shelf-stability and overall simplicity as determined by the number of ingredients in the product and the number of processing steps. Though smokeless tobacco products generally have a relatively neutral pH, CTP believes this to be an area where the model guidelines of food product categories do not fit precisely for describing tobacco product categories. Acidity during processing and storage can have a large impact on shelf-stability and consistency for canned and jarred food products, and is not a good indicator of manufacturing

process complexity for tobacco products. Lacking a tobacco-specific reformulation cost model, CTP's product scientists reviewed smokeless tobacco manufacturing processes in the context of the food reformulation cost model and determined that smokeless tobacco would generally fall under the reformulation model's low complexity category of products, mainly based on the fact that the products are shelf-stable, consist of one major ingredient and involve few processing steps, not unlike a packaged tea bag, for example. Specifically, CTP product scientists have used the comparison of smokeless tobacco to packaged tea bags in terms of manufacturing complexity. This is because smokeless tobacco is largely dried or moist tobacco leaf, cut or chopped or shredded to varying degrees, possibly with flavors added, then packaged in a shelf-stable form. This is in contrast to other products like chewing gum which are melted to strain natural impurities, mixed with sweeteners and flavors, flattened, mixed with additional sugars, then packaged. The melting process and chemical mixing of additives in semi-liquid form of such products makes the overall process more complex. As another example, non-fat dried powdered milk manufacturing begins with the raw liquid milk which is separated to remove cream or butterfat. The additional steps to reach a powder form include taking the resulting separated and condensed milk and either atomizing or spray drying the milk. Spray drying – the industry standard for a long time and still widely used – is where the condensed milk is sprayed through a nozzle into 400 degree swirling air where the moisture is separated from the milk particles. Those particles are collected as powdered milk. As a manufacturing process, this is significantly more complex than smokeless tobacco manufacturing. Thus, while smokeless tobacco may be consumed in a manner similar to chewing gum or be purchased in a form similar to powdered milk, the manufacturing process of these products is very different.

Second, a formulation is assumed to be subject to the cost reformulation model's "change in production process (with an ingredient change)" if it is "not nearly compliant". However, formulations that are "nearly compliant" are assumed to incur lower costs associated with the cost reformulation model's "substitution of a major ingredient," which is a less significant change in the cost reformulation model, with the idea that smokeless tobacco products with NNN levels that are closer to the proposed standard incur less costly reformulation changes since they will need to lower the NNN level less than a product that starts at a higher level. This classification effectively recognizes that "nearly compliant" formulations would incur fewer resources in terms of labor, materials and other related resources to bring the formulation back into full compliance than those that are "not nearly compliant" (see also preamble section IV.D.3).

The per-formulation costs by company size and complexity of the product category are summarized in Appendix Table 1. The per-formulation costs include activities associated with determining response to regulation, project management, process modification, production scale-up testing, analytical and consumer testing, and recordkeeping (Appendix Table 1). In the Reformulation Model, entities whose products already meet the proposed NNN standard only incur costs associated with responding to regulation and recordkeeping, which are estimated in this section. Additional compliance costs, such as batch testing and stability testing costs, for all entities are discussed in later sections.

Using the per-formulation costs in Appendix Table 1 and the data on the distribution of "core blend" formulations in Table 11, we estimate total reformulation cost as shown in Table 12. Total one-time reformulation costs are estimated to be between $80.11 million and $291.19 million. Most of the costs arise from chewing tobacco, followed by dry snuff and moist snuff

products. We consider the 5th percentile to be the low bound and the 95th percentile as the high bound of our estimates. The primary estimate is assumed to be the midpoint of the lower and the upper bound estimate. Thus, the primary estimate for manufacturers that reformulate would be $185.65 million.

Costs associated with responding to regulation and recordkeeping are estimated to be between $6.02 million and $23.17 million. The primary estimate is $14.59 million (= (23.17+6.02)÷2). Total costs for industry (including the cost to reformulate, review and understand the regulation, and recordkeeping) are estimated to be between $86.13 million and $314.36 million and the total primary cost estimate is $200.25 million.

The estimated costs are based on several key assumptions regarding anticipated industry response to reformulation decisions. FDA seeks comment and data supporting other assumptions regarding industry practice for reformulating products and their associated costs discussed in this section. First, in addition to the related activities mentioned above, manufacturers may need to discard unused inventory of raw materials. The reformulation model assumes that manufacturers would use any existing inventory of raw materials so that costs of discarding them would not be incurred. If manufacturers are not able to use existing raw materials then reformulation costs would be higher. Second, the estimated costs are based on the reformulation model which assumes a minimum of 24 months for reformulation for small and medium companies and a minimum of 36 months for large companies. Based on input from product formulation experts large firms put substantially more effort into coordinating and planning a reformulation than small firms. Shorter timelines can affect the availability of personnel to oversee and implement the changes, as well as availability of supply chain sources for ingredients and equipment, and the ability to conduct or contract research needed to implement the changes. Thus, shorter

compliance periods would incur overtime and rush charges, thereby increasing costs. We also note that we assume any one-time reformulation costs are incurred in the first year after publication of the final rule, rather than spread out over the first and second years after publication. If some reformulation costs can be pushed out further, costs may be slightly lower than what we have estimated. We request comment and data on our assumptions about the timing of costs for industry. Third, reformulation costs represented in the model are one-time costs of reformulation, and it does not include ongoing costs that may be associated with the reformulation. For example, if bringing the NNN levels in compliance requires increasing the proportion of certain ingredients, e.g., liquid smoke, to the core blends, then manufacturers would incur higher costs that are not included in the underlying assumptions of the model and would thus result in underestimating the costs. Fourth, capital equipment expenditures are not included in the model. The underlying assumption is that manufacturers would be able to use their current capital equipment to come in compliance. Finally, cost estimates assume that a moderate number of products are being reformulated at the same time. If all products within a product subcategory had to be reformulated at the same time, manufacturers would incur a higher initial cost. There may, however, also be cost savings from manufacturing efficiencies when reformulating several related products at the same time.

Table 12.- Estimated Costs to Industry Associated with Anticipated Reformulation of Products In Order to Meet the Proposed Requirements

	Action and Company Size	Product Subcategory (Primary Cost in $million)					Total Cost ($million)		
		Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Low	Primary	High
Panel A. Reformulate	Large Companies	$54.97	$0.00	$41.23	$31.32	$8.79	$59.78	$136.31	$212.84
	Medium Companies	$19.92	$0.00	$16.53	$3.39	$8.90	$20.08	$48.75	$77.41
	Small Companies	$0.24	$0.00	$0.00	$0.12	$0.24	$0.25	$0.60	$0.95
	Total	**$75.14**	**$0.00**	**$57.76**	**$34.83**	**$17.93**	**$80.11**	**$185.65**	**$291.19**
Panel B. Do Not Reformulate	Large Companies	$1.66	$1.66	$0.00	$1.66	$4.97	$4.11	$9.94	$15.78
	Medium Companies	$1.32	$0.00	$0.00	$0.66	$2.63	$1.90	$4.61	$7.32
	Small Companies	$0.00	$0.00	$0.00	$0.02	$0.02	$0.01	$0.04	$0.06
	Total	**$2.97**	**$1.66**	**$0.00**	**$2.33**	**$7.62**	**$6.02**	**$14.59**	**$23.17**
	Grand Total	**$78.11**	**$1.66**	**$57.76**	**$37.16**	**$25.56**	**$86.13**	**$200.25**	**$314.36**

Notes: Model assumes that all product subcategories are considered low complexity. Costs are in millions of USD. Firm size is determined differently than the definitions determined by the Tobacco Control Act and the Small Business Administration. In the reformulation model, “small companies” include firms with annual sales under $1 million, “medium-size companies” are those with annual sales between $1 and $500 million, and “large companies” are those with annual sales greater than $500 million. Formulations are based on core-blends per entity affected.

b) Product and Stability Testing

The proposed rule would require testing to assess the stability of the NNN levels in finished smokeless tobacco products and to establish and verify the product's expiration date and storage conditions, i.e., room temperature or refrigeration. Stability testing would be required initially and then annually. Initial testing could include real-time testing and accelerated testing. In addition, the proposed rule would require batch testing on each batch of finished smokeless tobacco products to determine whether the products conform to the proposed NNN standard. Under the proposed rule, the testing methods must comply with either a proposed standard method or an alternative method that would require prior notification to FDA. The proposed rule would also establish additional requirements related to product testing, including developing procedures for nonconforming products, documenting protocols, test results and source data, and designing and implementing sampling plans and sampling procedures.

This subsection presents cost estimates associated with the proposed batch and stability testing requirements, each discussed in turn.

Stability Testing

Using the FDA Registration and Listing database, we estimated that 784 products would be covered under the rule. Each product, however, would be assumed to be sampled and tested multiple times beginning in the year of the effective date. For purposes of this analysis we make several assumptions about the timing and frequency of testing on each product. FDA notes that the frequency or timing assumed in this analysis is not necessarily required by the proposed rule and that these decisions would vary by manufacturer. Specifically, we assume that each initial real-time test would be conducted at five time points and each test would be conducted seven

times in replicate with a sample of 3 products each (US Food Drug Administration, 2016c). Similarly, each initial accelerated test would be conducted at three time points with each test being conducted seven times in replicate including a sample of 3 products each (US Food Drug Administration, 2016c). In the first year, all products are assumed to be subject to initial real-time and accelerated testing, but after the first year, initial real-time and accelerated testing is assumed to be conducted on 4 percent of the total number of products in the market, with the remaining 96 percent of the total number of products being subject to annual real-time stability testing. This assumes that there is 4 percent churn in the smokeless tobacco product market to proxy for the amount of new products expected to be developed in Year 2 and every subsequent year. For products with a desired expiration date of six months or less, initial accelerated stability testing will not be necessary as initial real-time stability testing can be completed in the same amount of time. FDA does not currently have the data necessary to determine how many products will have a desired expiration date of six months or less. For purposes of this analysis, and informed by other internal data, FDA conservatively assumes all products will be subject to initial accelerated stability testing. No annual testing is assumed in Year 1. Thus, in the first year, we estimate there would be only 131,712 total initial real-time and accelerated tests [=784*(7*5*3 + 7*3*3)]. Each year following Year 1 total tests would include 5,268 (=131,712*0.04) initial real-time and accelerated tests. Annual testing involves samples tested three times a year, each requiring a sample of 3 being replicated 7 times. We estimate there would 47,416 annual tests (=784*(7*3*3)*0.96) in Year 2 and on. CTP experts estimate that each stability test costs $100 (US Food Drug Administration, 2016c)

In the first year, total stability testing is estimated at $13.17 million (=131,712 initial tests*$100 + 0 annual tests* $100). Similarly, after the first year, total stability testing costs are

estimated to be $5.27 million (=5,268 initial tests* $100 per test + 47,416 annual tests *$100 per test). These costs are summarized in Table 13.

We note that these cost estimates are based on an assumption that the overall number of products in the marketplace remains constant over time. The estimated costs would increase if the number of smokeless tobacco products increase in the future. Other factors such as a decrease in the average price of the test or a reduction in the frequency of the tests could decrease the estimated total costs. Finally, based on current practice FDA believes that testing on each product may not occur as frequently as it is assumed in this analysis, which could result in an overestimate of testing costs. For instance, manufacturers may not test at as many time points as in this analysis and some manufacturers may choose only to do real-time initial stability testing instead of both accelerated and real-time testing.

Table 13.- Estimated Costs Associated with Proposed Stability Testing Requirements

Period Cost is Incurred	Total Tests, Initial	Total Tests, Annual	Total Stability Testing Cost ($million)
First Year	131,712	0	$13.17
After First Year	5,268	47,416	$5.27

Notes: Costs are estimated assuming 784 products are in the market each year. In the initial year all products would undergo initial testing. Each year after the first year, 4 percent of products undergo initial testing and 96 percent undergo annual testing. Each initial real test is conducted 5 times, accelerated test is conducted three times a year, and each annual test is conducted three times. Each test is replicated seven times, and has a sample size of three. Per-test cost is assumed to be $100. All costs except per-test cost are in million dollars.

Batch Testing

In estimating the costs associated with the proposed requirements regarding batch testing we assume that each affected product would be associated with one to two batches per year, each requiring a sample size between 2 and 4 being replicated 7 times. The frequency of the batches and sample size of the replicates is based on information from CTP experts who conduct

inspections of tobacco products (US Food Drug Administration, 2016c). Table 14 below summarizes the possible number of batch tests that could arise from the proposed provision. When the batch size is one per product each year, the number of tests ranges between 10,976 (=784*1*7*2) and 21,952 (=784*1*7*4), while this range is between 21,952 (=784*2*2*7) and 43,904 (=784*2*4*7) when the batch size is assumed to be two per product each year. We note that the underlying estimates regarding sample size are based on small samples at the time this analysis was conducted. FDA seeks comments and data supporting other estimates and assumptions.

Table 14.- Estimated Number of Batch Tests

Period Cost is Incurred	Number of Products Tested	Number of Batches	Total Number of Batch Tests	
			Sample Size	
			2	4
Each Year	784	1	10,976	21,952
Each Year	784	2	21,952	43,904

Note: Total number of batch tests is determined by multiplying the number of products tested by the assumed batch size, the sample size and the number of replicates. The number of replicates required is assumed to be seven.

The per-test cost, as done for stability testing, is estimated to be $100 (US Food Drug Administration, 2016c). The estimated costs associated are then determined to be the product of number tests and per-test cost. The estimated cost is $1.10 million (=10,976*$100) and $4.39 million (=43,904*$100) (see Table 15). The primary cost estimate is $2.74 million. As with stability costs, the estimated costs of batch testing could change if changes occur to the average price per test, the number of products requiring testing, or the assumed sample and batch sizes.

Table 15.- Estimated Costs to Industry Associated with Proposed Batch Testing Requirements

Type of Estimate	Number of Products Tested	Assumed Batch Size [Sample Size]	Number of Tests	Batch Testing Costs ($million)
Low	784	1[2]	10,976	$1.10
Primary	784	*	27,440	$2.74
High	784	2[4]	43,904	$4.39

Notes: * Primary estimate is calculated as the midpoint between the Low and High estimate. All batch testing costs are in millions of dollars; per-test cost is in dollars. The number of tests is determined by multiplying the number of products tested by the batch size and sample size and the number of replicates. Sample size is in squared brackets, "[]". Number of replicates is assumed to be seven. Per-test cost is assumed to be $100.The primary estimate is the midpoint between the lowest and the highest estimated cost.

c) Labeling Costs

The proposed rule would require that product labeling bear a label with a manufacturing code, an expiration date, and storage conditions (if applicable). We estimate associated labeling costs based on the number of Universal Product Codes (UPCs) affected using a model developed by a contractor, RTI International (RTI) (RTI International, 2015b). To implement the Labeling Cost Model, we use the number of products based on retail scanner data by Nielsen, Inc. as a proxy for the number of UPCs affected. RTI's labeling cost estimates are based on the 6-digit North American Industry Classification System (NAICS) that corresponds to Beverage and Tobacco Product (NAICS code 312). Labeling costs include labor, material, inventory and recordkeeping, and vary based on the type of labeling change (minor, major, or extensive) on a per-UPC basis. The distribution of UPCs affected is then multiplied by the per-UPC labeling costs as determined by FDA's Labeling Cost model. Below we discuss the underlying assumptions of the estimated UPCs affected by the labeling provision.

To get the count of products that would require relabeling we first estimate the number of products with labels that are likely to already have similar kinds of information as the proposed

requirement and would therefore only require minor labeling changes or would involve primarily substitution of information rather than redesign of a label to accommodate the required information. To do so, we used a Code Date Catalog of products made publicly available by Eby-Brown, a convenience store supplier and wholesale distributor of tobacco, candy and convenience products (Eby-Brown, Undated). The catalog allows us to identify vendors who use the "Best by", "Manufactured on", and "Expired on" date on their products, which are matched to the products affected by the proposed rule. This information was also cross-referenced or supplemented with online searches conducted during February and March of 2016. Based on this analysis, most products in the dissolvables and moist snuff subcategories were found to have an "expired on", "best by", or "sell by" date. On the other hand, most of the chewing tobacco, dry snuff, and snus products had either lot or "manufactured on" information. Products with only manufactured on or lot information are assumed to incur costs associated with a label change that would add the expiration date information. We assume that this type of labeling change would be less costly than one that requires a substantial amount of new information to be added, which may involve redesigning the label and would be considered a "major" change in the context of the FDA Labeling Cost Model.

The proposed labeling provision would require manufacturers to also include storage information on products, if the manufacturer chooses to require specialized storage conditions. We are aware that certain products are currently refrigerated at the point of sale, but these products do not currently have information regarding storage conditions on their labels. One of the manufacturer's website indicates that their product is refrigerated to "maintain freshness, moisture and flavor of the product", and that once open their product does not need to be refrigerated. However, the manufacturer's website also indicates that under normal conditions

the product may maintain its freshness and flavor for up to 30 days if it is not refrigerated. In addition, through online searches we identified another product that displayed "No Refrigeration Required" on their label, and that marketing material described the product as "Fresh, refrigerated spit free pouches" or "spit free, sold cold" when it was initially launched. Based on a limited sample of products sold at convenience stores in the Maryland area during April 2016, it was observed that this brand is no longer refrigerated at the point of sale and that the labeling does not include information regarding storage conditions. Of note is that the literature reports that the levels of NNN found in these two sets of products would be in or nearly in compliance with the proposed NNN levels.

To derive the number of UPCs subject to a labeling change that includes adding storage information we assume that only those products that are currently refrigerated but for which we did not find evidence that storage condition labeling exists would incur such labeling change. We expect that because manufacturers can develop products that have stable NNN levels without requiring refrigeration, and requiring refrigeration increases costs of storage and shipment, manufacturers will not choose refrigeration in order to comply with this rule. Thus, we estimate that these different products that would likely be affected by labeling changes to include storage information would include up to 8 UPCs (derived by assuming that each product would be associated with one unique UPC[17]). Finally, based on collected data regarding current retail practices, we assume that the smokeless tobacco product subcategories of chewing tobacco, dissolvables, and moist snuff are not refrigerated and would not require refrigeration. We highlight that these estimates are based on online searches and limited field observations which

[17] Generally, each product is associated with multiple UPCs. FDA did not have data to estimate the actual number of UPCs that may be associated with this set of products and uses a conservative approach by assuming that each product is associated with one UPC.

may not reflect representative information about how industry practices could change in response to the rule. In particular, if NNN stability testing on smokeless tobacco products determines that refrigeration is necessary to maintain NNN levels under the product standard, more products may need to be refrigerated after the rule resulting in an underestimation of labeling costs in this NPRM. FDA seeks comments and data to support other estimates regarding refrigeration practices and related labeling across smokeless tobacco products and assumptions made in the associated costs discussed below.

Table 16 below summarizes our findings and assumptions regarding estimated practice surrounding labeling information and potential products affected. Data on the number of active UPCs are from Nielsen Inc., and the estimated percentage of products with expiration and storage information come from FDA Registration and Listing database (as of March 1, 2016) supplemented by online and field research. Consistent with the Labeling Cost Model, we also assume some costs associated with recordkeeping activities related to labeling, as discussed further below.

The number of UPCs subject to recordkeeping is determined by multiplying the number of UPCs in each product category by the percent of products with an expiration date information. Similarly, the number of UPCs subject to labeling changes is the product of the number of active UPCs and the percent of products with only production or lot information. Since all products already have either an expiration date or a manufactured on date, the labeling cost model assumes there are no costs associated with analytical tests, market tests or label redesign which would usually be associated with major labeling change decisions in the context of FDA's Labeling Model. That is, adding an expiration date or product instructions to labeling would be considered a "minor" change if extensive product redesign is not needed and "major" or

"extensive" if product redesign is needed. We seek comments on these assumptions. We assumed 36 months for compliance, consistent with the proposed effective date of the rule.

In the context of FDA's Labeling Cost Model, FDA assumes that labeling costs associated with adding an expiration date would be considered a minor change because existing labels could be more easily modified to accommodate the required information. Moreover, for products with an expiration date, we assume the additional cost associated with complying with the proposed requirement would be, within the context of the FDA Labeling Cost Model, those of recordkeeping to document that the label of the product is in compliance. We request comment on these assumptions. Taking a conservative approach, a labeling change associated with adding storage information is assumed to be a "major" labeling change as the kinds of label redesigning that would be needed may be more extensive. We note, again, that given the limited evidence regarding storage conditions and storage instructions on product labeling, there is uncertainty regarding the number of manufacturers and related products that would incur associated costs.

Table 17 presents a summary of the cost per-UPC associated with the proposed labeling requirements, which is used in conjunction with information in Table 16 to estimate labeling costs. Per-UPC costs represent low (the 5^{th} percentile), and high (95^{th} percentile) estimates. The estimated total labeling costs include recordkeeping costs (associated with UPCs that are assumed not to need labeling changes) and the labeling change cost (associated with UPCs that are assumed to need a labeling change) for either a minor or major label change (see Table 18). For manufacturers of snus products, total labeling costs are between $91,890 and $352,934, which include only recordkeeping costs associated with 229 UPCs and both labeling change costs and recordkeeping costs associated with another 38 UPCs. The total costs for other product

subcategories are estimated in a similar manner. Thus, total costs are estimated to be between $0.84 million and $3.40 million; the primary cost estimate is $2.12 million.

Table 16.- Products with Expiration and Storage Information

Panel A. Current Products with Relevant Labeling Information

Description	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	All Smokeless Tobacco Products
Percent of products with expiration date	42%	100%	0%	72%	88%	67%
Percent of products with lot or production date information[a]	58%	0%	100%	28%	12%	33%
Percent of products with refrigeration labeling[a]	0%	0%	0%	0%	0%	0%

Panel B. Estimated Number of UPCs: Active, and Subject to Changes under the Proposed Rule

Description	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	All Smokeless Tobacco Products
Active UPCs	266	3	95	632	259	1255
Number of UPCs with recordkeeping costs only	112	3	0	452	229	796

Description	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	All Smokeless Tobacco Products
Number of UPCs subject to labeling change regarding expiration information	154	0	95	180	30	459
Current number of UPCs that are refrigerated and potentially subject to labeling change regarding storage information	0	0	0	0	8	8

Notes: a. Estimates are based on data from FDA Registration and Listing containing product information supplemented with online and field research. UPC denotes universal product code. Totals may not add up due to rounding.

Table 17.- Labeling Cost Per UPC

Description		Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus
Recordkeeping Only	Low (5th percentile)	$33	$33	$33	$33	$33
	Primary	$71	$71	$71	$71	$71
	High (95th percentile)	$109	$109	$109	$109	$109
Minor Labeling Change	Low (5th percentile)	$1,702	$1,702	$1,702	$1,702	$1,702
	Primary	$4,336	$4,336	$4,336	$4,336	$4,336
	High (95th percentile)	$6,970	$6,970	$6,970	$6,970	$6,970
Major Labeling Change	Low (5th percentile)	$4,158	$4,158	$4,158	$4,158	$4,158
	Primary	$9,509	$9,509	$9,509	$9,509	$9,509
	High (95th percentile)	$14,860	$14,860	$14,860	$14,860	$14,860

Notes: The total number of affected UPCs is presented in Table 16.

Table 18.- Estimated Costs Associated with Proposed Labeling Requirements

Description		Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	All Smokeless Tobacco Products ($million)
Recordkeeping Only	Low: 5th percentile	$3,696	$99	$0	$14,916	$7,557	$0.03
	Primary	$7,952	$213	$0	$32,092	$16,259	$0.06
	High: 95th percentile	$12,208	$327	$0	$49,268	$24,961	$0.09
Minor Labeling Change: Expiration Information	Low: 5th percentile	$262,170	$0	$161,728	$306,432	$51,072	$0.78
	Primary	$667,767	$0	$411,934	$780,507	$130,085	$1.99
	High: 95th percentile	$1,073,365	$0	$662,141	$1,254,582	$209,097	$3.20
Major Labeling Change: Storage Information	Low: 5th percentile	$0	$0	$0	$0	$33,261	$0.03
	Primary	$0	$0	$0	$0	$76,069	$0.08
	High: 95th percentile	$0	$0	$0	$0	$118,876	$0.12
Total	Low: 5th percentile	$265,866	$99	$161,728	$321,348	$91,890	$0.84
	Primary	$675,719	$213	$411,934	$812,599	$222,412	$2.12
	High: 95th percentile	$1,085,573	$327	$662,141	$1,303,850	$352,934	$3.40

d) Costs Associated with Substantial Equivalence Report Submission

To legally market a new tobacco product in the United States, a tobacco product manufacturer must receive authorization from FDA permitting the marketing of the new tobacco product under one of three pathways for legally marketing a new tobacco product: (1) The manufacturer obtains an order under section 910(c)(1)(A)(i) of the FD&C Act (order after review

of a premarket tobacco application under section 910(b)); (2) the manufacturer obtains an order finding the new product substantially equivalent to a predicate tobacco product and in compliance with the requirements of the FD&C Act (order after review of a substantial equivalence (SE) report submitted under section 905(j)); or (3) the manufacturer makes a request under 21 CFR § 1107.1, obtains an exemption from the requirements related to substantial equivalence (section 905(j)(3)(A)), and at least 90 days before commercially marketing the product, submits a report under section 905(j) including the information required in section 905(j)(1)(A)(ii) and 905(j)(1)(B).

A smokeless tobacco product that has been modified to comply with the product standard would be considered a "new tobacco product" and subject to premarket review.[18] FDA believes that manufacturers would likely choose to comply with the proposed standard in a manner that would make the modified products eligible for the SE pathway, and estimates costs under this assumption. FDA requests comments as to the type of modifications (including but not limited to the types of manufacturing changes discussed in the preamble) that may allow a reduced amount of information to proceed through the SE pathway, and what types of brief, specific supporting information submitted as part of a substantial equivalence report could demonstrate that modifications made to comply with this product standard do not cause the new product to raise different questions of public health.

FDA assumes that SE reports for new tobacco products that are modified only to conform to the proposed NNN product standard would be limited in content and would not require any clinical data. The level of effort required to prepare such SE reports is assumed to vary

[18] A product that already complies with the proposed NNN limit and only undergoes changes to its labeling in order to comply with the standard would not be considered a new tobacco products and would not require premarket review.

depending on whether some information that has been prepared for one SE Report can be leveraged across multiple SE Reports for other similar products. For purposes of this analysis, we assume that the burden associated with developing and preparing a SE Report ranges between the costs of an "Initial SE Report" and an additional "Similar Product SE Report".

We assume that the level of effort to develop the "Initial SE Report" is higher than the level of effort to develop any additional "Similar Product SE Reports" for other similar products because we anticipate that the additional SE reports for other similar products could use a lot of the information already developed for the "Initial SE Report".

Additionally, the cost associated with submitting an SE Report will depend on the type of changes made to comply with the proposed NNN standard. In general, the less extensive the changes that are made, the fewer the burden hours would be required to prepare and submit an SE Report. CTP's estimates of the burden hours for the various types of reports that could be submitted are presented in Table 19.

In addition, an environmental assessment is required with a substantial equivalence report. Table 19 presents the estimates of the time it would take to prepare these reports based on FDA's experience with environmental assessments (EA) for currently regulated tobacco products. It is uncertain how frequently each type of change would occur. For our analysis, we use the lower and upper bound estimates from each compliance category. For instance, for initial SE reports associated with products that are "nearly compliant" with the proposed NNN standard the estimated number of hours ranges from 47 (the minimum of 47, 57, and 92) to 92 (the maximum of 47, 57, and 92). Remaining estimates by anticipated compliance status are calculated in a similar fashion for additional product SE reports for similar products. In addition, we note that our estimates do not include any potential cost for conducting clinical studies, and

that our estimates assume that none of the affected entities is performing any of these activities to comply with the NNN standard.

Table 19.- Estimated Time to Prepare a Substantial Equivalence (SE) Report under the Proposed Rule

Cost applicable to	Type of Change to Comply with the Standard	Initial SE Report			Similar Product SE Report		
		EA	SE	Total	EA	SE	Total
Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	1. Restrictions on major source ingredients	27	20	47	27	10	37
	2. Changes in processes	27	30	57	27	10	37
	3. Restrictions on major source ingredients, and change in processes	52	40	92	52	10-20	62-72
Not Nearly Compliant (mean NNN level is greater than 2x standard)	4. Changes in processes, change in major types of ingredients	52	100	152	52	10-20	62-72
	5. Changes in processes, change in major types and composition of ingredients	80	120	200	80	10-20	90-100

Note: EA denotes “Environmental Assessment”. SE denotes “Substantial Equivalence”. Total hours include time required for the initial and environment assessments. The proposed NNN standard is 1.0 micrograms per gram of tobacco by dry weight.

FDA estimates the number of SE reports based on current NNN standard compliance status and types of anticipated changes to products. We estimate SE related costs by applying the compliance rate to counts of products assumed to be the subject of initial SE reports, and separately for products assumed to be the subject of additional similar product SE reports. The estimated distribution is presented in Table 20.

Table 20.- Estimated Number of SE Reports by Anticipated NNN Compliance Status and Type of SE Report

Description	Chewing Tobacco	Dissolvables	Dry Snuff	Moist Snuff	Snus	Total
Total Number of Initial SE Reports	**47**	**0**	**22**	**23**	**9**	**101**
Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	12	0	1	19	9	41
Not Nearly Compliant (mean NNN level is greater than 2x standard)	35	0	21	4	0	60
Total Number of Similar Product SE Reports	**39**	**0**	**6**	**353**	**24**	**422**
Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	10	0	0	294	24	328
Not Nearly Compliant (mean NNN level is greater than 2x standard)	29	0	6	59	0	94
Total Number of SE Reports	**86**	**0**	**28**	**376**	**33**	**523**

Table 21 summarizes the estimated average cost per SE report. In valuing the time for preparing premarket submissions, FDA uses a composite wage calculated using the Bureau of Labor Statistics' national industry-specific occupational employment and wage estimates for the tobacco manufacturing industry.[19,20] We use a mix of 30 percent life, physical, and social science occupations (occupation code 19-0000); 20 percent architecture and engineering occupations (occupation code 17-0000); 30 percent office and administrative support occupations (occupation code 43-0000); and 20 percent legal occupations (occupation code 23-

[19] May 2015 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200—Tobacco Manufacturing. <http://www.bls.gov/oes/>

[20] The BLS did not publish wage estimates for legal occupations within the tobacco manufacturing industry in 2015. We use instead, the legal occupation wage reported for the beverage and tobacco manufacturing industry (NAICS 312000).

0000). This mix yields a composite wage of $36.52.[21] We double this to account for benefits and overhead, yielding an hourly labor cost of $73.04. Total estimated costs are then estimated by multiplying the hours by number of reports and hourly wage. The total estimated cost due to SE report submission is estimated to range between $2.12 million and $3.56 million—the primary cost estimate is $2.84 million—see Table 21.

[21] The calculation is 0.3*($29.16) + 0.2*($42.55) + 0.3*($19.46) + 0.2*($67.12) = $36.52.

Table 21.- Estimated Costs to Industry Associated with SE Report Submission

SE Report		Number of SE Reports	Hourly Wage	Time (Hours)		Estimated Cost ($million)			Average Cost per Report
				Low	High	Low	Primary	High	
Initial SE Reports	Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	41	$73.04	47	92	$0.14	$0.21	$0.28	$5,076.28
	Not Nearly Compliant (mean NNN level is greater than 2x standard)	60	$73.04	152	200	$0.67	$0.77	$0.88	$12,855.04
	Subtotal	**101**				**$0.81**	**$0.98**	**$1.15**	**$9,697.33**
Similar Product SE Reports	Nearly Compliant(mean NNN level is less than or equal to 2x standard but exceeds standard)	328	$73.04	37	72	$0.89	$1.31	$1.72	$3,980.68
	Not Nearly Compliant (mean NNN level is greater than 2x standard)	94	$73.04	62	100	$0.43	$0.56	$0.69	$5,916.24
	Subtotal	**422**				**$1.31**	**$1.86**	**$2.41**	**$4,411.82**
	Total	**523**				**$2.12**	**$2.84**	**$3.56**	**$5,432.54**

Notes: Costs are estimated based on a composite hourly wage of $73.04, which includes benefits and overhead. The proposed NNN standard is 1.0 micrograms per gram of tobacco by dry weight. The average cost per report is calculated by dividing the primary cost estimate by the number of SE reports. Total estimated cost numbers are rounded to the nearest hundredth. Totals may not add up due to rounding.

Almost all currently marketed smokeless tobacco products are either grandfathered tobacco products, products found to be substantially equivalent (SE), or provisional products that will either be found to be substantially equivalent or withdrawn from the market if found to be not substantially equivalent. Products that are grandfathered or found to be SE are eligible to serve as predicates for other products in a substantial equivalence application. Therefore, FDA believes that if the manufacturer chooses any of the types of changes discussed in the preamble to comply with the proposed NNN smokeless product standard the SE pathway would be the most reasonable and likely choice for seeking premarket authorization for their new smokeless tobacco product that is modified in order to meet the product standard.

FDA believes that changes made solely to bring a smokeless tobacco product in compliance with the proposed rule would be appropriate for an SE submission. FDA cannot guarantee that all of the changes that a manufacturer could implement to meet the product standard will automatically result in a finding of substantial equivalence as that is a review issue; however, FDA does believe that it is possible for manufacturers to modify their product so that it is both in compliance with this product standard and substantially equivalent to an appropriate predicate product. Therefore, FDA does not expect this rule to result in PMTA applications for modifications to existing products.

New smokeless tobacco products that are to be introduced into the market after the rule is in effect that are not modifications of existing products simply to conform to the standard will need to submit either a PMTA or an SE because these are new tobacco products, not as a result of this product standard.

e) Nonconforming Products Costs

The proposed rule would require manufacturers to establish, follow, and maintain procedures for handling products that do not meet the proposed requirements (referred to as nonconforming products). The procedures include identifying, investigating, segregating, and making disposition decisions (reject, rework, accept) about nonconforming products in order to prevent their release for commercial distribution. The anticipated costs from this requirement are based on the anticipated prevalence of nonconforming products and associated actions by the manufacturer as described below. A manufacturer may learn a product is nonconforming, for example, in the course of the manufacturing process during product batch testing before the product is distributed commercially or later on, after commercial distribution, if FDA conducts testing on product acquired from a retail establishment and subsequently notifies the manufacturer that the product is nonconforming. In the first case, the manufacturer would be required to follow its procedures to reject or rework the product. However, FDA anticipates that rejecting the product may be less costly than reworking it and estimates costs under the assumption that the product will be rejected. FDA welcomes comments and data supporting other assumptions. In case FDA notifies a tobacco product manufacturer that a distributed finished smokeless tobacco product does not conform to the proposed standard, the manufacturer would be expected to investigate the reasons underlying the nonconforming status of the product(s) as well as to document and provide solutions to prevent nonconforming products from being commercially distributed in the future. FDA assumes there could be between 1 and 5 events per year associated with nonconforming products after commercial distribution, and up to 3 events before commercial distribution.

We note that the proposed rule requires that all entities establish and follow procedures related to nonconforming products, including procedures for identifying, investigating, segregating, and making disposition decisions about nonconforming products. It is assumed that all 23 covered manufacturing establishments will incur a one-time cost to establish these procedures and a recurring cost to maintain them. It is possible that there may be differences in costs of developing procedures based on establishment size. However, in this analysis we assume costs would accrue uniformly across manufacturing establishments irrespective of establishment or corporate ownership size. In addition, each event associated with nonconforming product is assumed to incur investigation costs, disposal costs (time and value of dispose of product), and time to implement the developed procedures.

Labor hours are valued at the current market wage as reported by the May 2015 Occupational Employment Statistics published by the Bureau of Labor Statistics (US Bureau of Labor Statistics, 2015). Wages are doubled to account for benefits and overhead. All activities are assumed to be conducted by General and Operations Manager (SOC 111021) working in the Tobacco Manufacturing Industry (NAICS 312200), except for responding to FDA in the case of an FDA notification of nonconforming product. The value of time to respond to FDA in this circumstance is assumed to be a mix of 20 percent Office and Administrative Support (SOC 430000), 30 percent General and Operations Manager (SOC 111021), and 50 percent Legal (SOC 230000). Legal occupations are drawn from Beverage and Tobacco Product Manufacturing (NAICS 3120000).

Labor hours for investigations, following established procedures, and disposal of product are estimated using estimates from food manufacturing adjusted down to tobacco manufacturing processes. To proxy for the time needed to respond to FDA in case of an FDA notification of

nonconforming product, we use the average amount of time (16 business days) it takes to closeout FDA warning letters issued between November 2009 and March 2016 for violations of adulterated tobacco products (US Food Drug Administration, 2016b). We assume a maximum work day of 8 hours. FDA seeks comments or data on this set of assumptions. The value of the disposed product is estimated by multiplying the total number of units disposed per event by the per-unit price of the unit disposed. Because disposal of these products is assumed to occur before distribution, we adjust down the average price by the average retail and wholesale markup. The average price of smokeless tobacco products is assumed to be $3 per unit. The retail and wholesale markup is assumed to be 46 percent and 20 percent, respectively. The markup price is informed by a memorandum by the National Parks Services (NPS) to their regional concession chiefs, which provides 2012 industry statistics for pricing concessioner convenience items based on the 2012 National Association of Convenience Stores (NACS) as it relates to other tobacco items (NPS, 2012). FDA was unable to identify data on wholesale of smokeless tobacco products or tobacco products, and requests comments or data to support other estimates. Under these assumptions, the estimated value of the disposed unit is $1.71 (=($3÷(1+0.46))÷(1+0.20)). FDA assumes that each event involves 3,000,000 units of smokeless tobacco product; which FDA believes is within the range of units that could be affected per event given that we assume there are 1-2 batches per product each year.[22] Thus, the average value of disposed product is estimated at $5.14 million. This value would be $9 million (=3 million units priced at $3 each) if we assumed that the foregone cost includes forgone revenue. FDA assumes that the value of the disposed product represents the lower of the two values to reflect the expected behavior that manufacturer would not distribute nonconforming products at the risk of getting a warning letter

[22] Retail scanner data from Nielsen Inc. show that among 185 smokeless tobacco products the total number of units sold in 2015 was 796.32 million, this represents 4.3 million units per UPC per year.

and incurring even higher costs. The labor hours and associated wage and per-event values are shown in Table 22.

Table 22.- Estimated Labor Hours and Value of Activities Associated with Nonconforming Products Provision

Activity	Hourly Wage[a,b]	One-time (Labor Hours)		Recurring (Labor Hours)		Per Event		
		Low	High	Low	High	Hours -Low	Hours -High	Value ($million)
Nonconforming products	$141.52	2	12	1	6	1	6	
Rejected products	$141.52	2	12	1	6	1	6	
Reworking	$141.52	2	12	1	6	1	6	
Value of disposed products (per event)[c]								$5.14
Investigation	$141.52	0	0	1	6	1	6	
Respond to FDA in case of FDA notification of nonconforming product [d]	$117.36	0	0	N/A	N/A	8	128	

Notes: a. Hourly wage for activities other than responding to warning letter is based on wage date for the Tobacco Manufacturing industry (NAICS 312200) for General and Operations Managers (SOC 111021), adjusted for benefits and overhead. b. Hourly wage to respond to warning letters is based on a mix of 20 percent Office and Administrative Support (SOC 430000), 30 percent General and Operations Manager (SOC 111021), and 50 percent Legal (SOC 230000). c. Value of disposed products is estimated assuming 3,000,000 units per event are disposed at a value of $1.71 each ($3 market value discounted by a 46% retail markup and 20% wholesale markup). d. Duration of time to respond to FDA in case of FDA notification of nonconforming product is estimated based on time to respond to a warning letter, calculated using data on warning letters issued between November 2009 and March 2016 indicating a product was adulterated.

Using the assumptions and estimates from Table 22, we estimate one-time costs ranging between $19,530 (23*$141.52*2 to establish procedures regarding nonconforming products plus 23*$141.52*2 to establish procedures regarding rejection and 23*$141.52*2 to establish procedures regarding reworking) and $117,179 (23*$141.52*12 to establish procedures

regarding nonconforming products plus 23*$141.52*12 to establish procedures regarding rejection and 23*$141.52*12 to establish procedures regarding reworking of products). The primary cost estimate for one-time costs is $68,354, which is the midpoint between the high and the low estimates. Similarly, recurring costs are estimated to range between $5.15 million and $10.41 million—the primary cost estimate is $7.78 million. Most of the recurring costs are estimated to arise from the disposal value of rejected nonconforming products, which range between $5.14 million and $10.27 million. One-time and recurring costs disaggregated by activity and types of costs are shown in Table 23. We assume that manufacturers would improve their production process over time and thus there would be fewer non-conforming batches requiring disposal over time. We note that these costs do not include costs of disposing nonconforming products that may result from any future FDA enforcement actions.

Table 23.- Estimated Costs to Industry Associated with Provision on Nonconforming Products

Cost Activity	One-time Costs*		Recurring Costs* Maintain Procedures		Recurring Costs*: Reject, no FDA Notification		Recurring Costs*: Reject, FDA Notification		Total Recurring Costs		
	Low	High	Low	High	Low	High	Low	High	Low	Primary	High
Entities Affected, or Events	23	23	23	23	1	2	1	5			
Identify Product	$6,510	$39,060	$3,255	$19,530	$142	$1,698	$142	$4,246	$3,538	$14,506	$25,474
Reject Product	$6,510	$39,060	$3,255	$19,530	$142	$1,698	$142	$4,246	$3,538	$14,506	$25,474
Value of Disposed Nonconforming Product	$0	$0	$0	$0	$5,136,986	$10,273,973	$0	$0	$5,136,986	$7,705,479	$10,273,973
Reworking	$6,510	$39,060	$0	$0	$0	$0	$0	$0	$0	$0	$0
Investigate	$0	$0	$0	$0	$142	$1,698	$142	$4,246	$283	$3,113	$5,944
Respond to FDA Notification Regarding Nonconforming Products	$0	$0	$0	$0	$0	$0	$939	$75,110	$939	$38,025	$75,110
Total	**$19,530**	**$117,179**	**$6,510**	**$39,060**	**$5,137,411**	**$10,279,067**	**$1,363**	**$87,847**	**$5,145,284**	**$7,775,629**	**$10,405,974**

Note: * Row 1 (“Entities Affected, or Events”) denotes the number of entities or events that are used to estimate costs.

f) Reporting Costs

FDA identified an additional reporting activity associated with the proposed requirements that involves notifications by the manufacturer to FDA regarding the choice of an alternative testing method to meet the proposed requirements in § 1132.16. We note that estimates derived in this subsection are based on anticipated response and FDA experience; FDA seeks comments or data supporting other estimates.

The notification would include comprehensive information describing how the alternative method is intended to be used, its performance criteria and how it meets the proposed requirements. Thus, for purposes of this analysis, we estimate that the time it takes to gather this information would be similar to what it would take to gather information for a "Same Characteristics" SE report, and anticipate one notification per manufacturer. We anticipate that there would be between 1 and 23 manufacturing establishments affected. Similarly, the number of notifications in Year 2 and on is based on historic data regarding entities changing ownership, or revising information about a process or product that would require a new notification. The estimated costs are between $1,461 and $33,598 in Year 1, and between $1,461 and $5,843 in Year 2 and forward (see Table 24). The primary cost estimate is assumed to be midpoint between the low and high cost estimates, thus, in Year 1 the primary cost estimate is $17,530, and $3,652 in Year 2 and forward.

Table 24.- Estimated Costs to Industry Associated with Notifications to FDA Regarding Use of Alternative Testing Methods

Frequency	Time (hours)	Hourly Wage	Number of Notifications		Total Cost		
			Low	High	Low	Primary	High
Year 1	20	$73.04	1	23	$1,461	$17,530	$33,598
Annual after Year 1	20	$73.04	1	4	$1,461	$3,652	$5,843

g) Recordkeeping Costs

Under the proposed rule facilities are required to maintain a number of records, including records of stability testing protocols and results of stability testing, investigations related to shortening expiration dates based on results of annual stability testing, source data and results from batch testing, notifications of alternate test methods, sampling plans and reports, other sampling documentation, records related to nonconforming product investigations and their disposition decisions and procedures, as well as any other nonconforming product investigations. These documents are to be retained a minimum of four years. The associated recordkeeping activities and time costs are itemized in Table 25. Each hour of labor is valued at the wage rate of Office and Administrative Support Occupations (SOC 430000) in Tobacco Manufacturing (NAICS code 312200) adjusted for benefits and overhead, as reported by the Bureau of Labor Statistics. The costs incorporate variation in the frequency at which each of the activities is incurred, and the extent to which the costs are incurred at the entity level or by other relevant characteristics. That is, total cost per activity is calculated by multiplying the number of records produced by the frequency in which they occur each year, the time burden, and the wage rate. The estimated recordkeeping costs are between $129,175 and $234,629; the primary cost estimate is $181,902. We note that recordkeeping time burden associated with the reformulation and labeling activities are derived from the respective models (RTI International, 2015a; RTI International, 2015b); all other estimates are assumed. FDA seeks comments and data supporting other estimates.

Table 25.- Estimated Recordkeeping Costs to Industry

Recordkeeping Activity	Number Affected	Frequency per year	Unit	Time (Hours)		Hourly Wage Rate	Total Cost		
				Low	High		Low	Primary	High
Reformulation: Change in Process	68	1	Formulations	7	9	$38.92	$18,526	$21,172	$23,819
Reformulation: Ingredient Change	28	1	Formulations	7	9	$38.92	$7,628	$8,718	$9,808
Reformulation: No Change	60	1	Formulations	3	5	$38.92	$7,006	$9,341	$11,676
Labeling, Annual after Year 1	1255	1	UPCs	1.70	2.30	$38.92	$83,036	$97,689	$112,343
Initial Stability	23	8	Establishments	1	6	$38.92	$7,161	$25,064	$42,968
Annual Stability Testing	23	3	Establishments	1	6	$38.92	$2,685	$9,399	$16,113
Batch Testing	23	1	Establishments	1	6	$38.92	$895	$3,133	$5,371
Procedures for Nonconforming Products and Related Investigations	23	1	Establishments	1	6	$38.92	$895	$3,133	$5,371
SE reports	23	1	Establishments	1	6	$38.92	$895	$3,133	$5,371
Notifications of Alternate Testing Methods	23	2	Establishments	0.25	1	$38.92	$448	$1,119	$1,790
Total							**$129,175**	**$181,902**	**$234,629**

h) Summary of Industry Costs

The estimated total costs to industry include the costs from complying with the proposed provisions regarding product stability and batch testing, reformulation, review of the proposed regulation, labeling changes, submission of substantial equivalence reports, maintaining procedures about nonconforming products, and related investigations and decisions, alternative method notifications and recordkeeping. These costs are summarized in Table 26**.** Using a 20 year period and a 3 percent discount rate, annualized costs are estimated to be between $17.63 million and $41.11 million; the primary cost estimate is $29.37 million. Similarly, using a 7 percent discount range annualized costs range between $19.74 million and $48.43 million; the primary cost estimate is $34.08 million.

Table 26.- Summary of Estimated Costs to Industry in Response to the Proposed Regulation

Type of Cost (Incurred)	Estimated Cost ($million)			Present Discounted Value, 3% Discount Rate ($million)			Annualized at 3% ($million)			Present Discounted Value, 7% Discount Rate ($million)			Annualized at 7% ($million)		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
Initial Stability Testing (One time, Year 1)	$13.17	$13.17	$13.17	$12.79	$12.79	$12.79	$0.86	$0.86	$0.86	$12.31	$12.31	$12.31	$1.16	$1.16	$1.16
Annual Stability Testing(Annual, After Year 1)	$5.27	$5.27	$5.27	$73.27	$73.27	$73.27	$4.92	$4.92	$4.92	$50.89	$50.89	$50.89	$4.80	$4.80	$4.80
Batch Testing (Annual)	$1.10	$2.74	$4.39	$16.33	$40.82	$65.32	$1.10	$2.74	$4.39	$11.63	$29.07	$46.51	$1.10	$2.74	$4.39
Reformulation (One time, Year 1)	$80.11	$185.65	$291.19	$77.78	$180.25	$282.71	$5.23	$12.12	$19.00	$74.87	$173.51	$272.14	$7.07	$16.38	$25.69
Review of Regulation/no formulation (One time, Year 1)	$6.02	$14.59	$23.17	$5.84	$14.17	$22.49	$0.39	$0.95	$1.51	$5.62	$13.64	$21.65	$0.53	$1.29	$2.04
Labeling Changes (One time, Year 1)	$0.84	$2.12	$3.40	$0.82	$2.06	$3.31	$0.05	$0.14	$0.22	$0.79	$1.98	$3.18	$0.07	$0.19	$0.30
Substantial Equivalence Report (One time, Year 1)	$2.12	$2.84	$3.56	$2.06	$2.76	$3.46	$0.14	$0.19	$0.23	$1.98	$2.66	$3.33	$0.19	$0.25	$0.31
Nonconforming Product Procedures (One time, Year 1)	$0.02	$0.07	$0.12	$0.02	$0.07	$0.11	$0.00	$0.00	$0.01	$0.02	$0.06	$0.11	$0.00	$0.01	$0.01

Type of Cost (Incurred)	Estimated Cost ($million)			Present Discounted Value, 3% Discount Rate ($million)			Annualized at 3% ($million)			Present Discounted Value, 7% Discount Rate ($million)			Annualized at 7% ($million)		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
Nonconforming Product Procedures (Annual)	$5.15	$7.78	$10.41	$71.55	$108.13	$144.71	$4.81	$7.27	$9.73	$49.70	$75.11	$100.52	$4.69	$7.09	$9.49
Reporting Costs (One time, Year 1)	$0.00	$0.02	$0.03	$0.00	$0.02	$0.03	$0.00	$0.00	$0.00	$0.00	$0.02	$0.03	$0.00	$0.00	$0.00
Reporting Costs (Annual, after Year 1)	$0.00	$0.00	$0.01	$0.02	$0.05	$0.08	$0.00	$0.00	$0.01	$0.01	$0.04	$0.06	$0.00	$0.00	$0.01
Recordkeeping, (Annual after Year 1)	$0.12	$0.14	$0.16	$1.62	$1.90	$2.19	$0.11	$0.13	$0.15	$1.12	$1.32	$1.52	$0.11	$0.12	$0.14
Recordkeeping, (Annual)	$0.01	$0.04	$0.08	$0.19	$0.67	$1.15	$0.01	$0.04	$0.08	$0.14	$0.48	$0.82	$0.01	$0.04	$0.08
Total Costs				**$262.28**	**$436.95**	**$611.62**	**$17.63**	**$29.37**	**$41.11**	**$209.08**	**$361.08**	**$513.07**	**$19.74**	**$34.08**	**$48.43**

Note: Numbers are rounded to the nearest hundredth. Totals may not add up due to rounding.

2. Costs to Government

This section discusses the costs to government associated with the proposed provisions. Specifically, we estimate costs arising from 1) review of notifications indicating the manufacturer's use of alternative test methods, 2) enforcement activities associated with nonconforming products, and 3) review of substantial equivalence reports submitted to FDA. Each of the related cost activities is discussed in further detail in the following subsections. Government costs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the federal budget, or the total amount of tobacco industry user fees.

a) FDA Review of SE Reports

We estimate costs associated with review of 523 SE reports to be between $3.96 million and $23.08 million, and a primary cost estimate of $13.52 million. This is estimated assuming that the time to review an SE report ranges from 84 to 240 days, and that to complete a review cycle involves 3.3 to 6.7 full-time equivalent (FTE) employees whose combined daily wage is $960 (assumed work day is 8 hours at a hourly wage of $120), resulting in a cost per review cycle between $264,764 and $1,544,369. At each review cycle, it is assumed that each reviewer reviews up to 35 SE reports, so the cost per SE report is estimated to be between $7,564 and $44,125. These costs are summarized in Table 27. We note that these costs assume that this rule would not result in any incremental increase in the churn rate of new products. Therefore, we do not calculate SE costs associated with any such new products.

Table 27.- Estimated Costs to Government associated with Review of SE Reports

Description	Estimate		
	Low	Primary	High
FDA time (Business days) per review cycle	84	162	240
FTE Wage Cost (Daily)	$960	$960	$960
Number of FTEs per review cycle	3.30	5.0	6.70
Cost per Review Cycle	$264,754	$904,562	$1,544,369
Cost per SE Report	$7,564	$25,845	$44,125
Number of SE Reports	523	523	523
Total Cost ($million)	**$3.96**	**$13.52**	**$23.08**

Notes: It is assumed that one reviewer will review up to 35 SE reports per review cycle.

(a) Enforcement Costs Associated with Nonconforming Products

We estimate costs associated with anticipated enforcement activities beyond those currently performed by FDA. Specifically, we estimate that costs would arise from additional manufacturing inspections (for example, inspections of manufacturing facilities following discovery of nonconforming product at a retail establishment) and further investigative actions that may be needed to resolve issues related to nonconforming products (for example, reviewing inspection findings, corresponding with the manufacturer, etc.). Based on experience, FDA anticipates that 1-3 additional inspections would occur each year and that 1-5 events would result in further investigative action related to nonconforming products. The annual cost of inspections is valued using a daily wage of $960 (=$120*8 hours) and assuming that each inspection lasts one day and it involves one investigator. The costs of these additional inspections ranges between $960 (=$960*1*1) and $2,880 (=$960*1*3).

The costs associated with further investigative actions regarding nonconforming products is determined by multiplying a proxy measure that aims to account for review of inspection findings and review of manufacturer's response by the daily wage and the number of anticipated events. The proxy measure of time used is based on the average duration from issuing to resolving warning letters issued to tobacco manufacturers cited for adulterated products and whose warning letters had been closed during the period November 2009 and March 2016. The associated costs of further investigative actions associated with nonconforming products range between $15,360 (16*$960*1) and $76,800 (16*$960*5). Thus, total costs associated with certain enforcement activities in this subsection are estimated between $16,320 ($15,360+$960) and $79,680 ($76,800 + $2,880) and they are summarized in Table 28 below. The primary cost estimate is $48,000. Our estimates assume that reviewers allocate full days, which is likely going to lead to an overestimate.

Table 28.- Estimated Annual Costs to Governments Associated with Certain Enforcement Activities

Activity	Review Time (Business days)	Daily Wage	Annual Number of Events	Estimated Cost		
				Low	Primary	High
Additional Manufacturing Inspections	1	$960	1-3	$960	$1,920	$2,880
Further Investigative Actions Associated with Nonconforming Products	16	$960	1-5	$15,360	$46,080	$76,800
Total				**$16,320**	**$48,000**	**$79,680**

b) Costs Associated with Review of Notifications Regarding Alternative Testing Methods

Proposed § 1132.16(a) would require that manufacturers notify FDA regarding alternative test methods used and provide complete information about the alternative test method and its performance. This information would enable FDA to evaluate whether the information provided demonstrates that the alternative test method meets or exceeds the performance criteria of the standard test method as required by § 1132.16.

Based on FDA experience, most manufacturers are currently using a test method that is similar to the proposed standard method. The number of notifications in Year 1 is estimated assuming each manufacturer submits one notification. The number of notifications in Year 2 is based on the average number of entities that have changed ownership in the last 4 years; under the proposed rule a change in ownership would trigger a new notification if the new manufacturer intends to keep using the alternative method. The hourly wage is based on the cost of a fully-loaded full time equivalent (FTE) employee in FDA's Center for Tobacco Products. The estimated time to review a notification is 32 hours and it is based on the time that FDA anticipates it would take to review the detailed notification; this time allocation is slightly lower than the time it would take to review an environmental assessment report. Total costs are thus calculated by multiplying the estimated time to review the notification by the hourly wage and number of notifications. The estimate costs in Year 1 range from $3,840 (=1*$120*32) to $88,320 (=23*$120*32). Recurring costs after Year 1 range from $3,840 (=1*$120*32) to $15,360 (=4*$120*32) (see Table 29 below).

FDA believes these estimates are a conservative estimate of the time necessary to review these notifications. FDA expects that most manufacturers will have testing done by contract laboratories, which will have the information necessary for the notification readily available.

Where the contract laboratory is doing testing for multiple manufacturers, FDA expects the notifications to be reviewed quickly as the same information will likely be provided to the multiple manufacturers. For notifications submitted due to a change in ownership, FDA expects the new manufacturer will submit the same information previously submitted, which FDA can review for completion and accuracy in a timely manner to ensure the new manufacturer is correctly adopting the alternate test method.

Table 29.- Estimated Costs to Government Associated with Review of Alternative Testing Methods

Frequency	Time (hours)	Hourly Wage	Number of Notifications		Total Cost		
			Low	High	Low	Primary	High
Year 1	32	$120	1	23	$3,840	$46,080	$88,320
Annual after Year 1	32	$120	1	4	$3,840	$9,600	$15,360

c) Summary of Costs to Government

We estimate one-time costs from $3.96 million to $23.17 million and annual costs from $20,160 to $95,040 (see Table 30). Annualizing over 20 years and using a 3 percent discount rate, total costs range between $278,583 and $1,606,780 and between $369,504 and $2,138,656 using a 7 percent discount rate (see Table 31). The primary cost estimates are $942,682 and $1,254,080 using a 3 and 7 percent discount rate, respectively.

Table 30.- Summary of Estimated Costs to Government

Cost Activity	One-Time Costs ($million)			Annual Costs ($million)		
	Low	Primary	High	Low	Primary	High
Review of Alternative Testing Method	$0.00	$0.05	$0.09	$0.00	$0.01	$0.02
Additional Manufacturing Inspections				$0.00	$0.00	$0.00
Further Investigative Actions Associated with Nonconforming Products				$0.02	$0.05	$0.08
Review of SE Reports	$3.96	$13.52	$23.08			
Total	**$3.96**	**$13.56**	**$23.17**	**$0.02**	**$0.06**	**$0.10**

Note: Numbers are rounded to the nearest hundredth. Totals may not add up due to rounding.

Table 31.- Annualized Costs to Government

Type of Cost (Incurred)	Estimated Cost ($million)			Present Discounted Value, Discount Rate 3% ($million)			Annualized at 3% ($million)			Present Discounted Value, Discount Rate 7% ($million)			Annualized at 7% ($million)		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
Review of Alternative Testing Method (One time, Year 1)	$0.00	$0.05	$0.09	$0.00	$0.04	$0.09	$0.00	$0.00	$0.01	$0.00	$0.04	$0.08	$0.00	$0.00	$0.01
Review of Alternative Testing Method, (Annual)	$0.00	$0.01	$0.02	$0.06	$0.14	$0.23	$0.00	$0.01	$0.02	$0.04	$0.10	$0.16	$0.00	$0.01	$0.02
Additional Manufacturing Inspections (Annual)	$0.00	$0.00	$0.00	$0.01	$0.03	$0.04	$0.00	$0.00	$0.00	$0.01	$0.02	$0.03	$0.00	$0.00	$0.00
Further Investigative Actions Associated with Nonconforming Products (Annual)	$0.02	$0.05	$0.08	$0.23	$0.69	$1.14	$0.02	$0.05	$0.08	$0.16	$0.49	$0.81	$0.02	$0.05	$0.08
Review of SE Reports (One time, Year 1)	$3.96	$13.52	$23.08	$3.84	$13.12	$22.41	$0.26	$0.88	$1.51	$3.70	$12.63	$21.57	$0.35	$1.19	$2.04
Total Costs to Government				**$4.14**	**$14.02**	**$23.90**	**$0.28**	**$0.94**	**$1.61**	**$3.91**	**$13.29**	**$22.66**	**$0.37**	**$1.25**	**$2.14**

Note: Numbers are rounded to the nearest hundredth. Totals may not add up due to rounding.

3. Summary of Estimated Costs of the Proposed Rule

Table 32 summarizes the estimated costs to industry and government anticipated from the proposed regulation. Discounting over 20 years, estimated costs are between $17.91 million and $42.72 million using a 3 percent discount rate, and between $20.11 million and $50.57 million using a 7 percent discount rate. The primary cost estimate is $30.31 million annualized at a 3 percent discount rate, and $35.34 million discounted at a 7 percent rate. All costs are discounted over 20 years. (Appendix Table 2 presents the total estimated costs over the 20 year period.)

Table 32.- Estimated Costs of the Proposed Rule (in $millions)

Description	Cost to Industry ($million)			Cost to Government ($million)			Total Costs ($million)		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Present Discounted Value, 3% Discount Rate	$262.28	$436.95	$611.62	$4.14	$14.02	$23.90	$266.43	$450.97	$635.52
Annualized, 3% Discount Rate	$17.63	$29.37	$41.11	$0.28	$0.94	$1.61	$17.91	$30.31	$42.72
Present Discounted Value, 7% Discount Rate	$209.08	$361.08	$513.07	$3.91	$13.29	$22.66	$213.00	$374.36	$535.73
Annualized, 7% Discount Rate	$19.74	$34.08	$48.43	$0.37	$1.25	$2.14	$20.11	$35.34	$50.57

Notes: Costs are discounted over 20 years.

E. Distributional Effects

The costs of this regulation are likely to be concentrated in certain geographic areas, as particular regions of the country account for a greater share of the growing and manufacturing establishments within the smokeless tobacco industry. In identifying industry costs, the FDA

anticipates that, in order to meet the proposed NNN standard, smokeless tobacco manufacturers would modify processing methods and change certain inputs, such as the varieties of tobacco leaves used in smokeless tobacco products. While most costs of the rule would fall on smokeless tobacco manufacturers, some of the spillover changes in practices resulting from the rule may occur at the tobacco grower level, which we have not included in our main cost estimates.

Under the proposed rule, it is assumed both that tobacco leaves with lower NNN levels would be generally available and that the practices that result in reducing NNN levels can be readily adopted. Farms growing the tobacco varieties, such as dark air-cured and dark fire-cured, most commonly used in smokeless tobacco blends are concentrated in several counties within the states of Kentucky and Tennessee. These two states have the greatest levels of harvested acres, yield, and production of the tobacco types used in the affected products (USDA National Agricultural Statistics Service, 2015). A USDA report from 2000 confirms this geographic distribution for tobacco types: table 1 in *Tobacco and the Economy: Farms, Jobs, and Communities* (Economic Research Service, U.S. Department of Agriculture, Agricultural Economic Report No. 789) lists tobacco types, where they are grown domestically, and their primary end tobacco product. This table displays dark fire-cured and dark air-cured tobacco as the types used for chewing tobacco, along with the states where they are grown. Kentucky and Tennessee are the only states listed for dark air-cured tobacco. Kentucky, Tennessee, and Virginia are the only states listed for dark fire-cured tobacco (Gale, Foreman, & Capehart, 2000).

If geographic or climate factors affect the ability to switch to new types of leaves and techniques, then there may be differential impacts upon farms that are advantaged or disadvantaged on these factors. If manufacturers shift to different varieties of tobacco in formulating their blends for smokeless tobacco products, then growers who are able to produce

tobacco with lower levels of NNN would experience gains, potentially offsetting losses to those unable to change their growing practices. For example, the physical and chemical composition of the raw tobacco leaves that are formed into modern snus products fluctuates from year to year, partially due to variations in climate, growing, and curing conditions (Rutqvist, Curvall, Hassler, Ringberger, & Wahlberg, 2011). In response to demand for low NNN tobacco leaves, farms may need to select the appropriate tobacco seed variety and implement production techniques that result in lower NNN levels. Upon implementation of the rule, some farms may shift acreage from growing higher NNN level tobacco to those seed varieties that result in tobacco plants with lower NNN levels, or producing other agricultural products.

The benefits of this regulation will also be differentially distributed. Smokeless tobacco use has significantly pronounced regional and demographic patterns. The consumption of smokeless tobacco products is higher in the southern and upper Midwest states. High rates of use are also found among young adult males in general, and among non-Hispanic White males and American Indian/Alaskan Native males in particular (U.S. Department of Health and Human Services, 2014). Additionally, high school athletes use smokeless tobacco products at a higher rate than non-athletes (Agaku, et al., 2015).We request comment and data on distributional impacts of the proposed rule.

F. International Effects

The main analysis captures the impacts that accrue to U.S. citizens and domestic smokeless tobacco product entities, including U.S. subsidiaries of foreign entities. However, if any smokeless tobacco products that have been reformulated to meet the proposed NNN standard are exported to countries where smokeless tobacco products have NNN levels above those

considered in this proposed rule, we would expect that the health benefits from lower cancer risk would be extended to consumers in countries that import these newly formulated products.

As with domestic smokeless tobacco manufacturers, foreign manufacturers continuing to market in the U.S. will experience an increase in costs as a result of this final rule. The magnitude here is limited, however, as the volume of imported smokeless tobacco products is relatively small. In the calendar year 2015, approximately 118 million pounds of snuff and 19 million pounds of chewing tobacco were manufactured domestically. In comparison, in calendar year 2015, approximately 0.58 million pounds of snuff and 0.86 million pounds of chewing tobacco were imported (Alcohol and Tobacco Tax and Trade Bureau, 2015).

In dollar terms, for fiscal year 2015, the value declared for United States customs of imported chewing tobacco, snuff, snus, and dissolvable tobacco finished products was approximately $20.5 million. Imports from Sweden amount to 22% of this declared value total, the most of any manufacturer country exporting such products to the United States. Finally, based on internal data on import lines, this sum of $20.5 million represents approximately two percent of the declared value for all imported tobacco products over fiscal year 2015, which totaled $988 million. We request comment and data on the effects of the proposed rule on foreign entities.

G. Uncertainty and Sensitivity Analysis

1. Reformulation Costs under Alternative Definitions of Formulations and Reformulation Complexity

In estimating reformulation costs we assumed that manufacturers would incur costs based on an average number of core blends per entity affected and assumed a low level of

reformulation complexity. This category is used in our modeling for products characterized by few ingredients, and a technologically straightforward production approach, or minimal processing. In this subsection we present the results of what costs would be, assuming two higher levels of reformulation complexity—medium and high. In the medium and high assumptions, smokeless tobacco products would be comparable in complexity to frozen pizza or non-carbonated beverage mix, respectively. In addition, reformulation costs are estimated utilizing two separate definitions of formulations. In the first scenario we assume that the number of formulations is determined by the number of entities in each product subcategory. In the second case, each formulation is determined by the number of products derived from FDA's Registration and Listing data adjusted down by a factor of 1.125 to incorporate the fact that one formula could be associated with multiple products. The first case would represent a lower bound estimate of costs (the range is between $21.53 million and $78.59 million) while the second case would represent an upper bound (the range is between $599.12 million and $2.17 billion). These cost estimates are presented in Panel A of Table 33. Panel B of Table 33 presents the estimated change between each of the formulation combinations and the proposed rule. If the number of formulations were based on product counts derived from FDA's Registration and Listing and the level of complexity were high, the estimated costs would be almost $2 billion higher (or almost six times) relative to the costs estimated in the main analysis where we assumed that formulations are based on core blends and low and medium level of reformulation complexity. FDA asks for comments or data supporting the likelihood of the estimates under these various scenarios.

Table 33.- Estimated Costs of Reformulation under Varying Degrees of Reformulation Complexity

Panel A. Estimated Costs ($ millions) using Various Definitions of Formulation and Formulation Complexity

Formulation Counts Based On	Complexity	Reformulate Total Cost ($million)			Do Not Reformulate Total Cost ($million)			Grand Total Cost ($million)		
		Low	Primary	High	Low	Primary	High	Low	Primary	High
Entities	Low	$20.03	$46.41	$72.80	$1.50	$3.65	$5.79	$21.53	$50.06	$78.59
Entities	Medium	$25.28	$60.03	$94.78	$1.50	$3.65	$5.80	$26.78	$63.68	$100.58
Entities	High	$26.97	$63.51	$100.05	$1.50	$3.65	$5.80	$28.48	$67.17	$105.85
Core Blends*	Low	$80.11	$185.65	$291.19	$6.02	$14.59	$23.17	$86.13	$200.25	$314.36
Core Blends	Medium	$101.11	$240.12	$379.13	$6.02	$14.60	$23.19	$107.13	$254.73	$402.33
Core Blends	High	$107.90	$254.06	$400.22	$6.02	$14.60	$23.19	$113.91	$268.66	$423.41
Products	Low	$439.53	$992.44	$1,545.34	$31.70	$76.84	$121.97	$471.24	$1,069.27	$1,667.31
Products	Medium	$537.18	$1,247.32	$1,957.45	$31.70	$76.86	$122.02	$568.88	$1,324.18	$2,079.47
Products	High	$567.42	$1,308.05	$2,048.69	$31.70	$76.85	$122.00	$599.12	$1,384.91	$2,170.69

Panel B. Change in Estimated Costs between Each Formulation Combination and the Proposed Rule

Formulation Counts Based On	Complexity	Reformulate Total Cost ($million)			Do Not Reformulate Total Cost ($million)			Grand Total Cost ($million)		
		Low	Primary	High	Low	Primary	High	Low	Primary	High
Entities	Low	($60.09)	($139.24)	($218.40)	($4.51)	($10.94)	($17.38)	($64.60)	($150.18)	($235.77)
Entities	Medium	($54.84)	($125.62)	($196.41)	($4.51)	($10.94)	($17.37)	($59.35)	($136.56)	($213.78)
Entities	High	($53.14)	($122.14)	($191.14)	($4.51)	($10.94)	($17.37)	($57.65)	($133.08)	($208.51)
Core Blends*	Low	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Core Blends	Medium	$21.00	$54.47	$87.94	$0.00	$0.01	$0.03	$21.00	$54.48	$87.97
Core Blends	High	$27.78	$68.40	$109.02	$0.00	$0.01	$0.03	$27.78	$68.42	$109.05
Products	Low	$359.42	$806.78	$1,254.15	$25.69	$62.24	$98.80	$385.11	$869.03	$1,352.95
Products	Medium	$457.07	$1,061.66	$1,666.26	$25.69	$62.27	$98.85	$482.75	$1,123.93	$1,765.11
Products	High	$487.31	$1,122.40	$1,757.49	$25.69	$62.26	$98.84	$513.00	$1,184.66	$1,856.33

Note: * The costs estimated in the Proposed Rule assume formulations are based on core blends and low level of complexity. The formulations based on product counts are adjusted down by a factor of 1.125. The number of product counts is derived from FDA's Registration and Listing data. In Panel B, numbers in parentheses denote a reduction from the proposed rule. Numbers are rounded to the nearest hundredth.

2. Substantial Equivalence Costs under Varying Assumptions

In the section above we discussed the costs associated with submission and review of substantial equivalence reports where the number of SE reports was based on FDA Registration and Listing data. In this section, we estimate costs under a separate scenario where the estimated number of SE reports is based on the number of UPCs. However, in this case, UPC counts is derived from Nielsen Inc. data and it proxies for the number of products. Specifically, we estimate one initial SE report per branded product and one additional similar product SE report for every other product (UPC) associated with that branded product. In addition, because we only have access to the aggregated count of UPCs by product subcategory, we apply the percent of initial and additional similar product SE reports that is derived from the main analysis—which uses FDA Registration and Listing data--to obtain an estimate of the total number of initial and additional similar product SE reports that would be submitted using the UPC counts from Nielsen Inc. We then apply the compliance rate to estimate the total number of SE reports for products that are "nearly compliant" and "not nearly compliant" with respect to the NNN limit.[23] This case would result in a greater estimate for the number of SE reports and costs than those estimated in the main analysis. Table 34 shows the estimated costs under this set of assumptions would be higher by up to $2.65 million than what is estimated using the assumptions in the main analysis.

[23] For example, in the main analysis, it is estimated that there would be 47 initial SE reports (or 40 percent (=47/117)) associated with the chewing tobacco subcategory. We use the estimated 40 percent and multiply it by the number of UPCs in this product subcategory to obtain 107 (=266 UPCs * 40 percent) initial SE reports. The remaining number of initial and additional similar product SE reports across each product subcategory is calculated in a similar manner. The number of UPCs is 266 for chewing tobacco, 3 for dissolvables, 95 for dry snuff, 632 for moist snuff, and 259 in snus. The number of products is based on UPC counts from Nielsen Inc.

Table 34.- SE Costs Assuming Number of SE Reports is Based on UPCs, 1 Initial SE Report per Brand and 1 Similar Product SE Report per Different UPC Associated with the Brand

Type of Report		Number of SE Reports	Hourly Wage	Time (Hours)		Total Cost ($million)		
				Low	High	Low	Primary	High
Number of Initial SE Reports	Nearly Compliant[1]	77	$73.04	47	92	$0.26	$0.39	$0.52
	Not Nearly Compliant[2]	156	$73.04	152	200	$1.73	$2.01	$2.28
	Subtotal	**233**				**$2.00**	**$2.40**	**$2.80**
Number of Similar Product SE Reports	Nearly Compliant[1]	435	$73.04	37	72	$1.18	$1.73	$2.29
	Not Nearly Compliant[2]	155	$73.04	62	100	$0.70	$0.92	$1.13
	Subtotal	**590**				**$1.88**	**$2.65**	**$3.42**
Total		**823**				**$3.87**	**$5.04**	**$6.22**
Change from proposed rule		**300**				**$1.75**	**$2.20**	**$2.65**

Notes: 1. Nearly Compliant reports submitted for products that have a mean NNN level greater than the proposed standard but less than or equal to twice the proposed standard. 2. Not Nearly Compliant captures reports submitted for products that have a mean NNN level greater than 2 times the proposed standard. Number of products based on UPC counts derived from Nielsen Inc. Total Costs are rounded to the nearest hundredth. Totals may not add up due to rounding.

3. Uncertainty Regarding Dry Snuff Products

a. Costs of Market Adjustments

It is possible that some domestic manufacturers of smokeless tobacco products may choose to stop selling their products in the United States rather than bring their product into compliance if the costs of complying exceed the costs of exit. On the other hand, certain manufacturers of smokeless tobacco products may have a greater incentive to enter the US market, e.g., foreign manufacturers of snus products that already meet the proposed NNN standard. FDA does not have data to quantify the amount of potential exit or entry that could occur attributable to this rule. However, below we qualitatively discuss the impact associated with possible product exit of dry snuff products. There is uncertainty as to whether lowering the NNN level in dry snuff to meet the proposed standard could be more costly than for other affected products, given that the baseline NNN level for these products are higher on average.

Firms would produce only if doing so would be more profitable than not producing. That is, products could be withdrawn from the market or firms could shut down if the cost of complying with the proposed rule exceeds the cost of exiting—which include forgone profits. With regard to product or firm exit, we focus our discussion on dry snuff products, which on average have the highest level of NNN across all smokeless tobacco products. We estimate that there are about 28 different products in the dry snuff subcategory. Combined, dry snuff products account for about 4 percent (=28/784) of all the smokeless tobacco products. Nielsen Inc. data indicate that revenue from the sale of dry snuff products in 2015 accounted for $38,761,243 or 0.70 percent of the $5.4 billion in the smokeless tobacco industry. According to Nielsen Inc. data, the total volume of dry snuff products is estimated at around 10,722,335 ounces, which given the industry sales would represent an average price of $3.60 per ounce of dry snuff. FDA

registration and listing data indicate that these affected products are manufactured by 6 entities which also produce other smokeless tobacco products. Three of the six entities would be considered small under the SBA definition, and the average per firm sales is approximately $47.70 million. The remaining three firms would be considered large according to SBA, and their corporate revenues exceed $500 million each.

FDA does not have data on the percent of total sales that dry snuff products represent for these entities, but for most of them, dry snuff products represent 2 to 23 percent of the total number of smokeless tobacco products that each entity manufactures.[24] Using the percent of dry snuff products that each company's products represent over the total number of dry snuff products, we estimate the revenue from dry snuff products associated with each entity (see Table 35. (We estimated that the average cost per entity to comply with the proposed rule in Year 1 is between $2.67 million and $7.97 million (see section III. Small Entity Effects).) For all six entities, the estimated cost of reformulating dry snuff products would exceed the anticipated related revenue. A firm would be expected to cease production of dry snuff products rather than invest in reformulating its products if it anticipates being unprofitable in the future. Loss in producer surplus from product exit of dry snuff is difficult to determine; however, firm shut down appears less likely given that total firm revenues exceed the estimated cost of complying with the proposed rule. In addition, product exit may also be associated with one-time friction costs. Friction costs from product exit could include labor search costs, as displaced workers look for other jobs, and capital reallocation costs. However, FDA does not have data to estimate these costs.

[24] One of the entities producing 11 percent of its products in the dry snuff subcategory produces the remaining 89 percent of its products in the chewing tobacco subcategory. For this entity, the estimated costs of complying with the proposed requirements would represent up to 33 percent of its total sales.

Table 35.- Estimated Revenue and Costs of the Proposed Rule on Firms Manufacturing Dry Snuff Smokeless Tobacco Products

Entity ID	Company's Dry Snuff Products, as a Percent of Total Dry Snuff Products (N=28)	Company's Dry Snuff Products as Percent of Company's Total Smokeless Products	Estimated Revenue from Dry Snuff Products[1] ($million)	Estimated Cost Associated with Reformulating Dry Snuff Products (Primary Estimate)[2,5] ($million)	Estimated Revenue from Other Smokeless Tobacco Products[3] ($million)	Estimated Average Cost Associated with Complying with the Proposed Rule (Primary Estimate)[4,5] ($million)
1	29%	2%	$11.07	$13.74	$30.26	$13.67
2	4%	11%	$1.38	$5.51	$5.17	$2.61
3	25%	7%	$9.69	$13.74	$30.26	$13.67
4	29%	11%	$11.07	$13.74	$30.26	$13.67
5	11%	23%	$4.15	$5.51	$5.17	$2.61
6	4%	4%	$1.38	$5.51	$5.17	$2.61
Total	100%		$38.76	$57.76	$106.29	$48.85

Notes: 1 Estimated using the company's snuff products as a percent of total dry snuff products. 2 Estimated cost represents primary estimate and it does not include other activities associated with complying with the rule such as labeling, SE submission, reporting, and recordkeeping, or costs associated with nonconforming products. 3. Estimated using information on revenue of company's smokeless tobacco products. 4. Estimates based on the average per firm cost in the Regulatory Flexibility Act Analysis section; Firms 1, 3 and 4 are classified small according to SBA and Firms 2, 5 and 6 are classified as large according to SBA. 5. The estimates represent the on average cost per firm where the total costs of complying with the proposed rule for both compliant and noncompliant products, for this reason the cost differs from the cost of reformulating dry snuff products, which is based only on the assumption of noncompliance. Total Costs and Revenue are rounded to the nearest hundredth. Totals may not add up due to rounding.

b. Consumer Costs

If all dry snuff products came off the market, consumers may look for substitute products. FDA lacks data or information regarding which products would be considered close substitutes for discontinued products. FDA does not have baseline data on consumer valuation of dry snuff

products, making it difficult to estimate how these consumers would value the potential loss of dry snuff products. However, today snus and moist snuff products make up the largest share of the smokeless tobacco product market, both in terms of number of products and revenue. There would be costs for consumers to search for a suitable substitute (or endure not being able to find a perfect substitute), but FDA does not have data to quantify these costs. FDA requests data or comments on this issue.

4. Variation in the Timing of Benefits

In both the preamble and the main analysis, FDA assumes that the full public health impact of the rule will accumulate over a period of 10 years. As described in the preamble, this assumption is based on studies of cigarette smoking cessation that generally find higher risks for oral cancer for former smokers during the first 10 years after smoking cessation compared to never smokers, but not necessarily thereafter. In our analysis of reductions in new (i.e. incident) oral cancer cases, we assume that this period would begin on the effective date of the rule, which follows the publication date by 3 years. It is further assumed that reductions in oral cancer deaths due to the rule would not begin for an additional 3 years, implying a 16 year gap between publication of the rule and when the full health benefits begin to accrue. We recognize that there may be uncertainty regarding the timing of when the full benefit level is achieved. Therefore, in this section, we explore how the public health impact of the rule may change with variation in the timing of benefit accrual. We investigate the effects of 5 and 15 year accrual periods, and then compare overall health benefits from these scenarios with the 10 year accrual period from the main analysis. The 5 and 15 year accrual periods imply 11 and 21 year gaps, respectively, between rule publication and when the full benefit level of the rule is reached.

Table 36 summarizes the benefits associated with a 5 year period of accrual. Panel A presents combined morbidity and VSL mortality benefits in the first 20 years of the rule. The annualized values of these estimates range from approximately $360.7 million to $3.9 billion at a 3 percent discount rate, and from approximately $323.9 million to $3.5 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $1.4 billion at a 3 percent discount rate and $1.2 billion at a 7 percent discount rate.

In Panel B of Table 36 we summarize combined mortality and morbidity benefits using the QALY method. The annualized value of quality adjusted life-years gained from reduced mortality and morbidity ranges from approximately $249.5 million to $2.7 billion at a 3 percent discount rate, and approximately $261.4 million to $2.8 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $0.9 billion at both the 3 and 7 percent discount rates.

Table 36.- Present Discounted Value of All Health Benefits Assuming 5 Year Phase-In Period, 20 Year Period after Rule Publication

Panel A: Combined Morbidity and VSL Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$5,366.50	$20,145.24	$57,664.42
	7%	$3,430.97	$12,878.93	$36,861.74
Annualized Value of All Benefits	3%	$360.71	$1,354.08	$3,875.95
	7%	$323.86	$1,215.68	$3,479.49

Panel B: Combined Morbidity and QALY Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$3,711.89	$13,933.26	$39,878.45
	7%	$2,769.05	$10,393.87	$29,746.57
Annualized Value of All Benefits	3%	$249.50	$936.53	$2,680.46
	7%	$261.38	$981.11	$2,807.87

Note: Unlike estimates from the main benefits analysis, "Low" and "High" values in this table reflect the use low and high VSL values only. All estimates are based on the primary oral cancer relative risk estimate of 2.16.
Note: Values are shown in millions of dollars, using 2015 dollar values

Table 37 summarizes the public health impact of the rule with a 15 year accrual period for benefits. Panel A presents combined morbidity and VSL mortality benefits in the first 20 years of the rule. The annualized values of these estimates range from approximately $211.3 million to $2.3 billion at a 3 percent discount rate, and approximately $ 181.4 million to $1.9-billion at a 7 percent discount rate. Our primary annualized estimates are approximately $0.8 billion at a 3 percent discount rate and $0.7 billion at a 7 percent discount rate.

In Panel B of Table 37 we summarize combined mortality and morbidity benefits using the QALY method. The annualized value of quality adjusted life-years gained from reduced mortality and morbidity ranges from approximately $147.8 million to $1.6 billion at a 3 percent discount rate, and approximately $147.4 million to $1.6 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $554.6 million and $553.2 million at the 3 and 7 percent discount rates, respectively.

Table 37.- Present Discounted Value of All Health Benefits Assuming 15 Year Phase-In Period, 20 Year Period after Rule Publication

Panel A: Combined Morbidity and VSL Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$3,143.82	$11,801.38	$33,779.76
	7%	$1,921.39	$7,212.28	$20,642.20
Annualized Value of All Benefits	3%	$211.31	$793.24	$2,270.53
	7%	$181.37	$680.79	$1,948.48

Panel B: Combined Morbidity and QALY Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$2,198.28	$8,251.52	$23,615.88
	7%	$1,561.26	$5,860.22	$16,771.02
Annualized Value of All Benefits	3%	$147.76	$554.63	$1,587.36
	7%	$147.37	$553.16	$1,583.07

Note: Unlike estimates from the main benefits analysis, "Low" and "High" values in this table reflect the use low and high VSL values only. All estimates are based on the primary oral cancer relative risk estimate of 2.16. Values are shown in millions of dollars, using 2015 dollar values

In Table 38 we compare the benefit estimates associated with both of the accrual periods considered in this part with the estimates from the main analysis. Table 38 presents only combined estimates of morbidity and VSL mortality. In the first panel of this table we show estimates of the change in the value of benefits associated with the 5 year phase-in period. Relative to the proposed rule, the 5 year period raises primary annualized benefits by approximately $515.1 million at a 3 percent discount rate and $512.6 million at a 7 percent discount rate. In contrast, the 15 year phase-in period reduces benefits relative to the proposed rule. Our primary annualized estimates indicate a reduction in benefits of approximately $45.7 million at a 3 percent discount rate and $22.3 million at a 7 percent discount rate.

Table 38.- Estimated Change in Present Discounted Value of Combined Morbidity and VSL Mortality Benefits between Proposed Rule and 5 and 15 Year Phase-In Periods

Panel A: 5 Year Phase-In

	Discount Rate	Low	Primary	High
Change in Present Discounted Value	3%	$2,041.55	$7,663.90	$21,938.24
	7%	$1,446.55	$5,430.03	$15,542.27
Change in Annualized Value	3%	$137.22	$515.14	$1,474.59
	7%	$136.54	$512.56	$1,467.08

Panel B: 15 Year Phase-In

	Discount Rate	Low	Primary	High
Change in Present Discounted Value	3%	($181.13)	($679.96)	($1,946.42)
	7%	($63.03)	($236.62)	($677.27)
Change in Annualized Value	3%	($12.18)	($45.70)	($130.83)
	7%	($5.95)	($22.33)	($63.93)

Note: Values are shown in millions of dollars, using 2015 dollar values

5. Changes in Consumer Behavior

In the main economic analysis, we assume that, while the proposed NNN standard will reduce the health risks associated with smokeless tobacco product use, the prevalence of smokeless tobacco use will not change as a result of the rule. Although FDA does not anticipate that consumers will respond to the reduced cancer risk of smokeless tobacco with increased initiation or decreased cessation of smokeless tobacco use, we relax this assumption to investigate the potential public health impacts of an increase in the prevalence of smokeless tobacco use. The net effect of any behavioral change in consumption of smokeless tobacco use will depend on the extent to which increased use of smokeless tobacco comes from users switching from a more harmful tobacco product and the extent to which increased prevalence comes from those who would have otherwise never initiated or would have ceased using smokeless tobacco.

To illustrate the range of possible health impacts from changes in consumption behavior should such changes occur, we consider some behavior changes that decrease benefits separately from those that increase benefits. Consumer responses that decrease benefits include increased initiation from non-tobacco users and decreased cessation from current smokeless tobacco users. These responses are expected to decrease benefits because, even after implementation of the rule, the use of smokeless tobacco products would still entail health risks. In contrast, an increase in smokeless tobacco prevalence that is driven by initiation from current smokers seeking to quit or limit their smoking would increase the benefits associated with this rule. Because we lack sufficient information to forecast the magnitude of these behavioral responses, we do not present estimates of the net public health impact from all possible changes in behavior. We request comment and data regarding the behavioral changes that may result from this rule.

a. Increased Initiation from Non-Tobacco Users and Decreased Cessation from Current Smokeless Tobacco Users

In order to demonstrate how benefits may change with increased initiation from non-tobacco users and decreased cessation from current smokeless tobacco users, we estimate the increase in smokeless tobacco prevalence from these behaviors that is necessary to completely reverse the health benefits estimated in the main analysis. In this scenario, we find that an increase in smokeless tobacco prevalence of approximately 186 percent would be necessary to offset the health benefits from avoided oral cancer and deaths from the reduced relative risk for oral cancer corresponding with the proposed NNN standard. This is equivalent to a 6.13 percentage point increase in the proportion of the population over the age of 12 years using smokeless tobacco, from 3.3 percent to 9.43 percent, based on data from 2014 (Center for Behavioral Health Statistics and Quality, 2015b).

b. Increased Initiation from Smokers

In this scenario, we consider the implications of a rise in smokeless tobacco use driven entirely by smokers using smokeless tobacco instead of combustible tobacco products. In contrast to the scenario described above, smokers who switch to smokeless tobacco products would increase the health benefits associated with the rule. Smokers may choose to limit or quit their consumption of combustible forms of tobacco in response to the reduced risks from smokeless tobacco products. To inform our range of switch rates for this scenario, we look to the experience of other countries that have implemented policies that affect the availability of smokeless tobacco products. Comparing the smoking rate in Finland and Sweden, Maki (2015)

finds that a ban on oral tobacco in Finland increased the smoking rate in that country by 3.47 percentage points relative to Sweden. The smoking rate among males in Finland before the oral tobacco ban was 31.57 percent, implying that the oral tobacco ban increased the smoking rate by 10.99 percent. Maki (2015) argues that this demonstrates that the availability of a less harmful substitute to smoking may reduce smoking prevalence.

In addition to differences in cultural norms regarding smokeless tobacco use between Scandinavian countries such as Sweden or Finland and the United States, we would expect that compared with a policy that introduced or banned an entire product category, one that affects the relative health risks of an existing product would generate less of a consumer behavioral response in terms of substitution effects. Therefore, we use 10.99 percent as an upper bound of smokeless tobacco initiation from combustible tobacco smokers. This figure would represent a large increase in the prevalence of smokeless tobacco use. It corresponds to over 6 million smokers in the United States over the age of 12 years in 2014, or nearly 70 percent all smokeless tobacco users (Center for Behavioral Health Statistics and Quality, 2015b). In the analysis below, we also present estimates based on a cessation rate of 1 percent of all smokers. This helps provide a range of estimates and better illustrates how benefits associated with this rule may change with increased initiation of smokeless tobacco from smokers.

In order to provide a rough estimate of some of the public health impacts from smokers switching to smokeless tobacco, we estimate the difference between oral and lung cancer cases and deaths attributable to smoking in the baseline and what would occur if all smokers switched to smokeless tobacco. Attributable cancer cases and deaths are calculated using the same PAR formula as in the main analysis, but with different inputs for smoking prevalence and relative

risks for oral and lung cancer.[25] After calculating the difference in attributable cases and deaths for both oral and lung cancer, we multiply each difference by the 10.99 percent smoking cessation rate from Maki (2015) and the 1 percent cessation rate. The resulting products indicate the estimated reduction in cancer cases and deaths that would occur if 10.99 or 1 percent of smokers switched to smokeless tobacco as a result of the rule.

Next, we make assumptions about the timing of behavior changes among smokers. We assume that smokers will not change their behavior until they are able to observe that the rule is associated with a reduction in a cancer risk. This implies that there will be no behavioral change among smokers until 14 years after publication of the rule, or 1 year after the rule is estimated to reach the maximum level of benefits in the main analysis. From this point, reductions in oral and lung cancer incidence accrue over a period of 10 years until the full benefit level is reached. For reductions in oral and lung cancer mortality, we use an assumption from the main analysis and allow an additional 3 years before benefits begin accumulating. This implies that benefits from reduced cancer mortality begin 17 years after publication of the rule. Table 39 summarizes the cumulative reductions in oral and lung cancer in the first 20 years after publication.

[25] We use data on smoking prevalence from the 2014 National Survey on Drug Use and Health (Center for Behavioral Health Statistics and Quality, 2015b). Relative risk ratios are as follows: Thun et al. (2013) estimate a lung cancer relative risk of 24.97 for male smokers between 2000 and 2010, Freedman et al. (2007) estimate an oral cancer relative risk of 2.99 for male smokers, and Boffetta et al. (2008) report a lung cancer relative risk ratio of 5.6 among smokers that switch to smokeless tobacco.

Table 39.- Cumulative Reductions in Cancer Cases and Deaths from Smoking Cessation and Initiation of Smokeless Tobacco, 20 Year Period After Rule Publication

		Avoided Cases	Avoided Deaths
Panel A: Maki (2015) Smoking Cessation	Lung Cancer	24,494	6,518
	Oral Cancer	1,974	157
Panel B: 1.0% Smoking Cessation	Lung Cancer	2,228	593
	Oral Cancer	180	14

We value avoided cancer cases and deaths using the same VSL method as in the main analysis. Table 40 summarizes the benefits associated with reductions in lung cancer mortality from the initiation of smokeless tobacco use among former smokers in the 20 years after rule publication. Panel A presents estimates of these benefits using the smoking cessation rate from Maki (2015), 10.99%. The annualized values of these estimates range from approximately $1.4 billion to $4.7 billion at a 3 percent discount rate, and approximately $984.2 million to $3.2 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $3.1 billion at a 3 percent discount rate and $2.1 billion at a 7 percent discount rate. Panel B summarizes benefits from avoided lung cancer assuming that 1.0% of smokers quit smoking and initiate the use of smokeless tobacco products. The annualized values of these estimates range from approximately $131.3 million to $430.6 million at a 3 percent discount rate, and approximately $89.5 million to $293.6 million at a 7 percent discount rate. Our primary annualized estimates are approximately $284.0 million at a 3 percent discount rate and $193.7 million at a 7 percent discount rate.

Table 40.- Present Discounted Value of Reduced Lung Cancer Mortality, 20 Year Period after Rule Publication

		Discount Rate	Low	Primary	High
Panel A: Maki (2015) Smoking Cessation Rate	Present Discounted Value of Benefits	3%	$21,475.68	$46,447.41	$70,420.27
		7%	$10,426.61	$22,550.58	$34,189.59
	Annualized Value of Benefits	3%	$1,443.50	$3,122.00	$4,733.35
		7%	$984.20	$2,128.62	$3,227.26
Panel B: 1.0% Smoking Cessation	Present Discounted Value of Benefits	3%	$1,953.85	$4,225.78	$6,406.82
		7%	$948.61	$2,051.65	$3,110.56
	Annualized Value of Benefits	3%	$131.33	$284.04	$430.64
		7%	$89.54	$193.66	$293.62

Note: Unlike estimates from the main benefits analysis, "Low" and "High" values in this table reflect the use low and high VSL values only. All estimates are based on the primary oral cancer relative risk estimate of 2.16. Values are shown in millions of dollars, using 2015 dollar values

Table 41 summarizes the benefits associated with reductions in oral cancer mortality among smokers who switch to smokeless tobacco. Panel A presents estimates of these benefits using the smoking cessation rate from Maki (2015). The annualized values of these estimates range from approximately $34.9 million to $114.4 million at a 3 percent discount rate, and approximately $23.8 million to $78.0 million at a 7 percent discount rate. Our primary annualized estimates are approximately $75.4 million at a 3 percent discount rate and $51.4 million at a 7 percent discount rate. Panel B summarizes benefits from avoided oral cancer assuming a smoking cessation rate of 1.0%. The annualized values of these estimates range from approximately $3.2 million to $10.4 million at a 3 percent discount rate, and approximately $2.2 million to $7.1 million at a 7 percent discount rate. Our primary annualized estimates are approximately $6.9 million at a 3 percent discount rate and $4.7 million at a 7 percent discount rate.

Table 41.- Present Discounted Value of Reduced Oral Cancer Mortality, 20 Year Period after Rule Publication

		Discount Rate	Low	Primary	High
Panel A: Maki (2015) Smoking Cessation Rate	Present Discounted Value of Benefits	3%	$518.95	$1,122.37	$1,701.66
		7%	$251.95	$544.92	$826.17
	Annualized Value of Benefits	3%	$34.88	$75.44	$114.38
		7%	$23.78	$51.44	$77.98
Panel B: 1.0% Smoking Cessation	Present Discounted Value of Benefits	3%	$47.21	$102.11	$154.82
		7%	$22.92	$49.58	$75.16
	Annualized Value of Benefits	3%	$3.17	$6.86	$10.41
		7%	$2.16	$4.68	$7.10

Note: Values are shown in millions of dollars, using 2015 dollar values

H. Assessment of Regulatory Alternatives to the Proposed Rule

We have identified and quantitatively assessed three alternatives to the proposed rule as follows: a stricter NNN level requirement is analyzed as Alternative 1, a less stringent NNN level requirement is analyzed as Alternative 2, and extending the effective date is considered under Alternative 3. The benefits and costs of each of these alternatives are discussed in turn in this subsection. Regulatory Alternative 1 considers a requirement that the mean NNN level of any batch of finished smokeless tobacco products not exceed 0.50 micrograms per gram of tobacco on a dry weight basis, while Alternative 2 examines the potential impact to costs and benefits if the mean NNN level of any batch of finished smokeless tobacco were required not to exceed 1.50 micrograms per gram of tobacco on a dry weight basis. These two standards were determined by reviewing the distribution of NNN levels reported in the literature at which point the distribution exhibited a substantial decrease or increase. The affected ranges included: 0-

0.50, 0.50-1.50, and 1.50-14.0 micrograms. An NNN level of 0.50 micrograms represents approximately the 10th percentile of the distribution, while 1.50 represents approximately the 50th percentile (or median).

Not quantitatively assessed in the sections below is a regulatory alternative in which FDA delays this NNN standard until it can be coordinated with other potential smokeless tobacco product standards. (Note that by suggesting this theoretical alternative, we do not mean to imply that FDA is necessarily developing another smokeless tobacco product standard at this time.) Conducting an analysis of this alternative would involve making assumptions that would be difficult to inform. However, we request comment that might allow for at least partial quantification.

1. Regulatory Alternative 1: Establish More Stringent NNN Level Requirements: Mean NNN level in any batch of finished smokeless tobacco product not to exceed 0.50 micrograms per gram of tobacco on a dry weight basis

Under the proposed regulation, manufacturers would not be able to release for commercial distribution their smokeless tobacco products unless the NNN levels meet the proposed standard of not exceeding a mean level of 1.0 micrograms of NNN per gram of dry weight tobacco in any batch of finished smokeless tobacco product at any time through the product's labeled expiration date. Requiring a lower NNN level could result in additional potential benefits as exposure to consumers would be lower than under the proposed rule. However, there is currently limited information on lower NNN levels, and costs to industry would be higher to achieve them. The impact on costs and benefits under Alternative 1, which for purposes of this analysis is considered to be 0.50 micrograms per gram of tobacco, is further discussed below.

a. Estimated Benefits under Alternative 1

As an alternative to the proposed rule, a more stringent standard of not exceeding a mean NNN standard of 0.50 micrograms per gram of tobacco in any batch of finished smokeless tobacco product would result in a larger reduction in NNN exposure among users of smokeless tobacco. In this scenario, health benefits associated with the rule would increase.[26] We estimate that this alternative would result in 248 additional avoided cancer cases and 53 additional avoided deaths in each year after the phase-in period. This results in a new total of approximately 1,071 avoided oral cancer cases and 231 avoided deaths each year, once the effect of the rule is fully phased-in. For comparison, the fully phased-in effect of the rule in the main analysis of the proposed rule is 823 avoided cancer cases and 178 avoided deaths. Panel A of Table 42 summarizes the overall morbidity and VSL mortality benefits of this scenario. The annualized values of these estimates range from approximately $368.0 million to $4.0 billion at a 3 percent discount rate, and approximately $319.3 million to $3.5 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $1.4 billion at a 3 percent discount rate and $1.2 billion at a 7 percent discount rate. Panel B of Table 42 presents the combined QALY mortality and morbidity benefits. The annualized value of quality adjusted life-years gained from reduced mortality and morbidity ranges from approximately $255.6 million to $2.8 billion at a 3 percent discount rate, and approximately $258.4 million to $2.8 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $0.9 billion at the 3 and 7 percent discount rates.

[26] We calculate new ELCR estimates under different NNN standards using the ELCR formula shown in the preamble. These estimates are then used in the PAR formula from the preamble to determine avoided oral cancer cases and deaths under the different NNN standard alternatives. We note that there is currently limited information on reductions of NNN levels lower than the proposed standard.

Table 42.- Alternative 1: Present Discounted Value of Health Benefits Associated with Alternative NNN Standard of Not Exceeding a mean level of 0.50 micrograms of NNN per gram of tobacco, 20 year period after rule publication

Panel A: Combined Morbidity and VSL Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$5,474.79	$20,632.32	$59,580.14
	7%	$3,382.94	$12,748.50	$36,811.06
Annualized Value of All Benefits	3%	$367.99	$1,386.82	$4,004.72
	7%	$319.33	$1,203.37	$3,474.70

Panel B: Combined Morbidity and QALY Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$3,802.49	$14,329.42	$41,375.03
	7%	$2,737.65	$10,316.41	$29,786.29
Annualized Value of All Benefits	3%	$255.59	$963.16	$2,781.05
	7%	$258.42	$973.80	$2,811.61

Note: Values are shown in millions of dollars, using 2015 dollar values

b. Estimated Costs under Alternative 1

Under Alternative 1 (a more stringent NNN standard), the baseline compliance rate to meet the standard would be lower than that which is assumed under the proposed rule (see Appendix Table 3), and this would increase the number of products that need to be reformulated to conform to the alternative standard (Appendix Table 4). In this scenario, "nearly compliant" products are defined as those with an NNN level between 0.05 µg/g and 1.0 µg/g, and "not nearly compliant" products are those with NNN levels greater than 1.0 µg/g. Under Alternative 1, there would be 52 additional blends (96 blends in the proposed rule versus 148 blends in Alternative 1)[27] across product subcategories that would not meet the more stringent standard.

[27] In the Alternative 1 we assume there are a total of 96 blends that are noncompliant which include 36, 0, 24, 20, and 16 blends in chewing tobacco, dissolvable products, dry snuff, moist snuff and snus, respectively (see Table 11). In the baseline there are a total of 148 blends that are noncompliant which includes 48, 0, 24, 32, and 44 blends in chewing tobacco, dissolvable products, dry snuff, moist snuff, and snus (see Appendix Table 4).

Most of these blends are estimated to be associated with medium or large firms as measured by the revenue definition explained above. Moreover, most blends are distributed among snus, chewing tobacco and moist snuff. This change would in turn alter the estimated costs associated with the number of reformulations and substantial equivalence reports that would be submitted to FDA for review. We highlight that the estimated costs that we present below make the following key assumptions. First, we assume that achieving such level of NNN across all product subcategories, and under the proposed compliance period is technologically feasible. Second, we assume that the costs to achieve the level of NNN under Alternative 1 are the same as those needed to achieve the proposed NNN level. In other words, we assume that the complexity of the reformulation remains the same as under the proposed rule scenario (see costs in Appendix Table 1.- Per-formula Costs of Reformulation, by Company Size and Reformulation Complexity), where we assume that the product reformulation continues to be best modeled using the process for a low complexity product. As done in the proposed rule scenario, we then develop a distribution of "nearly compliant" and "not nearly compliant" products, based on the sum of "nearly compliant" and "not nearly compliant" product being equal to the total number of noncompliant products. However, we assume that "nearly compliant" products incur a lower cost than "not nearly compliant" products. Specifically, in the context of the reformulation model, "nearly compliant" products are assumed to incur costs associated with a "major ingredient change" while "not nearly compliant" products incur costs associated with a "change in production process". . Costs would be expected to be higher if any of these assumptions does not hold. FDA seeks comments or data relating to these assumptions.

Table 43 below presents the estimated costs to industry and government under Alternative 1. Under Alternative 1, using a 3 percent discount rate and discounting over 20 years,

the primary annualized cost estimate to industry is $84.12 million (the estimated range is between $40.85 million and $127.38 million). Similarly, annualized costs to government range between $0.40 million and $2.32 million. The estimated annualized total costs (those of industry and government) range between $41.25 million and $129.70 million; the primary annualized estimate is $85.48 million using a 3 percent discount rate. Using a 7 percent discount rate the primary annualized cost estimate is $109.91 million, and the estimated costs range between $51.66 million and $168.15 million.

For the interested reader, the undiscounted estimated costs to industry are presented in Appendix Table 5 and Appendix Table 6, respectively. We note that the change in costs assumes that the distribution of blends is as shown in Appendix Table 4. At the time of this analysis, this distribution was estimated by multiplying the number of blends by firm size and the estimated compliance rate as shown in Appendix Table 3.

Table 43.- Estimated Industry and Government Costs under Alternative 1

Description	Discount Rate	Cost to Industry ($million)			Cost to Government ($million)			Total Cost ($million)		
		Low	Primary	High	Low	Primary	High	Low	Primary	High
Present Discounted Value	3%	$607.80	$1,251.48	$1,895.16	$5.95	$20.20	$34.44	$613.75	$1,271.67	$1,929.60
Annualized Value	3%	$40.85	$84.12	$127.38	$0.40	$1.36	$2.32	$41.25	$85.48	$129.70
Present Discounted Value	7%	$541.65	$1,145.12	$1,748.60	$5.65	$19.23	$32.80	$547.30	$1,164.35	$1,781.40
Annualized Value	7%	$51.13	$108.09	$165.06	$0.53	$1.81	$3.10	$51.66	$109.91	$168.15

Note: All costs are discounted over 20 years. Alternative 1 assumes that the standard requires that the mean level of NNN in any batch of finished smokeless tobacco product not exceed 0.50 micrograms per gram of tobacco on a dry weight basis.

2. Regulatory Alternative 2: Establish Less Stringent NNN Level Requirements: Mean NNN level in any batch of finished smokeless tobacco product not to exceed 1.50 micrograms per gram of tobacco on a dry weight basis

Under this alternative, the proposed standard would require manufacturers to produce a product for commercial distribution that meets the standard of not exceeding a mean NNN level of 1.50 micrograms per gram of dry weight tobacco in any batch of finished smokeless tobacco product. This alternative would be less stringent and result in reduced costs as the number of products that would meet this standard would be higher than what is estimated in the proposed rule. However, the higher level of NNN would also reduce benefits as will be explained in more detail below.

c. Benefits under Alternative 2

An alternative standard of not exceeding a mean NNN level of 1.50 micrograms per gram of tobacco in any batch of finished smokeless tobacco product would increase total NNN exposure among smokeless tobacco users relative to the standard in the proposed rule. In this scenario, health benefits would be smaller than estimated in the proposed rule scenario. We estimate that this alternative would result in 176 (823 – 647) fewer avoided cancer cases and 38 (178 – 140) fewer avoided deaths in each year after the phase-in period. This amounts to approximately 647 avoided oral cancer cases and 140 avoided deaths each year, once the effect of the rule is fully phased-in. Panel A of Table 44 summarizes the overall morbidity and VSL mortality benefits of this alternative NNN standard. The annualized values of these estimates

range from approximately $223.9 million to $2.4 billion at a 3 percent discount rate, and approximately $194.3 million to $2.1 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $838.1 million at a 3 percent discount rate and $727.2 million at a 7 percent discount rate. Panel B of Table 44 presents combined QALY mortality and morbidity benefits. The annualized value of quality adjusted life-years gained from reduced mortality and morbidity ranges from approximately $155.5 million to $1.7 billion at a 3 percent discount rate, and approximately $157.2 million to $1.7 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $582.1 million and $588.5 million at the 3 and 7 percent discount rates, respectively.

Table 44.- Alternative 2: Present Discounted Value of Health Benefits Associated with Alternative NNN Standard of not exceeding a mean NNN level of 1.50 micrograms per gram of Tobacco, 20 Year Period After Rule Publication.

Panel A: Combined Morbidity and VSL Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$3,330.83	$12,468.70	$35,470.13
	7%	$2,058.13	$7,704.10	$21,913.89
Annualized Value of All Benefits	3%	$223.88	$838.09	$2,384.15
	7%	$194.27	$727.21	$2,068.52

Panel B: Combined Morbidity and QALY Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$2,313.38	$8,659.42	$24,630.52
	7%	$1,665.53	$6,234.22	$17,731.23
Annualized Value of All Benefits	3%	$155.50	$582.05	$1,655.56
	7%	$157.21	$588.47	$1,673.70

Note: Values are shown in millions of dollars, using 2015 dollar values

d. Estimated Costs under Alternative 2

Similar to the approach utilized under Alternative 1, in this scenario the costs are estimated based on a new distribution of blends and compliance rates as shown in Appendix Table 3 and Appendix Table 7.- Estimated Number of Blends under Alternative 2 by Anticipated Compliance

Status and Firm Size, respectively. In this scenario, “nearly compliant” products are defined as products with NNN level between 1.5 µg/g and 3.0 µg/g and “not nearly compliant” products are defined as those with NNN level greater than 3.0 µg/g. Furthermore, in this scenario we assume that the underlying costs to achieve the level of NNN under Alternative 2 are the same as those needed to achieve the NNN level in the proposed rule. In other words, we assume the complexity of the reformulation remains low and that the associated costs are as shown in Appendix Table 1.- Per-formula Costs of Reformulation, by Company Size and Reformulation Complexity. As done in the proposed rule scenario, we then develop a distribution of “nearly compliant” and “not nearly compliant” products, based on the sum of “nearly compliant” and “not nearly compliant” product being equal to the total number of noncompliant products. However, we assume that “nearly compliant” products incur a lower cost than “not nearly compliant” products. Specifically, in the context of the reformulation model, “nearly compliant” products are assumed to incur costs associated with a “major ingredient change” while “not nearly compliant” products incur costs associated with a “change in production process”. The estimated costs to the private and government sectors under Alternative 2 are presented in Table 45. In this scenario, there would be 40 additional blends across product subcategories that would meet the proposed standard and therefore would not require reformulation (96 blends in the proposed rule minus 56 blends in this alternative), 20 of the 40 blends would be in the moist snuff and 12 in the snus category. At least 80 percent of these blends are estimated to be associated with large- and medium-size firms. Annualized total cost estimates range between $15.71 million and $34.59 million using a 3 percent discount rate and discounting over 20 years. Using a 7 percent discount rate, the annualize costs range between $17.13 million and $39.58

million. The primary cost estimate is $25.15 million and $28.36 million using a 3 percent and 7 percent discount rate, respectively.

Appendix Table 8 and Appendix Table 9 present the undiscounted costs to industry arising from reformulation and SE report submission, respectively, under this alternative.

Table 45.- Estimated Costs under Alternative 2: Less Stringent NNN Standard than Proposed

Description	Discount Rate	Cost to Industry ($million)			Cost to Government ($million)			Total ($million)		
		Low	Primary	High	Low	Primary	High	Low	Primary	High
Present Discounted Value	3%	$232.11	$368.97	$505.83	$1.55	$5.17	$8.78	$233.67	$374.14	$514.61
Annualized Value	3%	$15.60	$24.80	$34.00	$0.10	$0.35	$0.59	$15.71	$25.15	$34.59
Present Discounted Value	7%	$180.07	$295.66	$411.26	$1.42	$4.76	$8.10	$181.49	$300.42	$419.36
Annualized Value	7%	$17.00	$27.91	$38.82	$0.13	$0.45	$0.76	$17.13	$28.36	$39.58

Note: Cost estimates are discounted over 20 years. Alternative 2 assumes that the standard requires that the mean level of NNN in any batch of finished smokeless tobacco product not exceed is 1.50 micrograms per gram of tobacco on a dry weight basis. Total costs are rounded to the nearest hundredth. Totals may not add up due to rounding.

3. Regulatory Alternative 3: Extend the Effective Date

The third alternative considered in this analysis is an extension of the effective date of the rule which would in essence extent the compliance period for smokeless tobacco product manufacturers. Currently, the proposed rule allows manufacturers up to 3 years from publication of the final rule to bring their products into compliance with the proposed rule's provisions and to obtain premarket authorization from FDA. In this alternative, we assume that there are two additional years to comply with the rule, which means that the effective date would be 5 years from the publication date.

a. Estimated Benefits under Alternative 3

Under this regulatory alternative, nonconforming products may remain on the market for an additional 2 years. For the purposes of this analysis we make the simplifying assumption that health benefits will begin accruing after year 5 when all smokeless tobacco products in commercial distribution will be in compliance with this standard. As a result, total benefits in the 20 year period following publication are smaller than under the effective date in the proposed rule. We estimate that this alternative would result in approximately 1,647 fewer avoided cancer cases and 355 fewer avoided deaths over the first 20 years of the rule. This amounts to 8,645 avoided oral cancer cases and 1,332 avoided deaths in the 20 years following publication. For comparison, the cumulative effect of the proposed rule is 10,291 avoided cancer cases and 1,687 avoided deaths. Table 46 summarizes the benefits associated with this regulatory alternative. Panel A presents combined morbidity and VSL mortality benefits. The annualized values of these estimates range from approximately $223.5 million to $2.4 billion at a 3 percent

discount rate, and approximately $187.3 million to $2.0 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $0.8 billion at a 3 percent discount rate and $0.7 billion at a 7 percent discount rate.

In Panel B of Table 46, we summarize combined mortality and morbidity benefits using the QALY method. The annualized value of quality adjusted life-years gained from reduced mortality and morbidity ranges from approximately $156.1 million to $1.7 billion at a 3 percent discount rate, and approximately $152.1 million to $1.6 billion at a 7 percent discount rate. Our primary annualized estimates are approximately $585.7 million and $571.0 million at the 3 and 7 percent discount rates, respectively.

Table 46.- Alternative 3: Present Discounted Value of Health Benefits Associated with Alternative Effective Date, 20 Year Period After Rule Publication

Panel A: Combined Morbidity and VSL Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$3,324.95	$12,481.34	$35,726.18
	7%	$1,984.42	$7,448.90	$21,319.47
Annualized Value of All Benefits	3%	$223.49	$838.94	$2,401.36
	7%	$187.32	$703.12	$2,012.41

Panel B: Combined Morbidity and QALY Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of All Benefits	3%	$2,321.58	$8,714.37	$24,940.66
	7%	$1,611.68	$6,049.49	$17,312.71
Annualized Value of All Benefits	3%	$156.05	$585.74	$1,676.40
	7%	$152.13	$571.03	$1,634.20

Note: Values are shown in millions of dollars, using 2015 dollar values

b. Estimated Costs under Alternative 3

The timing of reformulation costs shifts under Alternative 3 compared to the proposed rule. In this alternative we assume that there are two additional years to comply with the rule.

With this additional allowance, we expect that smokeless product manufacturers may continue reformulation activities through Year 3. For manufacturers of smokeless tobacco products that need to reformulate, reformulation costs estimated to be incurred in Year 1 in the proposed rule would be incurred in Years 1, 2, and 3 in this alternative. Thus, we assume that manufacturers that need to reformulate their products would do so during the first three years of the 20 year period examined. We also assume that the total undiscounted reformulation costs at the end of the three years would be equal to the total that is incurred in Year 1 under the proposed rule scenario. Specifically, we assume that a manufacturer would incur one third of the total cost in each year from Years 1 through 3. Furthermore, manufacturers that do not need to reformulate would begin incurring other non-reformulation related costs in Year 1. As we expect smokeless tobacco product manufacturers to continue engaging in some reformulation and compliance activities through Year 3, we make the simplifying assumption that all SE reporting costs are shifted by two years and are thus are incurred at the end of Year 3. Combined, this set of simplifying assumptions implies that manufacturers would perform activities needed to bring their products into compliance until after Year 2 and 3, but that their products in commercial distribution are not in compliance until after the additional two year compliance period. We seek data or comments to support other assumptions.

The estimated costs under Alternative 3 are presented in Table 47. Using a 3 percent discount rate and discounting over 20 years, annualized total costs are between $16.22 million and $44.52 million. Similarly, using a 7 percent discount rate, the estimated costs range between $17.56 million and $50.11 million. The primary cost estimate is $30.37 million and $33.83 million using a 3 percent and 7 percent discount rate, respectively. In Appendix Table 10 we present the total costs separately by year in which the total costs are incurred.

Table 47.- Estimated Costs under Alternative 3

Description	Discount Rate	Cost to Industry ($million)			Cost to Government ($million)			Total ($million)		
		Low	Primary	High	Low	Primary	High	Low	Primary	High
Present Discounted Value	3%	$237.45	$438.67	$639.89	$3.89	$13.16	$22.43	$241.33	$451.83	$662.33
Annualized Value	3%	$15.96	$29.49	$43.01	$0.26	$0.88	$1.51	$16.22	$30.37	$44.52
Present Discounted Value	7%	$182.58	$346.87	$511.16	$3.41	$11.58	$19.75	$185.99	$358.44	$530.90
Annualized Value	7%	$17.23	$32.74	$48.25	$0.32	$1.09	$1.86	$17.56	$33.83	$50.11

Note: Cost estimates are discounted over 20 years. Alternative 3 assumes that affected entities have 2 additional years to bring nonconforming products into compliance. Totals are rounded to the nearest hundredth. Totals may not add up due to rounding.

4. Summary of Alternatives to the Proposed Rule

In Table 48 we compare benefit estimates of the alternative policies with estimates for the proposed rule. These estimates focus on combined morbidity and VSL mortality benefits. In the first panel of this table we show estimates of the change in the value of benefits associated with a more stringent NNN standard of not exceeding a mean NNN level of 0.50 micrograms per gram. Relative to the proposed rule, this alternative standard is associated with an increase in primary annualized benefits of approximately $320.9 million at a 3 percent discount rate and $278.5 million at a 7 percent discount rate. In contrast, the less stringent Alternative 2 with the mean NNN level not exceeding 1.50 micrograms per gram of tobacco reduces benefits relative to the proposed rule. This alternative reduces our primary annualized estimates by approximately $227.8 million at a 3 percent discount rate and $197.7 million at a 7 percent discount rate. Finally, Alternative 3, in which there is a longer compliance period, reduces benefits relative to the proposed rule. Our primary estimates of annualized benefits are lower by approximately $226.9 million and $221.8 million at discount rates of 3 and 7 percent, respectively.

Table 48.- Summary of Estimated Change in Present Discounted Value of Combined Morbidity and VSL Mortality between Proposed Rule and Policy Alternatives

Alternative 1: mean NNN level not exceeding 0.50 micrograms per gram

	Discount Rate	Low	Primary	High
Change in Present Discounted Value	3%	$1,250.30	$4,774.14	$14,187.62
	7%	$772.60	$2,950.03	$8,766.46
Change in Annualized Value	3%	$84.04	$320.90	$953.63
	7%	$72.93	$278.46	$827.49

Alternative 2: mean NNN level not exceeding 1.50 micrograms per gram

	Discount Rate	Low	Primary	High
Change in Present Discounted Value	3%	($893.65)	($3,389.48)	($9,922.39)
	7%	($552.21)	($2,094.37)	($6,130.71)

	Discount Rate	Low	Primary	High
Change in Annualized Value	3%	($60.07)	($227.83)	($666.94)
	7%	($52.12)	($197.69)	($578.70)

Alternative 3: Extension of Effective Date

	Discount Rate	Low	Primary	High
Change in Present Discounted Value	3%	($899.54)	($3,376.83)	($9,666.34)
	7%	($625.92)	($2,349.57)	($6,725.13)
Change in Annualized Value	3%	($60.46)	($226.98)	($649.73)
	7%	($59.08)	($221.78)	($634.80)

Note: Values are shown in millions of dollars, using 2015 dollar values. Numbers in parentheses denote a decrease from the proposed rule; all estimates are discounted over 20 years

Table 49 compares the estimated costs under the three alternatives considered with estimated costs of the proposed rule. Under Alternative 1, considering a more stringent NNN standard, total costs increase for both the private and government sectors. Using a 3 percent discount rate, the annualized total change in costs represents an increase by between 130 percent ($23.35 million divided by $17.91 million) and 204 percent ($86.98 million divided by $42.72 million) over the estimated annualized costs under the proposed rule. Similarly, using a 7 percent discount rate the annualized total change in costs represents an increase between 157 percent ($31.56 million divided by $20.11 million) and 233 percent ($117.58 million divided by $50.57 million) over the estimated annualized costs under the proposed rule.

Under Alternative 2, considering a less stringent NNN standard, the total estimated costs would be lower than under the proposed rule. Discounting over 20 years, the primary annualized cost estimate is $5.16 and $6.98 million lower using a 3 percent and 7 percent discount rate, respectively. The estimated reduction in annualized costs is between 12 and 19 percent relative to the annualized costs under the proposed rule using a 3 percent discount rate, and is 15 and 22 percent of annualized costs using a 7 percent discount rate.

Under Alternative 3, the changes in total estimated costs are mixed, depending on the discount rate. Discounting over 20 years, the primary annualized cost estimate is higher by $0.06

million under a 3 percent discount rate, and lower by $1.50 million under a 7 percent discount rate. Relative to the annualized costs of the proposed rule under a 3 percent discount rate, this alternative could decrease total costs by 9 percent or increase costs by 4 percent. Relative to the annualized costs of the proposed rule under a 7 percent discount rate, this alternative could reduce total costs by up to 13 percent.

Table 49.- Estimated Change in Costs Between Proposed Rule and Policy Alternatives

Alternative 1: Mean NNN not to exceed 0.50 micrograms per gram of tobacco on a dry weight basis

Description	Discount Rate	Change in Cost to Industry Relative to the Proposed Rule ($million)			Change in Cost to Government Relative to the Proposed Rule ($million)			Change in Total Cost Relative to the Proposed Rule ($million)		
		Low	Primary	High	Low	Primary	High	Low	Primary	High
Present Discounted Value	3%	$345.51	$814.53	$1,283.54	$1.81	$6.17	$10.54	$347.32	$820.70	$1,294.08
Present Discounted Value	7%	$332.57	$784.05	$1,235.53	$1.74	$5.94	$10.14	$334.31	$789.99	$1,245.67
Annualized Value	3%	$23.22	$54.75	$86.27	$0.12	$0.41	$0.71	$23.35	$55.16	$86.98
Annualized Value	7%	$31.39	$74.01	$116.63	$0.16	$0.56	$0.96	$31.56	$74.57	$117.58

Alternative 2: Mean NNN not to exceed of 1.50 micrograms per gram of tobacco on a dry weight basis

Description	Discount Rate	Change in Cost to Industry Relative to the Proposed Rule ($million)			Change in Cost to Government Relative to the Proposed Rule ($million)			Change in Total Cost Relative to the Proposed Rule ($million)		
		Low	Primary	High	Low	Primary	High	Low	Primary	High
Present Discounted Value	3%	($30.17)	($67.98)	($105.79)	($2.59)	($8.86)	($15.12)	($32.76)	($76.84)	($120.91)
Present Discounted Value	7%	($29.02)	($65.41)	($101.81)	($2.50)	($8.53)	($14.56)	($31.51)	($73.94)	($116.37)
Annualized Value	3%	($2.03)	($4.57)	($7.11)	($0.17)	($0.60)	($1.02)	($2.20)	($5.16)	($8.13)
Annualized Value	7%	($2.74)	($6.17)	($9.61)	($0.24)	($0.80)	($1.37)	($2.97)	($6.98)	($10.98)

Alternative 3: Extension of Effective Date

Description	Discount Rate	Change in Cost to Industry Relative to the Proposed Rule ($million)			Change in Cost to Government Relative to the Proposed Rule ($million)			Change in Total Cost Relative to the Proposed Rule ($million)		
		Low	Primary	High	Low	Primary	High	Low	Primary	High
Present Discounted Value	3%	($24.83)	$1.72	$28.28	($0.26)	($0.87)	($1.47)	($25.09)	$0.86	$26.80
Present Discounted Value	7%	($26.51)	($14.21)	($1.92)	($0.50)	($1.71)	($2.91)	($27.01)	($15.92)	($4.83)
Annualized Value	3%	($1.67)	$0.12	$1.90	($0.02)	($0.06)	($0.10)	($1.69)	$0.06	$1.80
Annualized Value	7%	($2.50)	($1.34)	($0.18)	($0.05)	($0.16)	($0.27)	($2.55)	($1.50)	($0.46)

Notes: Costs are annualized over 20 years. Estimates are rounded to the nearest hundredth. Totals may not add up due to rounding.

Table 48 and Table 49 summarize the change in benefits and costs between each of the alternatives and the proposed rule. Next we discuss the estimated net benefits (benefits minus costs) under each scenario. We note that net benefits are shown separately under each of the two methodologies utilized to estimate benefits, and these are presented in Table 50 (combined morbidity and VSL mortality) and Table 51 (combined morbidity and QALY mortality). Alternative 1 (establishing a more stringent NNN standard) would maximize net benefits compared to the proposed rule and the other two alternatives examined in this section. Alternative 1 results in the largest net benefits, followed by the Proposed Rule, Alternative 2 (less stringent NNN standard), and Alternative 3 (extended effective date). Based on these estimates, Alternative 1 maximizes quantifiable net benefits. As discussed in the preamble, however, there is limited information to support an NNN level below 1.0 µg/g. In addition, there is greater uncertainty manufacturers will be able to achieve a more stringent NNN standard. Few currently available products, with the exception of dissolvable tobacco, are consistently below an NNN level of 0.5 µg/g. We request comments on the benefits and costs associated with a more stringent NNN standard. Considering the uncertainties about the effects of Alternative 1, the next best alternative that maximizes net benefits is the Proposed Rule.

Table 50.- Estimated Net Benefits of the Proposed and Policy Alternatives: Estimated Morbidity and VSL Mortality Benefits minus Costs ($millions)

Scenario	Description	Low	Primary	High
Proposed Rule	Present Discounted Value, 3%	$3,958.06	$15,407.20	$44,757.00
	Present Discounted Value, 7%	$2,397.34	$9,424.11	$27,508.87
	Annualized, 3%	$266.04	$1,035.61	$3,008.37
	Annualized, 7%	$226.29	$889.57	$2,596.64
Alternative 1: mean NNN not to exceed 0.50 micrograms per gram	Present Discounted Value, 3%	$4,861.05	$19,360.64	$57,650.54
	Present Discounted Value, 7%	$2,835.64	$11,584.14	$35,029.66
	Annualized, 3%	$326.74	$1,301.34	$3,875.02
	Annualized, 7%	$267.66	$1,093.46	$3,306.55
Alternative 2: mean NNN not to exceed 1.50 micrograms per gram	Present Discounted Value, 3%	$3,097.17	$12,094.56	$34,955.52
	Present Discounted Value, 7%	$1,876.65	$7,403.68	$21,494.53
	Annualized, 3%	$208.18	$812.94	$2,349.56
	Annualized, 7%	$177.14	$698.85	$2,028.93
Alternative 3: Extension of Effective Date	Present Discounted Value, 3%	$3,089.50	$12,016.87	$34,807.81
	Present Discounted Value, 7%	$1,872.15	$7,345.66	$21,382.99
	Annualized, 3%	$207.66	$807.72	$2,339.63
	Annualized, 7%	$176.72	$693.38	$2,018.40

Notes: All estimates are discounted over 20 years.

Table 51.- Estimated Net Benefits of the Proposed Rule and Policy Alternatives: Estimated Morbidity and QALY Mortality Benefits minus Costs ($millions)

Scenario	Description	Low	Primary	High
Proposed Rule	Present Discounted Value, 3%	$2,667.65	$10,562.55	$30,885.90
	Present Discounted Value, 7%	$1,899.41	$7,554.71	$22,156.46
	Annualized, 3%	$179.31	$709.97	$2,076.02
	Annualized, 7%	$179.29	$713.11	$2,091.41
Alternative 1: mean NNN not to exceed 0.50 micrograms per gram	Present Discounted Value, 3%	$3,097.17	$12,094.56	$34,955.52
	Present Discounted Value, 7%	$1,876.65	$7,403.68	$21,494.53
	Annualized, 3%	$208.18	$812.94	$2,349.56
	Annualized, 7%	$177.14	$698.85	$2,028.93
Alternative 2: mean NNN not to exceed 1.50 micrograms per gram	Present Discounted Value, 3%	$2,079.71	$8,285.28	$24,115.91
	Present Discounted Value, 7%	$1,484.05	$5,933.80	$17,311.87
	Annualized, 3%	$139.79	$556.90	$1,620.97
	Annualized, 7%	$140.08	$560.11	$1,634.12
Alternative 3: Extension of Effective Date	Present Discounted Value, 3%	$2,072.04	$8,207.59	$23,968.20
	Present Discounted Value, 7%	$1,479.54	$5,875.77	$17,200.33
	Annualized, 3%	$139.27	$551.68	$1,611.04
	Annualized, 7%	$139.66	$554.63	$1,623.59

Notes: All estimates are discounted over 20 years.

III. Small Entity Effects

A. Description and Number of Affected Small Entities

FDA has examined the economic implications of this proposed rule for small entities as required by the Regulatory Flexibility Act. If a 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 rule on small entities. FDA finds that the proposed rule would have a significant economic impact on a substantial number of small entities. Consequently, this analysis, together with other relevant sections of the economic analysis and the rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

This proposed rule would primarily affect tobacco product manufacturers of smokeless tobacco products. Manufacturers of tobacco products covered by this final rule would be designated under the North American Industry Classification System (NAICS) (312230) as "tobacco product manufacturers." The Small Business Administration (SBA) classifies an entity in this NAICS code as a "small business" if it employs fewer than 1,500 employees. (SBA, 2016). While the U.S. Census does not define what a small business is data sources such as the Statistics of US Businesses report data as "small businesses" for entities that employ fewer than 500 employees (Statistics of the U.S. Businesses, 2013).

Table 52 shows the number of businesses with employees in each of the categories described above. We note that there were three companies for which we had no data on employment size. For two of the three companies, revenue was also missing; FDA took a conservative approach and assumed that these companies would be considered small under the

SBA standards.[28] We categorized the third company, for which revenue data were available, as large (non-small) under the SBA standard because annual revenues for this firm were comparable to that of other non-small firms for which employment data exists. Thus, under the SBA standard, 72% of the entities would be considered small.

Another data limitation is that we were not able to individually identify any sales information for two small entities. In addition, for one non-small entity we could only identify corporate sales but not sales specific to smokeless tobacco products, and for a separate non-small entity we were not able to identify sales for one brand of smokeless tobacco product. However, using total industry data we estimate that the revenue that is not captured from these companies represent approximately 6 percent of total smokeless tobacco industry sales (or $314.51 million).[29] These estimates indicate that the revenue of non-small firms represent at least 94 percent of total smokeless tobacco industry sales, with 2% of the total smokeless tobacco industry sales captured by small firms with fewer than 50 employees (see Table 52).

We note that Table 52 presents both the smokeless tobacco revenue and corporate revenue information. This is because there are firms—non-small firms--that manufacture smokeless and non-smokeless tobacco products. Unlike non-small entities, small entities manufacture only smokeless tobacco products, and for this reason their corporate revenue and their smokeless tobacco revenue is the same. For purposes of this analysis, the impact to entities is determined relative to overall company sales. Using the available data, the average revenue per firm is $12.16 million among the firms with fewer than 50 employees, $58.32 million with

[28] Given the Census threshold is lower than the SBA threshold we determined there was not enough information to assess whether these companies that had missing employee information would be small or large according to the Census definition.

[29] We identified total sales of $5.09 billion among the entities with non-missing data. According to Nielsen, Inc., 2015 industry sales in smokeless tobacco included $5.408 billion dollars. Six percent ($314.51 million) is determined by dividing the revenue from the captured data by $5.408 billion.

employment size between 50 and 100. Among all SBA "small" firms, the average revenue is $16.46 million. The average revenue is $12.50 billion for non-small firms for which we have employee information. One firm with missing employee information that we designated as non-small has annual revenues of $3.8 billion.

Table 52.- Estimated Percentage of Small Firms Among Firms With Employees

Company Size by SBA Standard[a]	Employee Size	Number of Firms	Percent of Total	Smokeless Tobacco Revenue[b, c] ($million)	Corporate Revenue[c] ($million)	Average Smokeless Tobacco Revenue[c] ($million)	Average Corporate Revenue[c] ($million)
Small	Missing	2	11%	N/A	N/A	N/A	N/A
	<50	8	44%	$97.31	$97.31	$12.16	$12.16
	50-100	2	11%	$116.64	$116.64	$58.32	$58.32
	500-1499	1	6%	N/A	N/A	N/A	N/A
	Subtotal	**13**	**72%**	**$213.96**	**$213.96**	**$16.46**	**$16.46**
Non-small	Missing	1	6%	N/A	$3,850.71	N/A	$3,850.71
	1500+	4	22%	$4,879.53	$50,012.79	$1,219.88	$12,503.20
	Subtotal	**5**	**28%**	**$4,879.53**	**$53,863.51**	**$975.91**	**$10,772.70**
Total		**18**	**100%**	**$5,093.49**	**$54,077.46**	**$282.97**	**$3,004.30**

Notes: a. There are three firms with missing employee information, two of which have also missing revenue information; the two firms with missing revenue and employee information are assumed to be small, and the one firm with only missing employee information is assumed to be non-small according to SBA standards. b. Total smokeless industry revenue is from Nielsen Inc. in 2015 was reported to be $5.41 billion; the revenue captured by the data captured approximately 95% of the smokeless tobacco industry revenue. This includes one non-small company for which no smokeless tobacco products sales could be identified and another non-small company for which sales of one smokeless tobacco brand could not be disaggregated from other non-smokeless tobacco sales. c. N/A denotes data were not available. Company revenue is rounded to the nearest hundredth. Totals may not add up due to rounding.

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

We calculate costs per small entity by dividing total industry costs by the number of entities affected, which we conduct separately for the number of manufacturers and the number of firms.

Before doing so, we present again a summary of the costs in Table 53. These costs are disaggregated by the timing in which they are incurred. Furthermore, because reformulation costs were calculated based on firm revenue, we also present the reformulation costs that are associated with companies that are small or non-small according to the SBA. Specifically, based on the data it was determined that the costs associated with firm revenue below $500 million included firms that would be considered small under the SBA definition, and non-small if revenue is $500 million or greater.[30]

[30] For purposes of the reformulation cost model, a firm with revenue below $1 million was classified as "small", a firm with revenue over $1 million and below $500 million was considered medium, and firms with revenue over $500 were considered large.

Table 53.- Summary of Costs to Industry ($million)

Panel A. Itemized Costs

Cost Activity	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Stability Testing	$13.17	$13.17	$13.17				$5.27	$5.27	$5.27
Batch Testing				$1.10	$2.74	$4.39			
Reformulation Costs									
SBA Small: Companies with revenue $1-$500 million	$20.34	$49.35	$78.35						
SBA Non-small: Companies with revenue greater than $500 million	$59.78	$136.31	$212.84						
Review of Regulation/No formulation									
SBA Small: Companies with revenue $1-$500 million	$1.91	$4.65	$7.38						
SBA Non-small: Companies with revenue greater than $500 million	$4.11	$9.95	$15.78						
Labeling	$0.84	$2.12	$3.40						
Substantial Equivalence Reports	$2.12	$2.84	$3.56						
Nonconforming Products	$0.02	$0.07	$0.12				$5.15	$7.78	$10.41
Reporting Costs--Alternative Testing Method	$0.00	$0.02	$0.03				$0.00	$0.00	$0.01
Recordkeeping Costs				$0.01	$0.04	$0.08	$0.12	$0.14	$0.16

Panel B. Total Costs to Industry

Cost Activity	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Reformulation Costs: SBA Small[1]	$22.25	$53.99	$85.74						
Reformulation Costs: SBA Non-small[2]	$63.88	$146.25	$228.62						
All other Costs[3]	$16.15	$18.22	$20.29	$1.11	$2.79	$4.47	$10.53	$13.18	$15.84
Total Costs to Industry	**$102.28**	**$218.47**	**$334.65**	**$1.11**	**$2.79**	**$4.47**	**$10.53**	**$13.18**	**$15.84**

Notes: 1. SBA Small includes firms with revenue less than $1million. 2. SBA Non-small includes firms with revenue between $1 and $500 million. 3. All Other Costs include stability and batch testing, labeling, substantial equivalence reports, nonconforming products, reporting costs, and recordkeeping costs which combine SBA Small and SBA Non-small entities. Estimates are rounded to the nearest hundredth. Totals may not add up due to rounding.

Using the information from Table 52, we first estimate the average per firm and present it in Table 54. This is determined by dividing the total cost by cost category by the number of entities covered by the proposed rule in each cost category. The average industry cost of the proposed rule is then used to determine the percentage of average sales that the estimated costs would represent for the average firm. Specifically, the average reformulation costs for SBA small entities is based on 13 small entities, while the average reformulation costs for SBA Non-small entities is based on 5 entities. The overall estimates are disaggregated by cost activity. Reformulation costs, which vary by firm size, are also disaggregated by firm size as determined by the SBA size standard. The average cost in Year 1 (one-time and recurring), the largest of all the estimated costs, is estimated to be between $2.67 million and $7.97 million for small firms and between $13.74 million and $47.10 million for non-small firms. We further investigate the impact on small entities by estimating the average cost as a percent of sales for entities with fewer than 50 employees (see Table 55) and separately for those with 50-100 employees (see Table 56) For small firms—particularly those with fewer than 50 employees—most of the impact is derived from costs associated with submission of substantial equivalence reports and reformulation and testing requirements. For firms with fewer than 50 employees, the estimated one-time costs from reformulation account for about 54 percent of average revenue, substantial equivalence submissions account for about 2 percent, and stability testing costs account for up to 6 percent. If the estimated costs associated with activities to address nonconforming products were entirely attributed to small firms then the estimated costs represent at most 5 percent of their average sales. However, we have uncertainty regarding the distribution of nonconformance by firm size. These small firms with fewer than 50 employees represent at least 49 percent of all entities (8 of 18 entities) in the smokeless tobacco industry, covering about 130 different

products, and employing at least 170 individuals combined. For small firms with 50-100 employees, reformulation costs remain the largest percentage (between 3.0 and 11.0 percent) of total costs in Year 1, followed by stability testing costs at 1.25 percent. The combined number of employees for firms categorized with 50-100 employees each is 175. We estimate that small firms categorized with fewer than 100 employees each, combined employ at least 20 percent the total number of employees (345 divided by 1745) among all firms (those with fewer than 1500 employees) that are considered small under SBA standards. Thus, FDA anticipates that the proposed rule would have a significant impact on a substantial number of entities. There is some uncertainty as to the extent that small entities would engage in formulation activities as opposed to purchasing through contract manufacturing. FDA seeks data or comments on this issue.

Table 54.- Average Cost Per Firm ($million)

Panel A. Itemized Costs

Cost Activity	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Stability Testing	$0.73	$0.73	$0.73				$0.29	$0.29	$0.29
Batch Testing				$0.06	$0.15	$0.24			
Reformulation Costs									
SBA Small: Companies with revenue $1-$500 million	$1.56	$3.80	$6.03						
SBA Non-small: Companies with revenue greater than $500 million	$11.96	$27.26	$42.57						
Review of Regulation/No formulation									
SBA Small: Companies with revenue $1-$500 million	$0.15	$0.36	$0.57						
SBA Non-small: Companies with revenue greater than $500 million	$0.82	$1.99	$3.16						
Labeling	$0.05	$0.12	$0.19						
Substantial Equivalence Reports	$0.12	$0.16	$0.20						
Nonconforming Products	$0.00	$0.00	$0.01				$0.29	$0.43	$0.58
Reporting Costs--Alternative Testing Method	$0.00	$0.00	$0.00				$0.00	$0.00	$0.00
Recordkeeping Costs									

Panel B. Average Cost to Industry (per firm)

Cost Activity	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Reformulation Costs: SBA Small	$1.71	$4.15	$6.60						
Reformulation Costs: SBA Non-small	$12.78	$29.25	$45.72						
All other Costs[1]	$0.90	$1.01	$1.13	$0.06	$0.15	$0.25	$0.59	$0.73	$0.88

Panel C. Average Total to Industry by Firm Size

Cost Activity	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
SBA Small[2]	$2.61	$5.17	$7.72	$0.06	$0.15	$0.25	$0.59	$0.73	$0.88
SBA Non-small[3]	$13.67	$30.26	$46.85	$0.06	$0.15	$0.25	$0.59	$0.73	$0.88

Cost Activity	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Average: Small and Non-small	**$5.68**	**$12.14**	**$18.59**	**$0.06**	**$0.15**	**$0.25**	**$0.59**	**$0.73**	**$0.88**

Notes: 1. All Other Costs include stability and batch testing, labeling, substantial equivalence reports, nonconforming products, reporting costs, and recordkeeping costs which combine SBA Small and SBA Non-small entities. 2 SBA Small is the sum of "Reformulation Costs: SBA Small" and "All Other Costs". 3. SBA Non-small is the sum of "Reformulation Costs: SBA Non-small" and "All Other Costs". Estimates denoted in millions are rounded to the nearest hundredth. Totals may not add up due to rounding.

Table 55.- Average Estimated Cost per Firm as a Percent of Average Sales: Firm with Fewer than 50 Employees

Cost Activity	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Stability Testing	6.02%	6.02%	6.02%				2.41%	2.41%	2.41%
Batch Testing				0.50%	1.25%	2.01%			
Reformulation Costs									
SBA Small: Companies with revenue $1-$500 million	12.86%	31.20%	49.55%						
SBA Non-small: Companies with revenue greater than $500 million									
Review of Regulation/No formulation									
SBA Small: Companies with revenue $1-$500 million	1.21%	2.94%	4.67%						
SBA Non-small: Companies with revenue greater than $500 million									
Labeling	0.38%	0.97%	1.56%						
Substantial Equivalence Reports	0.97%	1.30%	1.63%						
Nonconforming Products	0.01%	0.03%	0.05%				2.35%	3.55%	4.75%

Cost Activity	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Reporting Costs--Alternative Testing Method	0.00%	0.01%	0.02%				0.00%	0.00%	0.00%
Recordkeeping Costs				0.01%	0.02%	0.04%	0.05%	0.06%	0.07%
Total	**21.44%**	**42.46%**	**63.48%**	**0.51%**	**1.27%**	**2.04%**	**4.81%**	**6.02%**	**7.23%**

Notes: Estimates are rounded to the nearest hundredth. Totals may not add up due to rounding.

Table 56.- Average Estimate Cost as Percent of Average Sales: Firms with 50-100 Employees

Cost Activity	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Stability Testing	1.25%	1.25%	1.25%				0.50%	0.50%	0.50%
Batch Testing				0.10%	0.26%	0.42%			
Reformulation Costs									
SBA Small: Companies with revenue $1-$500 million	2.68%	6.51%	10.33%						
SBA Non-small: Companies with revenue greater than $500 million									
Review of Regulation/No formulation									
SBA Small: Companies with revenue $1-$500 million	0.25%	0.61%	0.97%						
SBA Non-small: Companies with revenue greater than $500 million									
Labeling	0.08%	0.20%	0.32%						
Substantial Equivalence	0.20%	0.27%	0.34%						

Cost Activity	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Reports									
Nonconforming Products	0.00%	0.01%	0.01%				0.49%	0.74%	0.99%
Reporting Costs--Alternative Testing Method	0.00%	0.00%	0.00%				0.00%	0.00%	0.00%
Recordkeeping Costs				0.00%	0.00%	0.01%	0.01%	0.01%	0.02%
Total	**4.47%**	**8.86%**	**13.24%**	**0.11%**	**0.27%**	**0.43%**	**1.00%**	**1.26%**	**1.51%**

Notes: Estimates are rounded to the nearest hundredth. Totals may not add up due to rounding.

C. Alternatives to Minimize the Burden on Small Entities

Because approximately 72 percent of entities that would be affected by the proposed rule are estimated to be small, the regulatory alternatives Alternative 2 (establish a less stringent NNN standard) and Alternative 3 (extension of the effective date) analyzed in section II.G that would reduce costs for affected entities also offer potential regulatory relief options for small businesses. Here, we show the possible reductions in costs per establishment under these alternatives, which would largely be channeled through small businesses. We also note that elimination of individual provisions would provide relief.

Table 54 above can aid the interested reader in determining the relief that would be provided by eliminating specific provisions.

1. Establish an NNN Maximum Standard of not exceeding a mean NNN level of 1.50 micrograms per gram of Tobacco (Regulatory Alternative 2)

Panel A of Table 57 presents the average cost per small or non-small entity under Alternative 2. For comparison, in Panel B of Table 57 we present the change in average cost per firm between Alternative 2 and the Proposed Rule (Appendix Table 11 provides the average cost per firm by activity in more detail). Because Alternative 2 reduces the total number of reformulations that are affected, there is a reduction in total costs as well as in the average cost per entity. Under this alternative, the average cost per firm decreases by a range between $0.47 million and $1.68 million for small entities, which results in up to a 22 percent (=$1.68 million reduction in costs between Alternative 2 and the Proposed Rule÷ $7.72 million in costs from the Proposed Rule) reduction in one-time Year 1 costs from the proposed rule. Using the average cost per small firm as a percent of average sales in Alternative 2 and comparing it to the

Proposed Rule, we estimate that for small entities that are categorized as having fewer than 50 employees each, this alternative would reduce their burden by up to 14 percentage points as a percentage of revenue in Year 1 (=($6.29 million in estimated costs under Alternative 2 ÷ $12.16 million in average revenue for small firms categorized with fewer than 50 employees each) minus ($7.97 million in estimated costs under the Proposed Rule ÷ $12.16 million in average revenue for small firms categorized with fewer than 50 employees each). Similarly, for small entities categorized as having between 50 and 100 employees each, this alternative would reduce their burden by up to 3 percentage points as a percentage of revenues. The reduction arises from a lower reformulation costs.

Table 57.- Average Cost per Firm Under Alternative 2 (Less Stringent NNN Standard), and Its Impact on Small Entities

Panel A. Average Cost per Firm under Alternative 2 (mean NNN not to exceed 1.50 microgram/gram of tobacco) ($million)

Description[1]	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Reformulation Costs	$1.31	$3.17	$5.04						
All Other Costs[2]	$0.83	$0.92	$1.01	$0.06	$0.15	$0.25	$0.58	$0.73	$0.88
Average Total Cost: SBA Small	$2.14	$4.09	$6.04	$0.06	$0.15	$0.25	$0.58	$0.73	$0.88

Panel B. Change in Average Cost per Firm between Alternative 2 (mean NNN not to exceed 1.50 microgram/gram of tobacco) and the Proposed Rule (mean NNN not to exceed 1.0 microgram/gram of tobacco) ($million)

Description[1]	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Reformulation Costs	($0.41)	($0.98)	($1.56)						
All Other Costs[2]	($0.07)	($0.09)	($0.12)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Average Total Cost: SBA Small	($0.47)	($1.08)	($1.68)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00

Panel C. Change in Average Cost as a Percent of Average Revenue between Alternative 2 and the Proposed Rule by Small Entity Size (Percentage Points, pct. pt.)[3]

Description[1]	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
SBA Small: <50 Employees	-3.89 pct. pt.	-8.84 pct. pt.	-13.80 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.

Description[1]	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
SBA Small: 50-100 Employees	-0.81 pct. pt.	-1.84 pct. pt.	-2.88 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.
SBA Small	-2.88 pct. pt.	-6.54 pct. pt.	-10.20 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.	0.00 pct. pt.

Note: 1. Estimates in parentheses denote a reduction in costs between the policy alternative and the proposed rule in Panels A and B. In Panel C, a negative sign denotes a reduction in average cost as a percent of average revenue in percentage points. 2. All Other Costs include stability and batch testing, labeling, substantial equivalence reports, nonconforming products, reporting costs, and recordkeeping costs which are the same for both SBA Small and SBA Non-small entities. 2 SBA Small is the sum of "Reformulation Costs" and "All Other Costs". 3. "pct. pt." denotes percentage point. Estimates are rounded to the nearest hundredth. Totals may not add up due to rounding.

2. Extension of the Effective Date (Regulatory Alternative 3)

Panel A of Table 58 presents the average cost per small entity under Alternative 3. For comparison, in Panel B of Table 58 we present the change in average cost per firm between Alternative 3 and the Proposed Rule. (Appendix Table 12 provides the average cost per firm by activity in more detail.) Because Alternative 3 spreads upfront reformulation costs into the first three years, the average cost per entity decreases initially. Under this alternative, the average cost per firm decreases the most in Year 1 (by about $2 million (=$0.67 million under Alternative 3 minus $2.67 million[31] under the Proposed Rule) to $5.39 million dollars (=$2.58 million under Alternative 3 minus $7.97 million[32] under the Proposed Rule) per small entity), costs under this alternative are reduced by at least 68 percent (=$5.39 million in cost reductions between Alternative 3 and the Proposed Rule ÷ $7.97 million in costs under the Proposed Rule) of the estimated costs under Proposed Rule. For small entities that are categorized as having fewer than 50 employees each, this alternative would reduce their burden by between 16 (=5.49 percent of average revenue under Alternative 3 minus 21.95 percent of average revenue under the Proposed Rule) and 44 (=21.18 percent of average revenue minus 65.51 percent of average revenue) percentage points as a percentage of revenue. Similarly, for small entities categorized as having between 50 and 100 employees each, this alternative would reduce their burden by up to 9 percentage points. We note that under this alternative, although firms would have more time to bring their products into compliance, the total reformulation costs under this alternative remain the same as those under the proposed rule with the difference that under this alternative, the costs

31 Year 1 costs include one-time and recurring costs anticipated to be incurred in Year 1. Under the proposed rule, one-time and recurring costs incurred in Year 1 are estimated to be $2.61 million and $0.06 million for the low bound, respectively.

32 Year 1 costs include one-time and recurring costs anticipated to be incurred in Year 1. Under the proposed rule, one-time and recurring costs incurred in Year 1 are estimated to be $7.72 million and $0.25 million for the high bound, respectively.

are distributed among the first three years rather occurring all in the first year as assumed under the proposed rule.

Table 58.- Average Cost per Firm under Alternative 3 (Extended Effective Date) and Its Impact on Small Entities

Panel A. Average Cost per Firm under Alternative 3 (extended effective date) ($million)

Description[1]	Year 1			Year 2			Year 3			Year 4 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
Reformulation Costs	$0.67	$1.62	$2.58	$0.52	$1.27	$2.01	$0.52	$1.27	$2.01	$0.00	$0.00	$0.00
All Other Costs[2]	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.96	$1.53	$2.11	$0.65	$1.03	$1.42
Average Total Cost: SBA Small	$0.67	$1.62	$2.58	$0.52	$1.27	$2.01	$1.48	$2.80	$4.12	$0.65	$1.03	$1.42

Panel B. Change in Average Cost per Firm between Alternative 3 (extended effective date) and the Proposed Rule ($million)

Description[1]	Year 1			Year 2			Year 3			Year 4 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
Reformulation Costs: SBA Small	($1.04)	($2.53)	($4.02)	$0.52	$1.27	$2.01	$0.52	$1.27	$2.01	$0.00	$0.00	$0.00
All Other Costs[2]	($0.96)	($1.17)	($1.37)	($0.65)	($0.89)	($1.13)	$0.31	$0.65	$0.98	$0.00	$0.15	$0.29
Average Total Cost: SBA Small	($2.00)	($3.70)	($5.39)	($0.13)	$0.38	$0.88	$0.83	$1.91	$2.99	$0.00	$0.15	$0.29

Panel C. Change in Average Cost as a Percent of Average Revenue between Alternative 3 and the Proposed Rule by Small Entity Size (Percentage Points, pct.pt.)

Description[1]	Year 1			Year 2			Year 3			Year 4 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
SBA Small: <50 Employees	-16.46 pct.pt.	-30.39 pct.pt.	-44.32 pct.pt.	-1.03 pct.pt.	3.11 pct.pt.	7.24 pct.pt.	6.85 pct.pt.	15.71 pct.pt.	24.57 pct.pt.	0.00 pct.pt.	1.20 pct.pt.	2.41 pct.pt.
SBA Small: 50-100 Employees	-3.43 pct.pt.	-6.34 pct.pt.	-9.25 pct.pt.	-0.21 pct.pt.	0.65 pct.pt.	1.51 pct.pt.	1.43 pct.pt.	3.28 pct.pt.	5.12 pct.pt.	0.00 pct.pt.	0.25 pct.pt.	0.50 pct.pt.
SBA Small	-12.16 pct.pt.	-22.46 pct.pt.	-32.76 pct.pt.	-0.76 pct.pt.	2.30 pct.pt.	5.35 pct.pt.	5.07 pct.pt.	11.61 pct.pt.	18.16 pct.pt.	0.00 pct.pt.	0.89 pct.pt.	1.78 pct.pt.

Note: 1. Estimates in parentheses denote a reduction in costs between the policy alternative and the proposed rule in Panels A and B. In Panel C, a negative sign denotes a reduction in average cost as a percent of average revenue in percentage points. 2. All Other Costs include stability and batch testing, labeling,

substantial equivalence reports, nonconforming products, reporting costs, and recordkeeping costs which are the same for both SBA Small and SBA Large entities. 2 SBA Small is the sum of “Reformulation Costs” and “All Other Costs”. 3. “pct. pt.” denotes percentage point. Estimates denoted in millions are rounded to the nearest hundredth. Totals may not add up due to rounding.

3. Summary of Alternatives to Small Entities

Table 59 presents the average firm level cost to small entities using the SBA definition of "small" under the Proposed Rule, and Alternatives 2 and 3. We note that for brevity, this table presents the combined costs—one time and ongoing—incurred in any given year. Table 59 indicates that the lowest average costs in Year 1 are estimated under Alternative 3. However, under Alternative 3, the upper bound estimates in Year 2 and Year 3 are the highest compared to the other policy alternatives. This is because under Alternative 3, the reformulation costs are distributed across the first three years without reducing the total cost as estimated in the Proposed Rule scenario. In addition, in Alternative 3, most costs are shifted by two years, and in Year 3 each small entity would also incur costs associated with SE submissions.

While a comparison of the average cost is useful, the timing of costs makes an apples-to-apples comparison difficult. For ease of comparison, Table 60 presents the estimated discounted costs over 20 years using a 3 percent and 7 percent discount rate under the proposed rule, and Alternatives 2 and 3 (Appendix Table 13 provides the discounted cost estimates by major cost activity). Discounting over 20 years, the average total cost per entity is smallest under Alternative 2 (establish an NNN standard of 1.50 micrograms per gram of tobacco). Most of the reduction arises from reformulation costs. In Alternative 3, the lower bound estimates are reduced disproportionately relative to the Proposed Rule because reformulation costs and other recurring costs are distributed across the first three years. Similarly, the upper bound estimates are higher under Alternative 3 relative to the Proposed Rule because costs associated with SE reports as well as nonconforming products are incurred later.

Table 59.- Summary of Average Cost per Small Entity: Comparison of the Proposed Rule and Policy Alternatives ($million)

Panel A. Proposed Rule

Average Cost	Year 1			Year 2			Year 3			Year 4 and on		
	Low	High	Primary	Low	High	Primary	Low	Primary	High	Low	Primary	High
Reformulation	$1.71	$4.15	$6.60	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Other Costs	$0.96	$1.17	$1.37	$0.65	$0.89	$1.13	$0.65	$0.89	$1.13	$0.65	$0.89	$1.13
Total	**$2.67**	**$5.32**	**$7.97**	**$0.65**	**$0.89**	**$1.13**	**$0.65**	**$0.89**	**$1.13**	**$0.65**	**$0.89**	**$1.13**

Panel B. Alternative 2: NNN Standard of 1.50 micrograms per gram

Average Cost	Year 1			Year 2			Year 3			Year 4 and on		
	Low	High	Primary	Low	High	Primary	Low	Primary	High	Low	Primary	High
Reformulation	$1.31	$3.17	$5.04	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Other Costs	$0.89	$1.07	$1.26	$0.65	$0.89	$1.13	$0.65	$0.89	$1.13	$0.65	$0.89	$1.13
Total	**$2.20**	**$4.24**	**$6.29**	**$0.65**	**$0.89**	**$1.13**	**$0.65**	**$0.89**	**$1.13**	**$0.65**	**$0.89**	**$1.13**

Panel C. Alternative 3: Extension of Effective Date

Average Cost	Year 1			Year 2			Year 3			Year 4 and on		
	Low	High	Primary	Low	High	Primary	Low	Primary	High	Low	Primary	High
Reformulation	$0.67	$1.62	$2.58	$0.52	$1.27	$2.01	$0.52	$1.27	$2.01	$0.00	$0.00	$0.00
Other Costs	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.96	$1.53	$2.11	$0.65	$1.03	$1.42
Total	**$0.67**	**$1.62**	**$2.58**	**$0.52**	**$1.27**	**$2.01**	**$1.48**	**$2.80**	**$4.12**	**$0.65**	**$1.03**	**$1.42**

Note: Each period combines one-time as well as recurring costs and for this reason the totals in Year 1 may differ in this table from those presented in

Table 60.- Summary of Impact to Small Entities: Comparison between Proposed Rule and Policy Alternatives

Policy	Description	Average Firm Cost to SBA Small Entities ($million)			Change in Average Cost between Proposed Rule and Policy Alternative ($million)			Percent Change in Average Cost between Proposed Rule and Policy Alternative (%)		
		Low	Primary	High	Low	Primary	High	Low	Primary	High
Proposed Rule	Net Present Value, 3%	$11.59	$17.51	$23.42	N/A	N/A	N/A	N/A	N/A	N/A
	Annualized Value, 3%	$0.78	$1.18	$1.57	N/A	N/A	N/A	N/A	N/A	N/A
	Net Present Value, 7%	$8.74	$13.54	$18.34	N/A	N/A	N/A	N/A	N/A	N/A
	Annualized Value, 7%	$0.83	$1.28	$1.73	N/A	N/A	N/A	N/A	N/A	N/A
Alternative 2: Mean NNN level not to exceed 1.50 micrograms per gram	Net Present Value, 3%	$11.12	$16.46	$21.79	($0.46)	($1.05)	($1.63)	-4.01	-5.99	-6.97
	Annualized Value, 3%	$0.75	$1.11	$1.46	($0.03)	($0.07)	($0.11)	-4.01	-5.99	-6.97
	Net Present Value, 7%	$8.30	$12.54	$16.77	($0.45)	($1.01)	($1.57)	-5.10	-7.44	-8.56
	Annualized Value, 7%	$0.78	$1.18	$1.58	($0.04)	($0.10)	($0.15)	-5.10	-7.44	-8.56
Alternative 3: Extension of Effective Date	Net Present Value, 3%	$10.29	$17.78	$25.28	($1.30)	$0.28	$1.86	-11.21	1.59	7.93
	Annualized Value, 3%	$0.69	$1.20	$1.70	($0.09)	$0.02	$0.12	-11.21	1.59	7.93
	Net Present Value, 7%	$7.44	$13.14	$18.85	($1.30)	($0.40)	$0.50	-14.87	-2.94	2.74
	Annualized Value, 7%	$0.70	$1.24	$1.78	($0.12)	($0.04)	$0.05	-14.87	-2.94	2.74

Note: 1. Estimates in parentheses denote a reduction in costs between the policy alternative and the proposed rule in Panels A and B. In Panel C, a negative sign denotes a reduction in average cost as a percent of average revenue in percentage points. Average firm cost is discounted over 20 years.

IV. Appendix

Appendix Table 1.- Per-formula Costs of Reformulation, by Company Size and Reformulation Complexity

Reformulation Activity	Low Complexity			Medium Complexity			High Complexity		
	Small Company	Medium Company	Large Company	Small Company	Medium Company	Large Company	Small Company	Medium Company	Large Company
Determine response to regulation	$2,044	$23,052	$42,492	$2,044	$23,052	$42,492	$2,044	$23,052	$42,492
Project management	$6,260	$111,612	$223,042	$12,521	$173,618	$346,954	$18,781	$254,226	$508,039
Production scale-up testing	$10,010	$140,720	$338,120	$13,010	$160,720	$294,120	$13,010	$160,720	$388,120
Recordkeeping	$536	$120,720	$320,580	$536	$120,720	$320,580	$536	$120,720	$320,580
Analytical tests	$975	$975	$975	$975	$975	$975	$975	$975	$975
Consumer tests	$0	$38,250	$265,016	$0	$38,250	$265,016	$0	$38,250	$265,016
Total if company reformulates	**$19,825**	**$435,329**	**$1,190,225**	**$29,086**	**$517,335**	**$1,270,137**	**$35,346**	**$597,943**	**$1,525,222**
Total if company does not reformulate	**$2,580**	**$143,772**	**$363,072**	**$2,580**	**$143,772**	**$363,072**	**$2,580**	**$143,772**	**$363,072**

Notes: In the reformulation model, “small companies” include firms with sales under $1 million, “medium-size companies” are those with sales between $1 and $500 million, and “large companies” are those with sales greater than $500 million.

Appendix Table 2.- Estimated Costs of the Proposed Rule Incurred Over a 20-year Period

Year	Cost to Industry ($million)			Cost to Government ($million)			Total Cost ($million)		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
1	$103.39	$221.26	$339.12	$3.98	$13.62	$23.26	$107.37	$234.88	$362.38
2	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
3	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
4	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
5	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
6	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
7	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
8	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
9	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
10	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
11	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
12	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
13	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
14	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
15	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
16	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
17	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
18	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
19	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40
20	$11.64	$15.97	$20.31	$0.02	$0.06	$0.10	$11.66	$16.03	$20.40

Appendix Table 3.- Estimated Compliance Rates Under Various Scenarios

Scenario	Anticipated Compliance Status	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus
Proposed Rule: NNN standard of 1.0 μg/g	Compliant	26.90%	100.00%	0.00%	29.70%	66.70%
	Noncompliant	73.10%	0.00%	100.00%	70.30%	33.30%
	Nearly compliant	19.30%	0.00%	2.90%	58.60%	33.30%
	Not nearly compliant	53.80%	0.00%	97.10%	11.70%	0.00%
Alternative 1: More stringent NNN standard (0.50 μg/g)	Compliant	0.00%	100.00%	0.00%	0.00%	9.53%
	Noncompliant	100.00%	0.00%	100.00%	100.00%	90.47%
	Nearly compliant	26.90%	0.00%	0.00%	29.70%	57.17%
	Not nearly compliant	73.10%	0.00%	100.00%	70.30%	33.30%
Alternative 2: Less stringent NNN standard (1.50 μg/g)	Compliant	42.34%	100.00%	1.45%	88.30%	89.87%
	Noncompliant	57.66%	0.00%	98.55%	11.70%	10.13%
	Nearly compliant	46.90%	0.00%	1.45%	0.00%	10.13%
	Not nearly compliant	10.76%	0.00%	97.10%	11.70%	0.00%

Note: Noncompliant is the sum of “nearly compliant” and “Not nearly compliant. μg/g denotes micrograms per gram of tobacco on a dry weight basis. Compliant, noncompliant, nearly compliant or not nearly compliant denotes compliance with respect to the alternative standard being assessed.

Appendix Table 4.- Estimated Number of Blends under Alternative 1 by Anticipated Compliance Status and Firm Size

Panel A. Number of Blends that are Estimated to be Compliant and Noncompliant

Anticipated Compliance Status	Firm Size	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	**Total**
Total: Compliant and Noncompliant	Large	20	4	12	16	16	68
	Medium	24	0	12	8	24	68
	Small	4	0	0	8	8	20
	Total	**48**	**4**	**24**	**32**	**48**	**156**
Compliant	Large	0	4	0	0	0	4
	Medium	0	0	0	0	4	4
	Small	0	0	0	0	0	0
	Total	**0**	**4**	**0**	**0**	**4**	**8**
Noncompliant	Large	20	0	12	16	16	64
	Medium	24	0	12	8	20	64
	Small	4	0	0	8	8	20
	Total	**48**	**0**	**24**	**32**	**44**	**148**

Panel B. Number of Blends that are Estimated to be Noncompliant by Noncompliance Subcategory

Anticipated Compliance Status	Firm Size	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	**Total**
Nearly Compliant (mean NNN level less than or equal to 2x standard but exceeds standard)	Large	4	0	0	4	8	16
	Medium	4	0	0	0	12	16
	Small	0	0	0	0	4	4
	Total	**8**	**0**	**0**	**4**	**24**	**36**
Not Nearly Compliant (mean NNN level is greater than or equal to 2x standard)	Large	16	0	12	12	8	48
	Medium	20	0	12	8	8	48
	Small	4	0	0	8	4	16
	Total	**40**	**0**	**24**	**28**	**20**	**112**

Note: Noncompliant is the sum of "nearly compliant" and "Not nearly compliant. In Alternative 1 the standard is assumed to be 0.50 micrograms per gram of tobacco. In the reformulation model, "small companies" include firms with sales under $1 million, "medium-size companies" are those with sales between $1 and $500 million, and "large

companies” are those with sales greater than $500 million. Compliant, noncompliant, nearly compliant or not nearly compliant denotes compliance with respect to NNN standard.

Appendix Table 5.- Estimated Costs Associated with Decision to Reformulate under Alternative 1: NNN Standard is Lower than Proposed Standard

Panel A. Reformulate

Action and Company Size	Product Subcategory (Primary Cost in $million)					Total Cost ($million)		
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Low	Primary	High
Large Companies	$94.95	$0.00	$57.76	$61.52	$66.61	$120.96	$280.84	$440.72
Medium Companies	$123.53	$0.00	$75.51	$79.60	$85.35	$153.07	$363.98	$574.90
Small Companies	$130.74	$0.00	$80.02	$84.58	$90.00	$163.39	$385.34	$607.29
Total	**$349.21**	**$0.00**	**$213.30**	**$225.70**	**$241.96**	**$437.42**	**$1,030.17**	**$1,622.92**

Panel B. Do Not Reformulate

Action and Company Size	Product Subcategory (Primary Cost in $million)					Total Cost ($million)		
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Low	Primary	High
Large Companies	$0.00	$1.66	$0.00	$0.00	$0.66	$0.96	$2.32	$3.68
Medium Companies	$0.00	$1.66	$0.00	$0.00	$0.66	$0.96	$2.32	$3.68
Small Companies	$0.00	$1.66	$0.00	$0.00	$0.66	$0.96	$2.32	$3.68
Total	**$0.00**	**$4.97**	**$0.00**	**$0.00**	**$1.98**	**$2.87**	**$6.95**	**$11.03**
Grand Total	**$349.21**	**$4.97**	**$213.30**	**$225.70**	**$243.94**	**$440.29**	**$1,037.12**	**$1,633.95**

Panel C. Change from Proposed Rule

Action and Company Size	Product Subcategory (Primary Cost in $million)					Total Cost ($million)		
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Low	Primary	High
Reformulate	$274.07	$0.00	$155.53	$190.87	$224.03	$357.31	$844.51	$1,331.72

Action and Company Size	Product Subcategory (Primary Cost in $million)					Total Cost ($million)		
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Low	Primary	High
Do Not Reformulate	($2.97)	$3.31	$0.00	($2.33)	($5.65)	($3.15)	($7.64)	($12.14)
Total	**$271.10**	**$3.31**	**$155.53**	**$188.54**	**$218.38**	**$354.16**	**$836.87**	**$1,319.58**

Notes: Under Alternative 1, reformulation costs are assumed to be incurred assuming lower than 0.50 micrograms of NNN per gram of tobacco on a dry weight basis. Numbers in parentheses denote a decrease from the proposed rule. In the reformulation model, “small companies” include firms with sales under $1 million, “medium-size companies” are those with sales between $1 and $500 million, and “large companies” are those with sales greater than $500 million.

Appendix Table 6.- Estimated Industry Costs Associated with SE Reports under Alternative 1: NNN Standard is Lower than Proposed

Panel A. Number of Initial SE Reports

Type of Report	Number of SE Reports	Hourly Wage	Time (Hours)		Total Cost ($million)		
			Low	High	Low	Primary	High
Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	42	$73.04	47	92	$0.14	$0.21	$0.28
Not Nearly Compliant (mean NNN level is greater than 2x standard)	101	$73.04	152	200	$1.12	$130	$1.48
Subtotal	**143**				**$1.27**	**$1.51**	**$1.76**

Panel B. Number of Similar Product SE Reports

Type of Report	Number of SE Reports	Hourly Wage	Time (Hours)		Total Cost ($million)		
			Low	High	Low	Primary	High
Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	205	$73.04	37	72	$0.55	$0.82	$1.08
Not Nearly Compliant (mean NNN level is greater than 2x standard)	421	$73.04	62	100	$1.91	$2.49	$3.07
Subtotal	**626**				**$2.46**	**$3.31**	**$4.15**
Total	**769**				**$3.73**	**$4.82**	**$5.91**
Difference from Proposed Rule					**$1.61**	**$1.98**	**$2.35**

Notes: Costs are estimated based on a composite hourly wage of $73.04, which includes benefits and overhead. Under Alternative 1, reformulation costs are assumed to be incurred assuming lower than 0.50 micrograms of NNN per gram of tobacco. Numbers in parentheses denote a decrease from the proposed rule. Nearly compliant or not nearly compliant denotes compliance with respect to NNN standard.

Appendix Table 7.- Estimated Number of Blends under Alternative 2 by Anticipated Compliance Status and Firm Size

Panel A. Number of Blends that are Estimated to be Compliant and Noncompliant

Anticipated Compliance Status	Firm Size	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Total
Total: Compliant and Noncompliant	Large	20	4	12	16	16	68
	Medium	24	0	12	8	24	68
	Small	4	0	0	8	8	20
	Total	**48**	**4**	**24**	**32**	**48**	**156**
Compliant	Large	8	4	0	16	16	44
	Medium	12	0	0	8	20	40
	Small	0	0	0	8	8	16
	Total	**20**	**4**	**0**	**32**	**44**	**100**
Noncompliant	Large	12	0	12	0	0	24
	Medium	12	0	12	0	4	28
	Small	4	0	0	0	0	4
	Total	**28**	**0**	**24**	**0**	**4**	**56**

Panel B. Number of Blends that are Estimated to be Noncompliant: By Noncompliance Subcategory

Anticipated Compliance Status	Firm Size	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Total
Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	Large	8	0	0	0	0	8
	Medium	8	0	0	0	0	8
	Small	0	0	0	0	0	0
	Total	**16**	**0**	**0**	**0**	**0**	**16**
Not Nearly Compliant (mean NNN level is greater than 2x standard)	Large	4	0	12	0	0	16
	Medium	4	0	12	0	4	20
	Small	4	0	0	0	0	4
	Total	**12**	**0**	**24**	**0**	**4**	**40**

Note: Noncompliant is the sum of “nearly compliant” and “Not nearly compliant. In Alternative 2 the standard is assumed to be 1.50 micrograms per gram of tobacco. In the reformulation model, “small companies” include firms with sales under $1 million, “medium-size companies” are those with sales between $1

and $500 million, and “large companies” are those with sales greater than $500 million. Compliant, noncompliant, nearly compliant or not nearly compliant denotes compliance with respect to NNN standard.

Appendix Table 8.- Estimated Costs Associated with Decision to Reformulate under Alternative 2: NNN Standard is Higher than Proposed

Panel A. Reformulate

Action and Company Size	Product Subcategory (Primary Cost in $million)					Total Cost ($million)		
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Low	Primary	High
Large Companies	$31.32	$0.00	$41.23	$0.00	$0.00	$31.87	$72.55	$113.23
Medium Companies	$12.29	$0.00	$16.53	$0.00	$5.51	$14.14	$34.33	$54.52
Small Companies	$0.24	$0.00	$0.00	$0.00	$0.00	$0.10	$0.24	$0.38
Total	$43.85	$0.00	$57.76	$0.00	$5.51	$46.11	$107.12	$168.13

Panel B. Do Not Reformulate

Action and Company Size	Product Subcategory (Primary Cost in $million)					Total Cost ($million)		
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Low	Primary	High
Large Companies	$3.31	$1.66	$0.00	$6.63	$6.63	$7.53	$18.23	$28.94
Medium Companies	$1.98	$0.00	$0.00	$1.32	$3.29	$2.71	$6.59	$10.46
Small Companies	$0.00	$0.00	$0.00	$0.04	$0.04	$0.03	$0.07	$0.12
Total	$5.29	$1.66	$0.00	$7.98	$9.96	$10.26	$24.89	$39.52
Grand Total	$49.14	$1.66	$57.76	$7.98	$15.47	$56.38	$132.01	$207.65

Panel C. Change from Proposed Rule

Action and Company Size	Product Subcategory (Primary Cost in $million)					Total Cost ($million)		
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Low	Primary	High
Reformulate	($31.28)	$0.00	$0.00	($34.83)	($12.42)	($34.00)	($78.53)	($123.06)
Do Not Reformulate	$2.32	$0.00	$0.00	$5.65	$2.33	$4.25	$10.30	$16.35

Action and Company Size	Product Subcategory (Primary Cost in $million)					Total Cost ($million)		
	Chewing Tobacco	Dissolvable	Dry Snuff	Moist Snuff	Snus	Low	Primary	High
Total	($28.97)	$0.00	$0.00	($29.18)	($10.09)	($29.75)	($68.23)	($106.71)

Notes: Under Alternative 2, reformulation costs are assumed to be incurred assuming a maximum standard of 1.50 micrograms of NNN per gram of tobacco. Numbers in parentheses denote a decrease from the proposed rule. In the reformulation model, "small companies" include firms with sales under $1 million, "medium-size companies" are those with sales between $1 and $500 million, and "large companies" are those with sales greater than $500 million.

Appendix Table 9.- Estimated Industry Costs Associated with SE Reports under Alternative 2: NNN Standard is Higher than Proposed

Type of Report		Number of SE Reports	Time (Hours)		Total Cost ($million)		
			Low	High	Low	Primary	High
Panel A. Number of Initial SE Reports	Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	33	47	92	$0.11	$0.17	$0.22
	Not Nearly Compliant (mean NNN level is greater than 2x standard)	33	152	200	$0.37	$0.42	$0.48
	Subtotal	**66**			**$0.48**	**$0.59**	**$0.70**
Panel B. Number of Similar Product SE Reports	Nearly Compliant (mean NNN level is less than or equal to 2x standard but exceeds standard)	33	37	72	$0.09	$0.13	$0.17
	Not Nearly Compliant (mean NNN level is greater than 2x standard)	71	62	100	$0.32	$0.42	$0.52
	Subtotal	**104**			**$0.41**	**$0.55**	**$0.69**
Total		**170**			**$0.89**	**$1.14**	**$1.40**
Difference from Proposed Rule					**($1.23)**	**($1.70)**	**($2.17)**

Notes: Costs are estimated based on a composite hourly wage of $73.04, which includes benefits and overhead. Under Alternative 2, reformulation costs are assumed to be incurred assuming a maximum standard of 1.50 micrograms of NNN per gram of tobacco. Numbers in parentheses denote a decrease from the proposed rule. Nearly compliant or not nearly compliant denotes compliance with respect to NNN standard.

Appendix Table 10.- Estimated Costs and Related Timing under Alternative 3 (extended effective date)

Year	Cost to Industry ($million)			Cost to Government ($million)			Total Cost ($million)		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
1	$32.72	$76.48	$120.23	$0.00	$0.00	$0.00	$32.72	$76.48	$120.23
2	$26.70	$61.88	$97.06	$0.00	$0.00	$0.00	$26.70	$61.88	$97.06
3	$43.97	$89.48	$134.99	$3.98	$13.62	$23.26	$47.95	$103.10	$158.25
4	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
5	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
6	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
7	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
8	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
9	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
10	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
11	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
12	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
13	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
14	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
15	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
16	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
17	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
18	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
19	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67
20	$11.64	$18.61	$25.57	$0.02	$0.06	$0.10	$11.66	$18.67	$25.67

Note: Alternative 3 assumes that affected entities have 2 additional years to bring nonconforming products into compliance with proposed standard.

Appendix Table 11.- Average Cost per Entity under Alternative 2: Establish an NNN Standard of 1.50 micrograms per gram of Tobacco

Panel A. Itemized Costs

Description	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Stability Testing	$0.73	$0.73	$0.73				$0.29	$0.29	$0.29
Batch Testing				$0.06	$0.15	$0.24			
Reformulation Costs									
SBA Small: Companies with revenue $1-$500 million	$1.10	$2.66	$4.22						
SBA Non-small: Companies with revenue greater than $500 million	$6.37	$14.51	$22.65						
Review of Regulation/No formulation									
SBA Small: Companies with revenue $1-$500 million	$0.21	$0.51	$0.81						
SBA Non-small: Companies with revenue greater than $500 million	$1.51	$3.65	$5.79						
Labeling	$0.05	$0.12	$0.19						
Substantial Equivalence Reports	$0.05	$0.06	$0.08						
Nonconforming Products	$0.00	$0.00	$0.01				$0.29	$0.43	$0.58
Reporting Costs--Alternative Testing Method	$0.00	$0.00	$0.00				$0.00	$0.00	$0.00
Recordkeeping Costs				$0.00	$0.00	$0.00	$0.01	$0.01	$0.01

Panel B. Average Costs to Industry (per Firm)

Description	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
Reformulation Costs: SBA Small	$1.31	$3.17	$5.04						
Reformulation Costs: SBA Non-small	$7.88	$18.16	$28.43						
All Other Costs	$0.83	$0.92	$1.01	$0.06	$0.15	$0.25	$0.58	$0.73	$0.88

Panel C. Average Costs to Industry by Firm Size

Description	Year 1, one-time			Year 1 and on			Year 2 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High
SBA Small	$2.14	$4.09	$6.04	$0.06	$0.15	$0.25	$0.58	$0.73	$0.88
SBA Non-small	$8.71	$19.07	$29.44	$0.06	$0.15	$0.25	$0.58	$0.73	$0.88
Total: Small and Non-Small	$3.96	$8.25	$12.54	$0.06	$0.15	$0.25	$0.58	$0.73	$0.88

Notes: Estimates are rounded to the nearest hundredth. Totals may not add up due to rounding.

Appendix Table 12.- Average Cost per Entity under Alternative 3: Extend the Effective Date

Panel A. Itemized Costs

Description	Year 1			Year 2			Year 3			Year 4 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
Stability Testing	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.73	$1.10	$1.46	$0.29	$0.44	$0.59
Batch Testing	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.06	$0.15	$0.24	$0.06	$0.15	$0.24
Reformulation Costs												
SBA Small: Companies with revenue $1-$500 million	$0.52	$1.27	$2.01	$0.52	$1.27	$2.01	$0.52	$1.27	$2.01	$0.00	$0.00	$0.00
SBA Non-small: Companies with revenue greater than $500 million	$3.99	$9.09	$14.19	$3.99	$9.09	$14.19	$3.99	$9.09	$14.19	$0.00	$0.00	$0.00
Review of Regulation/No formulation												
SBA Small: Companies with revenue $1-$500 million	$0.15	$0.36	$0.57	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
SBA Non-small: Companies with revenue greater than $500 million	$0.82	$1.99	$3.16	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Labeling	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.05	$0.12	$0.19	$0.00	$0.00	$0.00
Substantial Equivalence Reports	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.12	$0.16	$0.20	$0.00	$0.00	$0.00
Nonconforming Products	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.01	$0.29	$0.43	$0.59
Reporting Costs--Alternative Testing Method	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Recordkeeping Costs	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.01	$0.01	$0.01

Panel B. Average Costs to Industry (per firm)

Description	Year 1			Year 2			Year 3			Year 4 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
Reformulation Costs: SBA Small	$0.67	$1.62	$2.58	$0.52	$1.27	$2.01	$0.52	$1.27	$2.01	$0.00	$0.00	$0.00
Reformulation Costs: SBA Non-small	$4.81	$11.08	$17.35	$3.99	$9.09	$14.19	$3.99	$9.09	$14.19	$0.00	$0.00	$0.00

Description	Year 1			Year 2			Year 3			Year 4 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
All Other Costs	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.96	$1.53	$2.11	$0.65	$1.03	$1.42

Panel C. Average Total Costs to Industry by Firm Size

Description	Year 1			Year 2			Year 3			Year 4 and on		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
SBA Small	$0.67	$1.62	$2.58	$0.52	$1.27	$2.01	$1.48	$2.80	$4.12	$0.65	$1.03	$1.42
SBA Non-small	$4.81	$11.08	$17.35	$3.99	$9.09	$14.19	$4.94	$10.62	$16.30	$0.65	$1.03	$1.42
Total: Small and Non-Small	**$5.47**	**$12.70**	**$19.92**	**$4.51**	**$10.35**	**$16.20**	**$5.47**	**$11.89**	**$18.31**	**$0.65**	**$1.03**	**$1.42**

Notes: Estimates are rounded to the nearest hundredth. Totals may not add up due to rounding.

Appendix Table 13.- Summary of Discounted Average Cost for Small Entities

Policy	Description	Average Cost to SBA Small Entities: Reformulation Costs ($million)			Average Cost to SBA Small Entities: Other Costs ($million)			Average Cost to SBA Small Entities: Total Costs ($million)		
		Low	Primary	High	Low	Primary	High	Low	Primary	High
Proposed Rule	Net Present Value, 3%	$1.66	$4.03	$6.40	$9.93	$13.47	$17.02	$11.59	$17.51	$23.42
	Annualized Value, 3%	$0.11	$0.27	$0.43	$0.67	$0.91	$1.14	$0.78	$1.18	$1.57
	Net Present Value, 7%	$1.60	$3.88	$6.16	$7.14	$9.66	$12.18	$8.74	$13.54	$18.34
	Annualized Value, 7%	$0.15	$0.37	$0.58	$0.67	$0.91	$1.15	$0.83	$1.28	$1.73
Alternative 2: Less Stringent NNN Standard (1.50 μg/g)	Net Present Value, 3%	$1.27	$3.08	$4.89	$9.85	$13.38	$16.90	$11.12	$16.46	$21.79
	Annualized Value, 3%	$0.09	$0.21	$0.33	$0.66	$0.90	$1.14	$0.75	$1.11	$1.46
	Net Present Value, 7%	$1.22	$2.96	$4.71	$7.08	$9.57	$12.07	$8.30	$12.54	$16.77
	Annualized Value, 7%	$0.12	$0.28	$0.44	$0.67	$0.90	$1.14	$0.78	$1.18	$1.58
Alternative 3: Extended Effective Date	Net Present Value, 3%	$1.62	$3.93	$6.23	$8.67	$13.86	$19.05	$10.29	$17.78	$25.28
	Annualized Value, 3%	$0.11	$0.26	$0.42	$0.58	$0.93	$1.28	$0.69	$1.20	$1.70
	Net Present Value, 7%	$1.51	$3.65	$5.80	$5.94	$9.49	$13.04	$7.44	$13.14	$18.85
	Annualized Value, 7%	$0.14	$0.34	$0.55	$0.56	$0.90	$1.23	$0.70	$1.24	$1.78

Note: Estimates are discounted over 20 years. μg/g denotes micrograms per grams of tobacco on a dry weight basis.

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