DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements

Docket No. FDA-2014-N-0189

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

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I. Introduction, Summary and Need for the Proposed Rule

A. Introduction and Summary

FDA has 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 (Public Law 104-4). Executive Orders 12866 and 13563 direct agencies 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). The agency believes that this proposed rule would be an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA has determined that this proposed rule would have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies 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 $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in a one-year expenditure that meets or exceeds this amount.

The proposed rule consists of two co-proposals, option 1 and option 2. The proposed option 1 deems all products meeting the statutory definition of "tobacco product," except accessories of a proposed deemed tobacco product, to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Option 1 proposes additional provisions that would apply to proposed deemed products as well as to certain other tobacco products. Once deemed, tobacco products become subject to the FD&C Act and its implementing regulations. The FD&C Act requirements that would apply to proposed deemed products include establishment registration and product listing, ingredient listing, submissions prior to the introduction of new products, and labeling requirements. Free samples of proposed deemed tobacco products would also be prohibited. The additional provisions of this proposed rule include minimum age and identification requirements, vending machine restrictions, and required warning statements for packages and advertisements. Although deeming and the associated "automatic provisions" of the FD&C Act could be implemented on their own, the additional provisions could not be implemented for proposed deemed products without deeming.

While FDA currently has authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco under chapter IX of the FD&C Act, all additional tobacco products that meet the statutory definition, except accessories of those proposed deemed tobacco products, would be subject to chapter IX of the FD&C Act and its implementing regulations

under option 1 of the proposed rule. These products would include cigars, pipe tobacco, hookah tobacco, electronic cigarettes, and other novel tobacco products such as dissolvable products and gels. Of these products to be deemed, cigars are the most commonly used.

The other co-proposal, option 2, is the same as option 1 except that it exempts premium cigars. The proposed rule would define premium cigars as cigars that are wrapped in whole tobacco leaf; contain a 100 percent leaf tobacco binder; contain primarily long filler tobacco; are made by manually combining the wrapper, filler, and binder; have no filter, tip, or non-tobacco mouthpiece and are capped by hand; do not have a characterizing flavor other than tobacco; weigh more than six pounds per thousand units; and sell for $10 or more per cigar.

The proposed deeming action differs from most public health regulations in that it is an enabling regulation. In other words, in addition to directly applying the substantive requirements of chapter IX of the FD&C Act and its implementing regulations to proposed deemed tobacco products, it enables FDA to issue further public health regulations related to such products. We expect that asserting our authority over these tobacco products will enable us to propose further regulatory action in the future as appropriate, and those actions will have their own costs and benefits. Without deeming these products to be subject to the FD&C Act, FDA would lack the authority to collect vital ingredient and health information about them. We would also lack the authority to take regulatory action with respect to them, if we determined it was appropriate to do so.

The direct benefits of making each of the proposed deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify without additional data, and we cannot predict the size of these benefits at this time. Among other effects, new products would be subject to evaluation to ensure they are appropriate for public health before they could be marketed, labeling could not contain misleading statements, and FDA would be made aware of the ingredients in proposed deemed tobacco products. If, without the proposed rule, new products would be developed that pose substantially greater health risks than those already on the market, the premarket requirements made effective by this proposed rule would prevent such products from appearing on the market and worsening the health effects of tobacco product use. The warning statements required by this proposed rule would provide information to consumers about the risks and characteristics of tobacco products. Consumers may act on this information by reducing their use of tobacco products. Consumers may also act on this information through compensating health behaviors. These responses would generate benefits associated with improved health and longevity.

The proposed rule as a whole would impose costs in the form of registration, submission, and labeling requirements. The deeming provision would impose immediate costs because manufacturers and importers of newly-regulated tobacco products would have to comply with registration, submission, and labeling requirements. Manufacturers of proposed deemed products, as well as some manufacturers of currently-regulated products, would have to comply with the warning label provisions, which would impose additional costs, including costs for signs with warnings at point-of-sale for cigars sold singly without packaging. There would also be potential costs for removing noncompliant point-of-sale advertising and complying with vending machine restrictions.

The up-front costs for option 1 are estimated to range from $74.3 to $347.0 million, with a primary estimate of $171.1 million, while the costs in subsequent years are estimated to range from $20.8 to $49.0 million, with a primary estimate of $30.6 million. The primary estimate for the present value of total quantified costs over 20 years is approximately $592.0 million at a 3 percent discount rate and $467.6 million at a 7 percent discount rate.

The up-front costs for option 2 are estimated to range from $60.5 to $258.5 million, with a primary estimate of $132.8 million, while the costs in subsequent years are estimated to range from $17.4 to $38.4 million, with a primary estimate of $25.0 million. The primary estimate for the present value of total quantified costs over 20 years is approximately $476.4 million at a 3 percent discount rate and $375.0 million at a 7 percent discount rate.

The quantified costs of both options for the proposed rule can also be expressed as annualized values, as shown in Table 1.

Table 1: Summary of Quantified Costs Over 20 Years ($ million)

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Present Value Option 1	**365.2**	**592.0**	**1,010.1**	**281.4**	**467.6**	**810.2**
Present Value Option 2	**304.0**	**476.4**	**779.2**	**233.8**	**375.0**	**622.6**
Annualized Value Option 1	**23.8**	**38.6**	**65.9**	**24.8**	**41.2**	**71.5**
Annualized Value Option 2	**19.8**	**31.1**	**50.8**	**20.6**	**33.1**	**54.9**

In addition to the benefits and costs of both options for the proposed rule, we assess the benefits and costs of several alternatives to the proposed rule (we note that some may be outside the scope of our current authority): deeming only, but exempt proposed deemed products from all labeling changes and premarket submission requirements; enforce premarket requirements only for machine-made cigars; change the grandfather date for new products to the date of final regulation; deeming only, but exempt proposed deemed products from all labeling changes; exempt handmade cigars from labeling changes; deeming only (no additional provisions); alter the compliance period for labeling changes. We note that not all of these regulatory alternatives are necessarily legally permissible.

Primary estimates of the costs of the regulatory alternatives appear as present values and annualized values in Table 2.

Table 2.—Primary Estimate of Quantified Costs for Regulatory Alternatives (Present and Annualized Values, $ million)[1]

Alternative	**Present Value (3%)**	**Present Value (7%)**	**Annualized Value (3%)**	**Annualized Value (7%)**
1 – Deeming only; exempt from labeling changes and new product submissions	10.3	8.3	0.7	0.7
2 --Enforce premarket requirements only for machine-made cigars	176.3	156.0	11.5	13.8

3 -- Change grandfather date to date of regulation	422.1	333.0	27.5	29.4
4-- Deeming only; exempt from labeling changes	475.9	360.8	31.1	31.8
Proposed Rule Option 2: Exempt Premium Cigars from Regulation	*476.4*	*375.0*	*31.1*	*33.1*
5--Exempt handmade cigars from labeling changes	500.0	384.2	32.6	33.9
6 -- Deeming only; no additional provisions	541.6	425.3	35.3	37.5
7a-- 36-month compliance period for labeling changes	572.3	447.1	37.3	39.4
Proposed Rule Option 1 – 24-month compliance period for labeling changes	*592.0*	*467.6*	*38.6*	*41.2*
7b--12-month compliance period for labeling changes	646.1	523.2	42.2	46.2

1 Nonquantified benefits are described in the text.

The majority of the compliance costs of this proposed rule are fixed, but a portion of the costs are variable. The costs imposed will be borne primarily by manufacturers and importers; some of the costs will be passed on to consumers in the form of higher prices. The average increase in the price of proposed deemed tobacco products, however, would be very small relative to current prices.

In addition to the costs described above, the proposed rule would lead to private costs in the form of reduced revenues for firms in affected sectors. Additionally, if excise taxes on tobacco products remain at current levels, annual tax revenues would fall with reduced use. Appendix Tables A1 and A2 summarize the costs, benefits, and distributional effects of the two co-proposals, option 1 and option 2.

FDA requests comments on all inputs, methods and results that appear in the following preliminary regulatory impact analysis.

B. Need for the Proposed Rule

Millions of people use tobacco products, such as cigars, pipe tobacco, and electronic cigarettes, that would be newly deemed by this proposed rule. Estimates from a national survey show that in 2010, nearly 13.2 million people aged 12 or older had smoked cigars of any type in the past month, and more than 2.1 million had smoked pipe tobacco (Ref. 46 [Substance Abuse and Mental Health Services Administration, 2011b]). Even though other tobacco products have not been studied as extensively as cigarettes, we have enough information to know that some of them cause serious health problems. A comprehensive review of the evidence shows that cigar smoking causes lung, oral cavity, larynx and esophagus cancer, and that heavy cigar smoking or inhalation of cigar smoke leads to increased risk of coronary heart disease and may cause chronic

obstructive pulmonary disease (COPD) (Ref. 72 [Shanks and Burns, 1998]). Similarly, smoking pipe tobacco has been linked to increased risk of death from lung cancer and other smoking-related diseases (Ref. 1 [Henley et al., 2004]; Ref. 3 [Tverdal and Bjartveit, 2011]).

Because tobacco products contain nicotine—an addictive substance (Ref. 2 [HHS, 1988])—their regulation is consistent with policy recommendations derived from economic models of addiction (examples include Gruber and Köszegi [Ref. 4, 2001]; Bernheim and Rangel [Ref. 6, 2004]; and Gul and Pesendorfer [Ref. 8, 2007]). Perhaps most notably, the Gruber-Köszegi model, which combines forward-looking behavior with time-inconsistent preferences, suggests opportunities for regulation of tobacco products to enhance social welfare for the population at large (Ref. 4). Time inconsistency exists when consumers use lower rates of discount for consequences far in the future than for consequences close to the present. Time-inconsistent consumers make current decisions that they would not make from the perspective of their future selves. For example, someone may plan and fully intend to stop smoking (or start a diet or begin exercising) tomorrow but when tomorrow comes, she puts it off one more day. Furthermore, when tomorrow becomes today, she regrets that she did not stop smoking (or start a diet or begin exercising) yesterday. Examples of private self-control devices for weight loss can vary from daily jogging pacts to gastric bypass surgery; similarly, smokers who attempt to quit may seek support from friends or various forms of therapy. Tobacco regulations can support or supplement self-control mechanisms.

Deeming all tobacco products, except accessories of a proposed deemed tobacco product, to be subject to chapter IX of the FD&C Act would enable FDA to tackle more fully the problem of youth initiation of tobacco product use. For example, of the more than 2.9 million people aged 12 and above who first used cigars of any type in 2010, nearly 1.1 million—or about 37 percent—were under the age of 18 at initiation (Ref. 12 [Substance Abuse and Mental Health Services Administration, 2011a]). (This amounts to nearly 3,000 youths initiating cigar use each day.) By comparison, of the nearly 2.4 million people aged 12 and above who first used cigarettes in 2010, 1.4 million—or about 58 percent--were under the age of 18 at initiation. (This amounts to 3,800 youths initiating cigarette use each day.) Furthermore, a recent study suggests that youth cigar usage may be underestimated because young people responding to surveys do not always recognize the products they use as cigars unless the question includes specific cigar brand names (Ref. 14 [Terchek et. al, 2009]). The National Cancer Institute has concluded that youths who initiate cigar smoking may face an even higher risk than adults of becoming dependent (Ref. 10 [Fant and Henningfield, 1998], p. 191).

Deeming all tobacco products, except accessories of a proposed deemed tobacco product, to be subject to chapter IX of the FD&C Act would also be the necessary first step to rectify an institutional failure in which tobacco products that are close substitutes are not regulated by FDA in a like manner. FDA currently regulates cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own (RYO) tobacco but not machine-made and handmade cigars, pipe tobacco and other tobacco products. When products are taxed or regulated differently, substitutions across products will occur.[1]

[1] Taxation falls under the jurisdiction of the U.S. Department of Treasury Tobacco Tax and Trade Bureau. Neither FDA's act of "deeming" nor any other FDA regulations directly affect the taxation of any tobacco product.

Industry documents indicate that tobacco firms have been aware of disparities in the legal treatment of cigarettes and cigars and have made efforts to develop cigars that cigarette smokers would smoke (Ref. 16 [Delnevo and Hrywna, 2007], Ref. 18 [Delnevo, 2006]). Sales of little cigars quadrupled in the early 1970s, when cigars were taxed at a much lower rate than cigarettes and cigarette advertisements, but not little cigar advertisements, were banned from television and radio (Ref. 16 [Delnevo and Hrywna, 2007]).

The Government Accountability Office (GAO) (Ref. 20 [GAO, 2012]) found that tax disparities provide an incentive for manufacturers to increase the weight of inexpensive small cigars to fit the definition of large cigars. They found that sales of small cigars decreased from 5.34 billion cigars in fiscal year 2008 to 0.91 billion in 2010 while sales of large cigars increased from 4.76 billion cigars to 9.88 billion. Consumption estimates from the Centers for Disease Control and Prevention (CDC) show the same changes (Ref. 22 [CDC, 2012]). The GAO also reported on the tax disparity between roll-your-own tobacco and pipe tobacco, finding that sales of roll-your-own tobacco decreased from 9.68 billion cigarette stick equivalents in fiscal year 2008 to 3.03 billion in 2010, while over the same time period, sales of pipe tobacco increased from 1.55 billion cigarette stick equivalents to 10.25 billion. As noted by the GAO, the Internal Revenue Code definitions of these products do not specify physical characteristics but instead consider the use for which the products are suited and how the products are offered for sale. Consumption estimates from the CDC again show the same changes.

To the extent that there is substitutability among tobacco products, regulatory gaps will exist if FDA regulates some tobacco products but not others.[2] Maintaining the status quo provides incentives for manufacturers to market new tobacco-based or tobacco-derived products that are not regulated by FDA and may induce people to switch to products that FDA does not regulate at all or with the same stringency. Recent years have seen the introduction of new nicotine-containing products, such as electronic hookahs, "vape sticks," and electronic cigarette liquids with fruit and candy flavorings that are not currently covered under FDA's regulatory authorities.

II. Preliminary Regulatory Impact Analysis

A. Benefits

This proposed rule, by deeming all products derived from tobacco to be subject to chapter IX of the FD&C Act, would extend the Agency's tobacco product authorities—which currently only apply to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco—to other categories of tobacco products, except accessories of those products, that meet the statutory definition of "tobacco product" in Section 201(rr) of the FD&C Act. We expect that asserting our authority over these tobacco products will enable us to take further regulatory action in the

[2] Products that have substantially higher prices or substantially different product characteristics than regulated products may not be close substitutes for the regulated products and in this case regulatory gaps may be less of a concern.

future as appropriate, and those actions will have their own costs and benefits, which can only be estimated as these regulations are issued.[3]

Because we propose to deem all products derived from tobacco to be subject to chapter IX of the FD&C Act, this proposed rule would allow FDA to regulate additional categories of tobacco products that are not now subject to federal product regulation. It would immediately enable FDA to determine the number of regulated entities, establish effective compliance programs, and monitor the amount and types of products that are being sold to the public. It would also authorize the agency to take action against products that are determined to be adulterated and misbranded, reducing the potential public health dangers of such products.[4] By regulating these currently unregulated tobacco products, FDA would also be correcting any possible misperception that, because they are not regulated, they must be safe.

Chapter IX of the FD&C Act also contains requirements for the introduction of new tobacco products to the market.[5] If, without the proposed rule, new products would be developed that pose substantially greater health risks than those already on the market, these new products could worsen the health effects of tobacco product use. The premarket requirements made effective by this proposed rule would prevent such products from appearing on the market.

Under chapter IX of the FD&C Act, a proposed deemed tobacco product in package form would need to add to its label: the name and place of business of the tobacco product manufacturer, packer, or distributor; an accurate statement of the quantity of the product's contents in terms of weight, measure, or numerical count; a statement of the percentage of the tobacco used in the product that is grown domestically; and the statement "sale only allowed in the United States" (this final requirement would apply to shipping containers as well as product packages). These labeling changes required by the FD&C Act do not communicate health information to consumers, and so we do not expect that this information would motivate consumers to reduce tobacco product use or lead to other behavioral changes that might improve their health. However, modified-risk descriptors such as "light," "mild," and "low," would also need to be removed from tobacco product labeling and advertising unless the appropriate FDA order is in effect for the relevant product; prohibiting such descriptors will help consumers better understand and appreciate the relative risk of the tobacco product and could lead to behavioral changes that would positively affect consumers' health.[6]

Existing regulations prohibit the distribution of free samples of any tobacco product except for smokeless tobacco samples distributed in a qualified adult-only facility (21 CFR § 1140.16). This provision would automatically apply to proposed deemed tobacco products.

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[3] It is impossible to predict the effects of rulemaking before the contents of the rules themselves have been conceived.

[4] We do not have the evidence to quantify the extent of this public health risk. Nevertheless, we do receive adverse event reports and complaints indicating that a product may be adulterated or misbranded. (Even though we do not systematically collect data on not-yet-deemed products, we do, for example, receive telephone complaints about electronic cigarettes.) Only after deeming would we have the authority to take action to mitigate any potential risks (among the newly deemed products).

[5] See section II.B.3.e for more details about the FD&C Act's premarket requirements.

[6] See sections 903(a)(2), 920(a) and 911 of the FD&C Act for more details about the labeling requirements.

The proposed rule's additional provisions (beyond deeming) could generate a variety of benefits. FDA anticipates, however, that the largest benefit of the proposed provisions would be the improvements in health and life expectancy resulting from reductions in the use of combustible tobacco products deemed under this proposed rule. Most notably, the required warning labels on product packaging and advertising can more effectively inform potential users of the health risks of cigars and the addictiveness of cigars and other covered tobacco products, cigarette tobacco, and roll-your-own tobacco. Consumers may respond to this information by reducing their use of these products or engaging in compensating health behaviors.

Other benefits may arise from nationwide uniformity of vending machine, minimum age, and identification standards across all covered tobacco products, which could lead to more efficient enforcement. All 50 states and the District of Columbia currently prohibit the sale of tobacco products to minors or the purchase (or possession) of certain tobacco products by minors (Ref. 24 [ERG, 2011]). However, the definition of "tobacco products" varies among states; in most states the term covers products such as cigars and pipe tobacco but does not explicitly cover all proposed deemed products derived from tobacco, which are included in the Tobacco Control Act's definition of "tobacco product" and the Agency's proposed definition of "covered tobacco product." As such, minors may have retail access to some products derived from tobacco, such as electronic cigarettes, that are not currently the subject of age restrictions in most states (Ref. 25 [CDC, 2013]).) The proposed deeming action would enable uniform nationwide tobacco enforcement in spite of variable state definitions of "tobacco product" and the uncertainty surrounding future rates of state-level enforcement and implementation of community education programs; such enforcement could lead to more efficient enforcement and increased compliance by tobacco product retailers (i.e., reduced sales to youth), More effective enforcement could potentially lead to reductions in youth smoking rates, although the literature shows mixed results on the latter point (Ref. 26 [Stead and Lancaster, 2005]). Electronic cigarettes and other novel tobacco products may raise potentially distinct access issues not covered in the existing literature.[7]

Another important effect of enhanced restrictions on youth access to tobacco products is the potential effect on social norms (Ref. 28 [Fichtenberg and Glantz, 2002]; Ref. 30 [Stead and Lancaster, 2000]; Ref. 32 [Rigotti et al., 1997]; Ref. 34 [Altman et al., 1999]; Ref. 36 [Cummings et al., 2003]; Ref. 38 [Forster et al., 2003]; Ref. 40 [Jansen et al., 2011]; Ref. 42 [Warner and Mendez, 2010]). As the Institute of Medicine puts it, the value of strict access restrictions lies in their "capacity to symbolize and reinforce an emerging social norm that disapproves of tobacco use" (Ref. 44 [IOM, 2007], p. 204). In this analysis, we do not attempt to estimate the effect on social norms of enhanced youth access restrictions.

Removal of vending machines, as required by the proposed rule, would reduce minors' access to tobacco products. As discussed in section II.B.5.c, however, vending machine tobacco product sales have dwindled in recent decades. Accordingly, although a restriction on vending

[7] The available literature predates the widespread availability and use of electronic cigarettes and other novel tobacco products. Therefore, we cannot be certain that the existing literature would apply to these products.

machine sales of tobacco products to minors would close a regulatory loophole and could prevent future substitution effects (i.e., increased purchase of proposed deemed tobacco products from vending machines when other retail access is prohibited), there is currently little scope for the proposed rule to reduce the already negligible consumption facilitated by vending machine sales.[8] If, in the absence of the proposed rule, future years were to see a major expansion in vending machine sales of proposed deemed products, this prohibition would generate a much larger public health benefit than the one described here.

We do not quantify the benefits of this proposed rule here because we lack sufficient evidence to estimate within acceptable levels of certainty how consumers will use the new label information. We expect that consumers will respond with changes in their use of tobacco products and with changes in other behaviors. However, reliable evidence on the effects of warning labels and other restrictions on users of cigars and other covered tobacco products, cigarette tobacco, and roll-your-own tobacco does not, to our knowledge, exist. Estimating the effects of the proposed rule on users of these products would require extrapolating from the experience of other products and other warning labels. This extrapolation would require evidence on the baseline practices, knowledge, and attitudes toward risk of current and potential users of proposed deemed products. The combined uncertainties of inferring changes in behavior based on different products, different warnings, different baseline practices, and different risk profiles create too wide a band of uncertainty to allow us to quantitatively estimate the effects of the proposed rule. In what follows, we describe the potential benefits and how they might be estimated with more data.

1. Welfare Gains

Although we cannot quantify the benefits of the proposed rule, much of the rule's benefits are likely to come from reducing the number of users of tobacco products, which would reduce the health losses associated with consuming those products. Other benefits would stem from other changes in consumer behavior, such as compensating health behaviors. Provisions that reduce the number of combustible tobacco product users could lead to welfare gains. We lack sufficient information on consumers of cigars and other combustible products to make direct inferences on the welfare gains from decreased use but because cigarettes are the closest products to the products covered by the proposed rule, we can make inferences about the welfare effect based on welfare effects associated with reducing the use of cigarettes. We acknowledge, however, that the effects of using other tobacco products may differ from the effects of smoking cigarettes; some may have very similar effects to cigarettes, while others may differ substantially.

[8] We again note that the definition of "tobacco products" varies among the states and generally does not cover all proposed deemed products derived from tobacco, which are included in the Tobacco Control Act's definition of "tobacco product" and the Agency's proposed definition of "covered tobacco product."

Although we currently have less detailed data and research results covering proposed deemed products than we have covering cigarettes, a comprehensive review of the evidence shows that cigar smoking causes lung, oral cavity, larynx and esophagus cancer, and that heavy cigar smoking or inhalation of cigar smoke leads to increased risk of coronary heart disease and may cause chronic obstructive pulmonary disease (COPD) (Ref. 72 [Shanks and Burns, 1998]). Similarly, smoking pipe tobacco has been linked to increased risk of death from lung cancer and other smoking-related diseases (Ref. 1 [Henley et al., 2004]; Ref. 3 [Tverdal and Bjartveit, 2011]). In our description of the components of welfare gains, we use cigarettes results for illustration and discuss some of the known differences for cigars.

a. Willingness to Pay for Cessation Programs

One method for estimating how consumers value information that may help them stop tobacco product use is to look at tobacco product cessation programs. The amount tobacco users' are willing to pay to participate in cessation programs gives us information about their gains from stopping tobacco product use. Warner et al. (Ref. 64 [2004]) use the choke price, or the price at which no cigarette smokers would participate in cessation programs, to estimate an average willingness-to-pay among potential cessation program participants. A similar method could potentially be used to estimate the direct willingness-to-pay for cessation among users of other tobacco products but as explained in the next section, that estimate would likely greatly understate welfare gains. We request comments on consumers' willingness to pay for cigar, pipe tobacco, hookah tobacco, and other covered tobacco product cessation programs.

b. Full Welfare Gains

Estimating consumers' full benefits from stopping tobacco product use is complicated because consumers only internalize part of the health or well-being effects from stopping tobacco use. Consumers revealed preferences, through participation in cessation programs or other quit attempts, therefore reflect revealed consumer choices but may not fully reflect underlying preferences. Consumers may suffer from time-inconsistent behavior, problems with self-control, addiction, and poor information, which prevent them from fully internalizing the benefits of reducing tobacco use. By reducing tobacco product use, however, the gains that are not directly internalized are nonetheless realized. These additional health gains are proportional to the level of market failure generated by internalities and should be added to the willingness to pay estimates to give the full welfare gain.

When a (current or potential) tobacco product user is dissuaded, his or her full welfare gain is composed of the sum of two portions: (1) the portion that the user would be willing to pay for (perhaps via the use of cessation aids) and (2) the portion that exceeds the user's revealed willingness-to-pay because he or she has not fully incorporated long-term consequences into his or her decisions—that is, the difference between the actual value and the dissuaded user's perceived value of the health gains represents the additional welfare gains from reduction of tobacco product use.

As a means of estimating the full value of the welfare gains attributable to the reduction in tobacco product use, such that it captures welfare gains from both portions, we could use tools

based on the economics literature, medical evidence, and the value of a statistical life to convert the effects of smoking reduction on life-years gained and other health improvements into the monetary values of the full welfare gains accrued to the dissuaded tobacco product user. The full welfare gains realized from reduction of tobacco product use could be much larger than the estimates implied by the direct willingness to pay for cessation.

For cigarettes, estimation of the increase in health and longevity associated with smoking cessation or non-initiation is possible because there exist high-quality, evidence-based comparisons of the expected life-cycle events of smokers with those of nonsmokers. Nonsmokers tend to live longer and develop fewer cardiovascular, pulmonary, and other diseases, so the relevant benefits include the discounted value of life-years gained, health status improvements and medical services freed for other uses. They also include certain other financial effects tied to a person's status as a smoker or nonsmoker.

In an earlier analysis (76 *FR* 36628 at 36721-22 and 36772-75), we showed that the level of the optimal tax bounds the welfare gain (that is, the sum of portions (1) and (2) that a smoker would gain as a result of smoking reduction). Gruber and Köszegi (Ref. 4 [2001]) estimate an internal health cost, based on the value of life-years lost from smoking, of $30.45 per pack of cigarettes. In the best-supported set of estimates, Gruber (Ref. 66 [2002-2003]) further suggests that it would take an excise tax in the a range of five to ten dollars per pack to produce the same level of cigarette smoking that would hold in the absence of internalities or other market failures. This calculation yields an internal welfare gain estimate of 16 to 33 percent of the monetary value of the health gains. That is, a dissuaded smoker pays $0.67 to $0.84 to receive a full $1 in health improvements, leaving her with a net gain of $0.16 to $0.33. (We note that, if consumers were fully rational in their use of tobacco products, and understood and appreciated all relevant health and other risk information, there would be no welfare gains realized. However, the literature provides supporting evidence that for addictive goods such as tobacco products there is at least some irrationality in consumption that leads to suboptimal choices.) The welfare gain ratios for users of other tobacco products may differ.

Using the suggested welfare gain ratios would require an estimate of the value of health improvements realized by individuals who are dissuaded from using tobacco products; therefore, we now turn to a discussion of the mortality, morbidity, and other effects of tobacco product use.

i. Expected Life-Years Saved

The largest health consequence of smoking is the increased rate of mortality from pulmonary and cardiovascular disease, cancer, and certain other illnesses. Controlling for differences between smokers and nonsmokers and taking into account observed probabilities of quitting at every age, Sloan et al. (Ref. 68 [2004]) find that the life expectancy of a typical 24-year-old female cigarette smoker is reduced by 2.4 years and the life expectancy of a typical 24-year-old male smoker is reduced by 4.4 years. The effects of other combustible tobacco products on mortality may differ. For example, there is evidence to show that cigar smoking causes many of the same diseases as cigarette smoking, although likely at lower rates due to lower frequency or lower intensity of use and less tendency to inhale (Ref. 70 [1998] at ii-iii). Shanks and Burns' (Ref. 72 [1998]) analysis of the Cancer Prevention Study I shows that mortality risk of cigar

smokers who never smoked any other type of tobacco, relative to never-smokers, is 1.08.[9] Cigar smoke contains many of the same toxic and carcinogenic compounds as cigarette smoke and may have higher concentrations of some constituents, such as nitrogen oxide, ammonia, and tobacco-specific nitrosamines. Cigar smoking is strongly related to certain cancers (including oral, esophageal, laryngeal, and lung cancers), heart disease, and premature death (Ref. 70). Cigar smokers who inhale have a similar risk of death and disease as cigarette smokers (see, for example, Burns et al. Ref. 70 [1998]). Research suggests that smoking small cigars, in particular, is associated with smoke inhalation that leads to significant exposure to carbon monoxide and presumably other toxic components of tobacco smoke, which can lead to respiratory diseases usually associated with cigarette smoking (Ref. 73 [Fabian et al. 2012]). Moreover, regardless of whether cigar smokers claim to inhale, smoke particles are deposited in the lung.

ii. Improved Health Status (or Reduced Morbidity)

Tobacco use also imposes costs in the form of pain, distress, and impaired function before these illnesses cause fatalities. Sloan et al. (Ref. 68 [2004]) examine survey respondents' self-reported health status (which can be categorized as poor, fair, good, very good or excellent) and estimate that a 24-year-old cigarette smoker can expect, on average, an extra 1.086 discounted years (using a discount rate of 3 percent and averaging over Sloan's estimates for males and females) or 0.521 discounted years (using a discount rate of 7 percent and again averaging over males and females) of fair or poor health over his or her lifetime, as compared with a nonsmoker having similar demographic and other characteristics.[10]

The effect of other tobacco products on morbidity may differ.

iii. Medical Services

Sloan et al. (Ref. 68 [2004]) estimate that cigarette smokers use more medical services over their life cycles than do comparable nonsmokers, with a specific net cost of $5,822 per female 24-year-old smoker and $4,056 per male 24-year-old smoker.[11] Users of other tobacco products would also use more medical services than nonusers, but the amounts would depend on the illnesses caused by other tobacco products.

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[9] This study had a sufficiently large sample of cigar smokers to provide meaningful results. The confidence interval for the risk ratio is 1.05 to 1.12.

[10] In order to express the value of rule-induced reductions in years spent in fair or poor health in units comparable to life-years, one can use the ratio representing the tradeoff individuals are willing to make between time spent in best-possible and lesser levels of health.

[11] The Sloan et al. costs were updated to current dollars using the Bureau of Labor Statistics Consumer Price Index (http://data.bls.gov/cgi-bin/surveymost). The present value calculation used a 3 percent discount rate

iv. Other Financial Effects of Smoking Cessation

Sloan et al. (Ref. 68 [2004], page 255) estimate the effect of cigarette smoking on net Social Security, private pension and life insurance outlays, as well as on income tax payments. In the cases of Social Security and private pension outlays, tobacco-related premature mortality causes smokers to collect less from the programs than they contribute during their lifetimes. Therefore, any rule-induced reduction in the U.S. smoking population would shift value from members of the general public who pay Social Security taxes and who contribute to private pension plans to the individuals who are dissuaded from smoking by the regulation. Sloan et al. find over their study period that failure to charge an actuarially fair life insurance surcharge for smoking caused nonsmokers to subsidize smokers. Due to premature morbidity and mortality, smokers would face reduced earnings and pay less in income taxes. Therefore, a transfer from individuals dissuaded from smoking by the regulation to the general public would occur through life insurance programs and income taxes. These financial effects can take the form of subsidies or costs; the net effect is a smoking subsidy, which individuals relinquish when they avoid initiating or quit smoking. The financial effects of using other tobacco products may differ.

Reduced morbidity and mortality is the primary mechanism through which smoking affects Social Security, income tax, pension, and life insurance payments and receipts. Therefore, the loss of the net smoking subsidy may already be included in smokers' willingness to pay for reduced morbidity and mortality. In this case, the amount of the net smoking subsidy would represent benefits to the general public of no longer providing the subsidy. However, there may be additional ways in which smoking affects Social Security, income tax, pension and life insurance payments and receipts, so we are unsure to what extent these transfers would be captured by smokers' willingness to pay for reduced morbidity and mortality.

2. Effects by product type

a. Summary of Benefits for Combustible Tobacco Products

Any provisions that reduce the number of users of combustible tobacco products would lead to welfare gains similar to those described above. The cigar warning labels would be expected to have the largest welfare effect. The behavioral effects of adding a single tobacco addiction warning to pipe tobacco, hookah tobacco, cigarette tobacco, and roll-your-own tobacco are less certain. The proposed prohibition on free samples could also reduce the number of users of cigars, pipe tobacco, and hookah tobacco.[12] We expect the effect of the free samples prohibition to be small because the baseline levels of free samples are small. (The Federal Trade Commission (FTC) reports that in 1997, the dollar value of cigar samples was $423,000 (Ref. 58 [U.S. Federal Trade Commission, 1999])).

Any reduction in use of combustible tobacco products may lead to a corresponding reduction in second-hand smoke exposure. Exposure to second-hand smoke from products other

[12] The free samples prohibition for cigarette tobacco and roll-your-own tobacco would not be attributable to this proposed rule because those products are already regulated under chapter IX of the FD&C Act and its implementing regulations.

than cigarettes, and the effects of such exposure, have not been extensively documented. There is evidence, however, that second-hand cigar smoke presents significant public health risks due to the harmful substances it contains (Ref. 70 [Burns et al., 1998], pp. 76-83).

Warning labels may lead to behavioral changes other than possible cessation (or avoided initiation) of tobacco product use. For example, warning labels may lead to an increase in compensating health behavior. Specifically, when informed and reminded of the negative effects of tobacco use, the user may attempt to compensate through other changes in behavior.

Requirements that reduce the harmful effects of tobacco product use could also produce benefits, provided they do not lead to an offsetting increase in use. (Offsetting increases in tobacco product use could occur if more people use these products or current users increase their intensity of use.) Provisions such as registration and product listing, ingredient listing, adulteration, and misbranding potentially fall into this category, though we expect any effects to be very small.

We expect cigars, pipe tobacco, and hookah tobacco products that are new to be marketed primarily through the substantial equivalence (or exemptions) pathway. If, without the proposed rule, new products would be developed that pose substantially greater health risks than those already on the market, these new products could worsen the health effects of tobacco product use. The premarket requirements made effective by this proposed rule would prevent such products from appearing on the market. Additionally, clarifying regulatory pathways could stimulate innovation of products that present less risk to public health. However, the costs incurred to market new proposed deemed products could discourage development of new products in general. Premarket requirements could reduce the negative health effects of using combustible tobacco products below what they would be in the absence of this proposed rule. We expect the effects of premarket requirements to be qualitatively similar for handmade cigars, machine-made cigars and pipe tobacco, but we have not quantified the benefits of rule-induced new product requirements.

b. Electronic Cigarettes and Other Non-Combustible, Novel Tobacco Products

Due to the emerging nature of these products, their health effects, which are not fully known, and their yet-to-be established relationship to other tobacco products, the benefits of including electronic cigarettes in this proposed rule are unknown and therefore cannot be quantified.

The size of the health and welfare effects of electronic cigarettes depends in part on how widespread their use becomes. The use of this product has grown rapidly in recent years but we cannot predict if that growth will continue. The use of electronic cigarettes could level off at current levels or it could continue to grow rapidly and perhaps eventually – as some predict—rival traditional cigarettes in popularity. The directions of the effects we describe here do not depend on how large the market for electronic cigarettes becomes but the size of these effects will be proportional to the size of the market.

The direction of the effects of electronic cigarettes on health and welfare depend on two characteristics:

- Relative health effects. Are electronic cigarettes safer than the reference products, which would likely be cigarettes or cigars? In other words, are there negative health effects associated with electronic cigarettes? And, if so, are they less than, greater than, or about the same on average as the tobacco products consumers now use?
- Relationship with other products. Are electronic cigarettes on balance substitutes, complements, or not closely related to other tobacco products?[13]
    - Substitutes. Substitutes are competing goods. If electronic cigarettes are substitutes for cigarettes and cigars, then consumers would use electronic cigarettes instead of these other tobacco products. All else the same, as more electronic cigarettes are consumed, fewer cigarettes and cigars are consumed.
    - Complements. Complements are goods that are consumed together. If electronic cigarettes are complementary to traditional tobacco products, then as more electronic cigarettes are consumed, more cigarettes and cigars are consumed.
    - Not closely related. If the consumption of electronic cigarettes has no effect on the consumption of other tobacco products (and vice versa) then the two goods are not related. We would think of the two activities and possibly the two groups of consumers as independent.

The possible welfare outcomes associated with the growing consumption of electronic cigarettes are shown in Table 12. If electronic cigarettes are substitutes for traditional cigarettes, then their effect on welfare depends on the relative health effect. If electronic cigarettes are safer, then substituting them for cigarettes and cigars increases health and welfare; if they are less safe, such substitution decreases welfare. If electronic cigarettes are complementary to cigarettes and cigars, then their growth always reduces welfare because it encourages consumption of cigarettes or cigars. Finally, if electronic cigarettes are not closely related to other tobacco products, then their effect on welfare depends on their effects on health. If those effects are of the same order of magnitude as cigars and cigarettes, we would expect the welfare effect to be negative. If they are much safer than cigarettes and cigars, then the welfare effects depends partly on their safety compared with substitute products and partly on other characteristics such as degree of addictiveness and the consumer's ability to recognize and internalize potential health costs.

Table 12. Potential Welfare Effects of Electronic Cigarettes

Electronic cigarettes compared with other tobacco products	Safer	About the same	Less safe
Substitutes	+	0	-
Complements	-	-	-
Not related	?	-	-

[13] Different consumers could treat these products differently, with some using electronic cigarettes as complements to traditional cigarettes and some as substitutes. The analysis presented here is based on the overall market effect. In technical terms, goods are substitutes if the market cross-price elasticity of demand is greater than zero, complements if the market cross price elasticity of demand is less than zero, and not closely related if the market cross-price elasticity of demand is approximately zero.

If electronic cigarettes are deemed to be subject to chapter IX of the FD&C Act, the cost of premarket applications would increase the cost of entering and remaining in the market. (It is uncertain whether there are any valid predicates for the electronic cigarette products currently on the market. If no such predicates exist or if they are hard to identify, then all or most electronic cigarettes would require premarket applications in order to remain on the market.) In addition, warning labeling would serve as a negative signal to consumers and possibly discourage use. The combined effects of these two requirements would reduce consumption below levels that would be observed without regulation. It is important to note that this comparative reduction is a separate consideration from any general secular trend toward greater use of electronic cigarettes.

This discussion would also apply to other novel non-combustible tobacco products, such as certain nicotine gels. We focus on electronic cigarettes because they are the most widely used novel non-combustible product.

B. Costs

Deeming tobacco products, except accessories of a proposed deemed tobacco product, that are currently unregulated to be subject to chapter IX of the FD&C Act and its implementing regulations would create new burdens for some domestic manufacturers of tobacco products, as well as for some foreign manufacturers or importers.[14] Several reports or submissions of information to FDA would be needed on an ongoing basis: registration and product listing, ingredient listing, submissions required prior to the introduction of new products, and others. We note that analogous costs may be generated whenever Congress grants an Agency—such as FDA—authority over a product, but those costs go unstated when the authorization is explicitly granted in a Congressional statute, rather than resulting from an Agency rulemaking. The additional provisions of the proposed rule include warning statement provisions, minimum age and identification check provisions, and vending machine restrictions. The additional provisions would affect retailers in addition to manufacturers and importers.

Throughout the detailed analysis of costs, we show costs for option 1 disaggregated by product and provision. The costs for option 2 are obtained by removing the costs for premium cigars.

1. Number of Affected Entities

a. Manufacturers and Importers

Based on aggregate information obtained from the Alcohol and Tobacco Tax and Trade Bureau (TTB), in 2012 there were 14 domestic manufacturers of small cigars, 107 manufacturers

[14] Provisions of chapter IX of the FD&C Act and its implementing regulations would automatically apply to the proposed deemed products wherever the term "tobacco product" is used. For a description of FD&C Act provisions applying to all tobacco products and the intended public health benefits, see section IV of the proposed rule's preamble.

of large cigars, and 73 manufacturers of pipe tobacco; in addition, there were 222 importers of small or large cigars and 48 importers of pipe tobacco. Summing, we estimate that 194 domestic manufacturing establishments and 270 importers would be affected by the deeming action. Based on aggregate information from TTB, an additional 23 manufacturers and 21 importers of roll-your-own tobacco would be affected by the other provisions of this rule. Thus, (excluding manufacturers and importers of electronic cigarettes) an estimated total of 217 manufacturers and 291 importers would be affected by this proposed rule.

These numbers could be over- or underestimates. An establishment is counted once for each type of tobacco product it manufacturers or imports, which over-counts establishments that produce multiple types of tobacco products or engage in both manufacturing and importing. However, we include manufacturers and importers of only the largest product categories affected by the deeming provision, cigars and pipe tobacco. We do not attempt to estimate the number of manufacturers of other types of newly-regulated tobacco products, such as electronic cigarettes, because very little information about them is available. We request comment on the number of manufacturers of electronic cigarettes and other proposed deemed tobacco products. Due to lack of data, we do not estimate the number of cigarette tobacco manufactures that, along with roll-your-own tobacco manufacturers, would be affected by the additional provisions of this proposed rule.

Some manufacturers or importers may cease to sell products in the U.S. rather than bear the cost of complying with this proposed rule. The handmade segment of the cigar market is made up of a large number of low volume industry players and is overwhelmingly composed of imports, and some cigar importers may choose not to continue to operate in the U.S. under the proposed rule.[15] We note that under these assumptions, foreign producers of handmade cigars would not necessarily cease to operate; rather, they would cease to sell their products in the U.S. Although we do not have an estimate of the number of electronic cigarette manufacturers and importers affected by this proposed rule, we similarly expect that rather than bear the cost of compliance, some would cease to offer their products in the U.S. The total costs of complying with the proposed rule would create the potential for exit; for simplicity we assume throughout this analysis that potential market exits occur at the end of the first year, halfway through the compliance period for labeling requirements and premarket submissions.

Table 14 summarizes information about the current number of manufacturers and importers affected by this proposed rule. In estimating costs, FDA assumes a 10 percent annual rate of turnover among manufacturers and importers.

Table 14: Number of Tobacco Product Manufacturers and Importers Affected

Domestic Manufacturing Establishments	
Large Cigars	107
Small Cigars	14
Pipe Tobacco	73
Electronic Cigarettes	not estimated

[15] The Internal Revenue Code does not define a "premium cigar," and whether a cigar is handmade or machine-made does not affect its tax classification. Accordingly, FDA estimates of the number and market composition of "Machine-Made," "Premium," and "Non-Premium Handmade" cigars are not based on information from TTB.

Subtotal for deeming, excluding electronic cigarettes	**194**
Roll-your-own tobacco	23
Total, excluding electronic cigarettes	**217**
Importers	
Cigars	222
Pipe Tobacco	48
Electronic Cigarettes	not estimated
Subtotal for deeming, excluding electronic cigarettes	**270**
Roll-your-own tobacco	21
Total, excluding electronic cigarettes	**291**

b. Retailers

Point-of-sale advertising that does not comply with applicable warning statement provisions would be removed by manufacturers (or importers) and retailers. New restrictions on the sale of tobacco products (e.g., age and identification requirements and restrictions on vending), could also potentially affect retailers.

We use data from the 2007 Economic Census report on product line sales to estimate the percentage of various types of establishments that sell tobacco products (Ref. 90 [2007 Economic Census retail trade]; Ref. 92 [2007 Economic Census accommodation and food service]).[16] We update the number of establishments with employees using 2008 Statistics of U.S. Businesses data (Ref. 94) but assume the share of establishments selling tobacco products is unchanged since 2007 within each category. Likewise, we lack data on product line sales for nonemployer establishments but assume that, within a NAICS category, the share of establishments selling tobacco products will be the same for nonemployer establishments in 2009 as for establishments with payroll in the 2007 Census (Ref. 96 [Nonemployer statistics, retail trade and accommodation and food services]). As shown in table 15, about 247,000 retail establishments with payroll and 123,000 nonemployer establishments sell tobacco products.[17]

Table 15. Establishments that Sell Tobacco Products

			Establishments with Employees		Nonemployer Establishments	
Kind of Business	**NAICS**	**Percentage Selling Tobacco Products [a]**	**Number [b]**	**Estimated Number Selling Tobacco Products**	**Number [c]**	**Estimated Number Selling Tobacco Products**
General merchandise stores	452	17%	45,683	7626	32,515	5,428

[16] The Economic Census is conducted every 5 years, and the relevant data from the 2012 census has not been released yet. The 2007 data predates widespread electronic cigarette retailing.

[17] These totals do not include establishments that primarily sell electronic cigarettes. The Economic Census is conducted every five years, and the 2012 Census has not yet been released. The 2007 data are too old to reflect a significant number of electronic cigarette retailers.

Food & beverage stores	445 excluding 44512	66%	118005	77969	100,579	66,455
Convenience stores	44512	100%	25,670	25670	e	
Gasoline stations with convenience stores	44711	92%	95,093	87432	e	
Gasoline stations	44719	30%	19,051	5668	9,017	2,683
Health & personal care stores	446	18%	88,445	16331	136,964	25,289
Other retail stores	D	1%	595,470	2987	715,332	3,588
Accommodation and food services	72 excluding 7224	1%	591,512	7126	279,946	3,373
Drinking places	7224	19%	45,074	8774	27,708	5,394
Tobacco stores	453991	100%	6,463	6463	e	
Non-store retailers	454 excluding 4542	1%	53,001	625	752,250	8,872
Vending machine operators	4542	6%	4,889	298	26,060	1,590
Total		**15%**	**1,688,356**	**246,969**	**2,080,371**	**122,672**

a Percentage of establishments of firms with payroll. Sources: Ref. 90 [2007 Economic Census: United States: Retail Trade: Subject Series-Product Lines] and Ref. 92 [2007 Economic Census: United States: Accommodation and Food Services: Subject Series-Product Lines]
b Ref. 94 [2008 Statistics of U.S. Businesses]
c Ref. 96 [2009 Nonemployer Statistics]
d Includes NAICS 441, 442, 444, 448, 451, 453 excluding 453991
e Data on nonemployer establishments unavailable for this NAICS category

2. Number of Affected Products

a. Number of Products

Many costs of this proposed rule depend on the total number of affected products, measured as the number of unique product formulations or universal product codes (UPCs), depending on the provision. (The number of UPCs exceeds the number of product formulations because the same product can be packaged in multiple ways, with each packaging configuration receiving its own UPC.)

Perelman's Pocket Cyclopedia of Cigars (Ref. 98 [Perelman, 2010]) provides a comprehensive list of cigar brands marketed nationally in the U.S.[18] Using the information provided, we estimate that 1,473 brands, 11,169 formulations, and 11,449 UPCs for cigars are marketed nationally. Option 1 of the proposed rule would cover all cigars and UPCs, but option 2 would exempt premium cigars.

[18] Perelman (Ref. 98 [2010]) notes that readers may come across brands at their local tobacco shop that are not included in the Pocket Cyclopedia. These could include cigars marketed only regionally or close-outs of discontinued brands that are no longer being produced.

See Table 16, below, for disaggregation into machine-made, premium,[19] and non-premium handmade subcategories. We disaggregate handmade cigars into premium and non-premium based on our estimate that approximately 36 percent of handmade cigars meet the proposed definition of premium.[20] In Table 17, cigars are further disaggregated by foreign or domestic origin.

To develop a lower bound estimate of the number of pipe tobacco formulations and UPCs (including hookah tobacco), we count the products on a web site with a broad product offering, <http://www.pipesandcigars.com/>. We estimate formulations with the number of the distinct product names and UPCs with the number of distinct product-package combinations, which yields an estimated 901 pipe tobacco product formulations and 1,185 pipe tobacco product UPCs.[21]

This proposed rule would also extend the FD&C Act tobacco authorities to tobacco products that do not fit into traditional product categories, such as electronic cigarettes or nicotine gels. Current estimates in the press indicate that sales of electronic cigarettes are expected to be between $1.0 billion and $1.7 billion in 2013. Cigar sales are forecast to be about $8.1 billion in 2013 (Ref. 49, [Euromonitor, 2012]). Therefore, forecasted sales for electronic cigarettes are 12 to 21 percent of forecasted cigar sales. Using 15 percent as our best estimate of the size of the electronic cigarette market relative to the cigar market, and assuming the number of products and UPCs is proportional to dollar sales, we estimate there currently are 1,675 e-cigarette formulations and 1,717 electronic cigarette UPCs.[22] We are unable to quantify the cost of including other novel tobacco products, such as nicotine gels or lozenges, due to lack of data.

Components and parts of proposed deemed tobacco products would also be deemed to be subject to chapter IX of the FD&C Act, though the additional provisions of this proposed rule would not apply to components or parts that do not contain tobacco or nicotine. We have not

[19] We note that there is no single accepted definition for premium cigars. The definition FDA developed for the proposed rule is intended to reflect a subset of cigars which some have described to FDA as having a different public health impact. The proposed rule invites comment on this definition.

[20] Based on the cigar cyclopedia (Ref. 98 [2010]), about 10 percent of handmade cigars would be excluded from the premium category based on non-price criteria. We sampled prices for handmade cigars sold singly on two well-known Internet sites. On one site 31 percent of these cigars had prices greater than or equal to $10 apiece. On the other site 13 percent were priced $10 or higher. Taking into account the possibility that some manufacturers offering cigars with prices close to $10 might raise the prices of these cigars to avoid regulation, we estimated that no more than 40 percent of handmade cigars would sell for $10 or more. We assume that non-price criteria and price are unrelated. Therefore, we estimate that 36% (= 40% * 90%) of handmade cigars would qualify as premium with a $10 price point.

[21] We count tobacco offered in tins, "bulk" tobacco that is prepackaged in some form, but we exclude true bulk tobacco that is not prepackaged. We also include every product listed as offered, even if it was out of stock at the time.

[22] A single online retailer, myvaporstore.com, claims to sell over 1,000 unique products <http://www.myvaporstore.com/aboutus.asp>. FDA analysts counted over 150 unique products among just the top 5 brands.

quantified the cost of deeming tobacco product components and parts that do not contain tobacco or nicotine, but we request comment on this issue.

Using scanner data from AC Nielsen, we estimate that 167 cigarette tobacco and roll-your-own tobacco UPCs would be affected by the non-deeming provisions of this proposed rule.[23] If retailers outside of Nielsen's coverage carry a large number of unique cigarette tobacco or smoking tobacco UPCs, these data will yield an underestimate.

Table 16 summarizes the number of products affected by this proposed rule, while Table 17 provides cigar product detail by foreign and domestic origin.

Table 16: Number of Products Affected by this Proposed Rule

	Brands	**Products**	**UPCs**
Cigars:			
Machine-made	152	1,062	1,150
Premium [1]	476	3,639	3,708
Non-Premium Handmade [1]	845	6,468	6,591
Cigar Total[1]	**1,473**	**11,169**	**11,449**
Pipe and Hookah Tobacco (Tinned and Bagged)		901	1,185
Electronic Cigarettes[2]		1,675	1,717
Cigarette tobacco and Roll-Your-Own Tobacco			167

1 We assume that 50 to 90 percent of handmade cigar products and UPCs remain on the market under option 1 of the proposed rule. Thus, 5,054 to 9,906 handmade products and 5,150 to 9,269 handmade UPCs would remain.
2 If there is no valid predicate tobacco product for e-cigarettes, the number of products or UPCs on the market under the proposed rule would depend on the number of marketing authorizations obtained through premarket tobacco applications.

Table 17: Number of Existing Cigar Products by Foreign and Domestic Origin

	US Products	**Imported Products**	**Total Products**	**US UPC**	**Imported UPC**	**Total UPC**
Machine-made Cigars	698	364	1,062	763	387	1,150
Premium Cigars	362	3,276	3,639	377	3,331	3,708
Non-Premium Handmade Cigars[1]	644	5,825	6,468	669	5,922	6,591
Total	**1,704**	**9,465**	**11,169**	**1,809**	**9,640**	**11,449**

It may not be profitable for firms to bear the per-product costs of this proposed rule for the large number of products that currently exist. The market for handmade cigars is characterized by a very large number of relatively low volume products. Some domestic producers may cease to sell their products domestically or discontinue some products. Foreign producers may cease selling their products to the US or reduce the number of distinct products they sell in the US. To account for this, under Option 1, we assume that 50 to 90 percent of handmade cigar products will continue to be marketed in the U.S. The wide range reflects uncertainty in the extent of product consolidation and exit that would occur. There is much product differentiation in the market for handmade cigars, and the norm is to produce several variants under a given brand

[23] We assume that any smoking tobacco not categorized as pipe tobacco is cigarette tobacco or roll-your-own tobacco and count any UPC for which sales were greater than zero in 2008 (the most recent complete year for which we have data) as an active UPC.

name. For the purposes of this analysis, each variant is a different product; much of the product consolidation and or exit we anticipate would be driven by a reduction in the number of product variants, as opposed to complete brand exit. A reduction in product variation is most likely to involve low-volume products, and does not necessarily reflect a reduction in total sales volume. The principal cost of these anticipated changes is the reduction in variation for consumers to choose from.

In addition, we assume that the per-product (or per-UPC) costs of this proposed rule, including labeling changes and premarket tobacco product applications (PMTAs) are costly, and if there are no valid predicate products for substantial equivalence submissions, electronic cigarettes would necessarily be marketed through the premarket tobacco application pathway. There are currently a large number of electronic cigarette products being marketed, some of which have very little market share while others represent product variation among larger market players. Products that do not have sufficient sales to justify incurring the costs of complying with the proposed rule would exit. Products with larger sales will more likely bear these costs to come into compliance with any final rule, but we expect some reduction in the variety of products offered even among larger players. Therefore, we expect that considerable product consolidation and exit would occur, as well as the entry, exit, and consolidation that would be expected to occur in an emerging market and that would occur under baseline conditions. (For example, consolidation might occur under the baseline as large manufacturers of traditional tobacco products enter this market and perhaps absorb smaller manufacturers and products.) Entry of future electronic cigarette products onto the market would be determined by the number of marketing authorizations obtained.

For simplicity, we assume throughout this analysis that potential market exits occur at the end of the first year, halfway through the compliance period for labeling requirements and premarket submissions.[24]

We acknowledge that product exit reduces product variety and the range of choices available to consumers, but we do not estimate the value of this loss of consumer choice.

b. Changes in products

FDA uses a variety of approaches to derive a general estimate of the rate at which new tobacco products within well-established tobacco product categories are introduced. First, we look to FDA's experience with substantial equivalence reports for currently-regulated tobacco products introduced into interstate commerce after February 15, 2007 but before March 22, 2011. Manufacturers of these products needed to submit substantial equivalence reports no later than March 22, 2011, or else the products would be deemed misbranded and adulterated. By the end of March, 2011, FDA had received approximately 3,141 substantial equivalence reports. Scanner data from AC Nielsen indicate that approximately 5,325 cigarette, smokeless, cigarette or smoking tobacco and cigarette paper UPCs had nonzero sales in 2008. If the number of UPCs

[24] Labeling changes and premarket submissions are the most costly requirements, and are there most likely to trigger exit.

did not change substantially between 2008 and 2011, then approximately 59 percent of all product UPCs were considered new in 2011 under the statutory definition. If different grandfathered products were replaced each year to make room for new products (rather than products in certain segments of the market being replaced repeatedly), the number of new products introduced each of the four-plus years between February 15, 2007, and March 22, 2011, would have been nearly 15 (=59÷4) percent of the existing stock of products. If new products had the same chance of being replaced as grandfathered products, this proportion would have been higher.

The Pocket Cyclopedia of Cigars (Ref. 98 [Perelman, 2010]) reports that 223 new cigar brands were introduced in 2010, which is approximately 15 percent of the total number of cigar brands. However, handmade cigars may be atypical. Excluding handmade cigars yields a count of 12 new brands, which is approximately 8 percent of 152, the total number of machine-made brands.

Using scanner data from AC Nielsen, we estimate the proportion of UPCs with positive sales in 2008 that appear to be new, meaning that sales are zero in the final weeks of 2007. Using this definition, the share of new products is about 9 percent for pipe tobacco and 15 percent for cigars.

Based on this information, FDA assumes that within well-established product categories, the number of new products introduced each year equals 5 to 15 percent of the number of existing products. We assume that an equal number of products are removed from the market each year, so the total does not increase.

To allow for a potential spike at the initial (24-month) deadline for premarket submissions, we assume that 20 to 80 premarket tobacco applications would be submitted for electronic cigarettes during the first 24 months, while 10 to 20 would be submitted annually in subsequent years. For electronic cigarette marketing authorizations obtained through premarket tobacco applications, we assume that due to the high cost of submitting a new application, those products would remain on the market once marketing authorizations are obtained. If some authorizations are obtained by way of substantial equivalence reports, costs per authorization would be lower and the products would be more likely to be modified over time.

3. Private Sector Deeming-Specific Costs

a. Annual Registration and Product Listing

Chapter IX of the FD&C Act requires annual registration by owners and operators of domestic tobacco product manufacturing establishments and immediate registration of new owners-operators and new establishments. [25] The number of establishments would be the main determinant of this cost. Product listing for registered establishments is also required.[26]

[25] See Section 905(b).

[26] See Section 905(i). The product listing includes accompanying information, such as all labeling and a representative sample of advertising.

Changes in the product list (new and discontinued products) are to be reported twice a year. The number of products would be the main determinant of the product listing cost.

Based on FDA experience with currently regulated tobacco products, we estimate that it would take 3 hours per manufacturing establishment to complete the annual registration (Ref. 100 [Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, 2009]). Although this requirement only applies to domestic manufacturing establishments, importers who repack or relabel would fit the FD&C Act definition of tobacco product manufacturer. To account for this, we include both domestic manufacturing establishments and importers in our upper bound estimates. For the purpose of attributing costs to machine-made or handmade cigars, we assume for analytical simplicity that domestic manufacturers produce machine-made cigars while importers market handmade cigars. Likewise, for the purpose of attributing costs to premium cigars and non-premium handmade cigars, we assume that 36 percent of importers of handmade cigars import premium cigars, following our product estimate above.

FDA interprets the product listing requirement to apply to tobacco products that differ from each other in any way other than packaging differences that do not affect characteristics of the product (Ref. 100 [Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, 2009]). We estimate the number of products using the number of unique formulations. For the reasons described above, we include only domestic products in the lower bound cost estimates but also include imported products in our upper bound. Lacking estimates of the number of pipe tobacco products and electronic cigarettes produced domestically, we assume that 33 percent of pipe tobacco products are manufactured domestically, roughly mirroring the proportion of manufacturers and importers that are categorized as domestic manufacturing establishments. Finally, based on FDA experience with currently regulated tobacco products, we estimate that it takes 0.75 hours per product to complete the product listing (Ref. 100 [Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, 2009]).

In valuing the time spent complying with this provision, FDA uses the Bureau of Labor Statistics mean wage in the tobacco manufacturing industry for office and administrative support occupations, $19.16 per hour.[27] We double this to account for benefits and overhead, yielding an hourly cost of $38.32.

Table 18 shows establishment registration and product listing costs. Throughout this document, when only upper and lower bounds are presented, we use the midpoint as our primary estimate. The table reflects that some producers may cease to sell their products domestically or discontinue some products. Foreign producers may cease selling their products to the US or reduce the number of distinct products they sell in the US. To account for this, under option 1,we assume that 50 to 90 percent of handmade cigar products will continue to be marketed in the U.S.

[27] May 2012 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200--Tobacco Manufacturing. <http://www.bls.gov/oes/>

The wide range reflects uncertainty in the extent of product consolidation and exit that would occur. There is much product differentiation in the market for handmade cigars, and the norm is to produce several variants under a given brand name. For the purposes of this analysis, each variant is a different product; much of the product consolidation and or exit we anticipate would be driven by a reduction in the number of product variants, as opposed to complete brand exit. A reduction in product variation is most likely to involve low-volume products, and does not necessarily reflect a reduction in total sales volume. The principal cost of these anticipated changes is the reduction in variation for consumers to choose from.

There are currently a large number of electronic cigarette products being marketed, some of which have very little market share while others represent minor product variation among larger market players. Products that do not have sufficient sales to justify incurring the costs of complying with the proposed rule would exit. Products with larger sales will more likely bear the costs to come into compliance with any final rule, but we expect some reduction in the variety of products offered even among the larger players. Therefore, we expect that considerable product consolidation and exit would occur; much of it among low-volume products and driven by a reduction in the number of product variants, as opposed to complete brand exit. Consumers would choose from the remaining products. A reduction in product variation does not necessarily imply reduction in total sales volume. We do not currently have an estimation of the number of electronic cigarette establishments that would register annually. The number of electronic cigarettes products that would be listed and delisted in years 1 and 2 is also affected by the 24-month compliance period for the labeling and premarket requirements. The wide ranges reflect uncertainty about electronic cigarette product listing and delisting. We do not attempt to estimate the effect of FDA's proposed policy of continuing enforcement discretion during product review. We assume that between 168 and 1,675 electronic cigarette products could be listed in year 1, and that anywhere from 10 to 20 additional products could be listed in year 2. Approximately between 158 and 1,615 products might be delisted sometime during the 24-month period of enforcement discretion; it is important to note, however, that a reduction in product variation does not necessarily imply reduction in total sales volume or production capacity. Moreover, how the reduction in product variety relates to the number of electronic cigarette producers is unclear.

Table 18: Establishment Registration and Product Listing Requirements (Based on Option 1)

	Year 1 Lower Bound	Year 1 Upper Bound	Year 2 Lower Bound	Year 2 Upper Bound
Annual Establishment Registration[1]				
Total number of establishments (excluding electronic cigarettes)	**194**	**464**	**213**	**510**
Time (Hours)	3	3	3	3
Registration Cost ($)[2]	**22,302**	**53,341**	**24,532**	**58,676**
Number of Product Listings[3]				
Machine-made Cigars	698	1,062	35	159
Premium Cigars	362	3,639	9	491
Non-Premium Handmade Cigars	644	6,468	16	873
Pipe and Hookah Tobacco	300	901	15	135
Total number of product listings (including electronic cigarettes)	**2,172**	**13,745**	**85**	**1,679**
Number of De-Listings[3]				

Machine-made Cigars			35	159
Premium Cigars	181	364	9	491
Non-Premium Handmade Cigars	322	647	16	873
Pipe and Hookah Tobacco			15	135
Total number of de-listings (including electronic cigarettes)	**661**	**2,626**	**75**	**1,659**
Time (Hours)	0.75	0.75	0.75	0.75
Product Listing and Delisting Cost ($)[2]	**81,401**	**470,494**	**4,602**	**95,925**
Total Cost				
Machine-Made Cigars ($)	33,971	44,432	17,307	24,458
Premium Cigars ($)	15,613	124,225	520	38,350
Non-Premium Handmade Cigars ($)	27,756	220,819	925	68,149
Pipe and Hookah Tobacco ($)	17,024	39,805	10,094	23,070
Electronic Cigarettes ($)	9,341	94,555	287	575
Total Cost ($)[2]	**103,704**	**523,835**	**29,135**	**154,601**

1 See table 14. All existing establishments register in the first year. In years 2 through 20, registrations equal 110 percent of the number of establishments that continue past the first year, to account for turnover.
2 The hourly labor cost is $38.32.
3 See tables 16 and 17. The lower bounds include only domestic products, while the upper bounds also include imported products. Existing products are listed in the first year. For handmade cigars and electronic cigarettes, we assume for analytical convenience that the products that exit are delisted at the end of the first year. For all products except e-cigarettes, the number of product listings and de-listings in years 2 through 20 is equal to 5 to 15 percent of the number of products within the category in years 2 through 20. For e-cigarettes, we assume the number of new products listed in years 2-20 equals to the number of premarket tobacco applications submitted annually in the years after the initial premarket submission deadline
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b. Ingredient Listing

Chapter IX of the FD&C Act requires tobacco product manufacturers or importers to submit a listing of all product ingredients by brand and by quantity for each brand and sub-brand.[28] Initially, an ingredient list must be submitted for each of a manufacturer's products, which FDA would request 6 months after the effective date of the final rule. Ingredient lists must also generally be submitted 90 days prior to introducing a new product into interstate commerce or changing additives in an existing product.[29] However, in specific circumstances, such as when an additive is eliminated or decreased, the new ingredient list can be submitted up to 60 days after introduction of the new product.[30]

As with product listing, FDA interprets the ingredient listing requirement to apply to tobacco products that differ in any way other than packaging differences that do not affect characteristics of the product (Ref. 102 [Guidance for Industry: Listing of Ingredients in Tobacco Products, 2009]). Therefore, we estimate the number of products using the number of unique formulations. The number of products would be the main determinant of the ingredient listing cost.

[28] See Section 904(a)(1).
[29] See Sections 904(c)(1) and 904(c)(2).
[30] See Section 904(c)(3).

Based on FDA experience with currently regulated tobacco products, we estimate that it requires 3 hours per product to submit an ingredient list (Ref. 102 [Guidance for Industry: Listing of Ingredients in Tobacco Products, 2009]). We request comment on whether the cost of ingredient listing would be substantially different for any proposed deemed tobacco products. In valuing the time for complying with this provision, 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.[31] We use a mix of 30 percent life, physical, and social science occupations; 20 percent architecture and engineering occupations; 30 percent office and administrative support occupations; and 20 percent legal occupations. This mix yields a composite wage of 33.25.[32] We double this to account for benefits and overhead, yielding an hourly labor cost of $66.50. Table 19 shows the cost of ingredient listing.

Table 19: Ingredient Listing

	Year 1	Year 1	Years 2-20	Years 2-20
	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Number of ingredient lists[1]				
Machine-Made Cigars	1,089	1,142	53	159
Premium Cigars	3,729	3,911	91	491
Non-Premium Handmade Cigars ()	6,630	6,954	162	873
Pipe and Hookah Tobacco	924	969	45	135
Electronic Cigarettes[2]	1,717	1,801	10	20
Total Number of Ingredient Lists	**14,089**	**14,776**	**361**	**1,679**
Time (Hours)	3	3	3	3
Total Ingredient Listing Cost				
Machine-Made Cigars ($)	217,159	227,752	10,593	31,779
Premium Cigars ($)	744,009	780,303	18,148	97,988
Non-Premium Handmade Cigars ($)	1,322,684	1,387,205	32,264	174,201
Pipe and Hookah Tobacco ($)	184,238	193,225	8,987	26,962
Electronic Cigarettes ($)	342,506	359,214	1,995	3,990
Total Ingredient Listing Cost ($)[3]	**2,810,596**	**2,947,698**	**71,987**	**334,921**

1 See table 16. For premium cigars, non-premium handmade cigars, machine-made cigars, and pipe tobacco, the number of new products expected to be introduced each year is 5 to 15 percent of the total number of products. Because ingredient listing would be implemented 6 months after the effective date of a final rule, the number of ingredient lists in year 1 would equal 102.5 to 107.5 percent of the number of products in year 1. The number of new product ingredient lists in years 2 through 20 would be 5 to 15 percent of number of products in years 2 through 20.

2 In year 1, the number of electronic cigarette ingredient lists is calculated in the same way as for other categories of products. In years 2-20,, we assume the number of new electronic cigarette ingredient lists equals the number of premarket tobacco applications submitted annually in the years after the initial premarket submission deadline .

3 Time is valued at $66.50 per hour.

c. Potentially Harmful Constituents

Chapter IX of the FD&C Act requires submission of a listing by brand and quantities by brand or sub-brand of all tobacco product constituents (including smoke constituents) identified by the Secretary as harmful or potentially harmful, beginning three years after enactment of the

[31] May 2012 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200--Tobacco Manufacturing. <http://www.bls.gov/oes/>

[32] The calculation is 0.3*(35.65) + 0.2*(41.88) + 0.3*(19.16) + 0.2*(42.15) = 33.25.

statute.[33] FDA would set a compliance date for submission of this information three years after a final deeming rule becomes effective. Although this provision would create an obligation that imposes costs, the Secretary is also required to promulgate regulations concerning the testing and reporting of constituents.[34] We will estimate the cost of compliance with testing and reporting when those regulations are promulgated; this cost includes not only the cost of submitting the required information, but also the cost of prerequisite product testing if such testing is not already conducted for other reasons.

d. Tobacco Health Documents

Chapter IX of the FD&C Act requires tobacco product manufacturers or importers to submit to FDA documents "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives" if those documents were developed after June 22, 2009."[35] Documents are "developed" when they are created or modified in any way (Ref. 104 [Guidance for Industry: Tobacco Health Document Submission, 2010]).

This is an ongoing reporting requirement, but firms that do not anticipate ever having any health documents may state it in a single submission and would not be obligated to report again unless documents are developed. Because most newly-regulated tobacco product manufacturing businesses would be small, FDA assumes that very few routinely develop health documents. Furthermore, this provision would generally serve as a disincentive to continue developing or start developing health documents in the future. Therefore, we expect the cost of this provision to be small and include it under miscellaneous costs. We request comments about the cost of complying with this provision.

e. Requirements for New Tobacco Products

Chapter IX of the FD&C Act requires premarket review of tobacco products not marketed as of February 15, 2007, unless they are found to be "substantially equivalent" to products already on the market or are found to be exempt from demonstration of substantial equivalence.[36] Thus, before bringing a new product to market, a manufacturer or importer must submit a premarket tobacco application, a 905(j) report demonstrating substantial equivalence, or a 905(j) report citing one or more exemptions.[37] Proposed deemed products not marketed as of the February 15, 2007, cutoff (grandfather date) would be new tobacco products, and the compliance date for premarket review requirements would be 24 months after the effective date of the final rule. Only products remaining on the market past the compliance date would need to comply with these requirements.

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[33] See Section 904(a)(3).
[34] See Section 915.
[35] See Section 904(a)(4).
[36] See Section 910(b), Section 905(j)(1)(A)(i), and 905(j)(3).
[37] Cigarettes, smokeless tobacco, roll-your-own and cigarette tobacco products first marketed after February 15, 2007, and prior to the statutory compliance date (21 months after enactment of the Tobacco Control Act), could be marketed provided that a substantial equivalence report was submitted within that 21-month period and the Secretary had not issued an order finding the product to be not substantially equivalent.

Under the proposed rule, if a manufacturer of a proposed deemed tobacco product first marketed between February 15, 2007, and the 24-month proposed compliance date submits a substantial equivalence report or premarket tobacco application by the compliance date, FDA does not intend to initiate enforcement action against the product unless and until FDA issues an order denying the substantial equivalence submission or the premarket tobacco application.[38]

We use the composite labor cost described above, $66.50 per hour, to value the time spent on all premarket submissions.

i. Number of New Products

For categories of products that were well established before February 15, 2007, (cigars and pipe tobacco) we estimate the number of new products introduced each year to be 5 to 15 percent of the number of unique formulations on the market. In determining the proportion of products on the market at the end of the 24 months that would be new, we assume each product has the same chance of being changed regardless of how long it has been on the market. Since about 9 years will have lapsed between February 15, 2007, and 24 months after a final rule is issued, we estimate that 37 to 77 percent of products would be new by the time requirements for new products go into effect.[39] In deciding which handmade cigars to continue marketing beyond the first year, we assume that manufacturers and importers give priority to grandfathered products; this minimizes the number of new products subject to premarket requirements. Details appear in Table 20.

For newer categories of products that were not well established before 2007, such as electronic cigarettes or other novel tobacco products, we assume that all products currently on the market would be considered new. The number of such products remaining on the market under the proposed rule is uncertain, as discussed below.

Table 20: Number New Tobacco Products, Excluding Products Expected to be Removed From the Market

	First 24 months Lower Bound	First 24 months Medium	First 24 months Upper Bound	Years 3-20 Lower Bound	Years 3-20 Medium	Years 3-20 Upper Bound
Machine-Made Cigars [1]	393	648	818	53	106	159
Premium Cigars [1,2]	0	1,127	2,438	91	255	491
Non-Premium Handmade Cigars [1,2]	0	2,006	4,334	162	453	873
Pipe and Hookah Tobacco [1]	333	550	694	45	90	135
Electronic Cigarettes[3]	20	50	80	10	15	20

[38] See the subsections of the preamble entitled "Compliance policy for substantial equivalence submissions" and "Compliance policy for premarket tobacco product applications" [Insert FR Ref.] for a complete description of FDA's proposed compliance policies.

[39] If 5 percent of products are replaced each year, then 63 percent (=100*(1-0.05)^9) of products remain on the market unchanged for 9 years and the other 37 percent are changed at least once. Likewise, if 15 percent of products are replaced each year, then 23 percent (=100*(1-0.15)^9) of products remain on the market unchanged for 9 years and the other 77 percent are changed at least once.

Total	**746**	**4,381**	**8,363**	**361**	**919**	**1,678**

1 See table 16. The proportion of products considered to be new at the end of 24 months is 0.37 (lower bound), 0.61 (medium), or 0.77 (upper bound). The number of new products introduced in subsequent years is expected to range from 5 percent to 15 percent of the total number of products.
2 There are currently 10,107 handmade cigar products, 3,740 to 7, 782 of which would be considered new 24 months after a final rule is issued. This corresponds to 6,367 to 2,325 products that would be grandfathered. In deciding which handmade cigars to continue marketing, we assume that manufacturers and importers give priority to grandfathered products.
3 All electronic cigarettes currently marketed are expected to be considered new products. The number remaining on the market under the proposed rule is uncertain, as discussed below.

ii. Premarket Tobacco Applications

Among traditional product categories such as cigars and pipe tobacco, the proportion of proposed deemed products that would not be found substantially equivalent to a valid predicate product is uncertain. Therefore, the number of new products requiring premarket tobacco applications within those categories would also be uncertain, though our best forecast is that it would be small. (As of November 2012, no premarket tobacco applications had been submitted to FDA for currently-regulated products.) By contrast, it is uncertain whether there exists a valid predicate for the electronic cigarette products currently on the market. Because all electronic cigarettes are expected to qualify as new products, if no such predicates exist or if they are hard to identify, then all or most electronic cigarettes would require premarket applications in order to remain on the market. In this analysis, we assume that cigars and pipe tobacco products have valid predicates and would be marketed through substantial equivalence reports or substantial equivalence exemptions, but electronic cigarettes would be marketed through premarket tobacco applications. Other novel products would also be expected to be marketed through premarket tobacco applications, although we do not separately quantify them.

FDA's Center for Tobacco Products estimates that conducting the necessary scientific investigations and preparing a premarket tobacco application would take 5,000 hours. This estimate includes the time to conduct a chemical analysis and any necessary nonclinical or clinical studies, though it is possible that based on existing studies, an applicant may not need to conduct any new nonclinical or clinical studies. Clinical studies addressing perception, use pattern, or health impact may be appropriate; FDA does not expect most applications to include randomized clinical trials. For tobacco products already on the market at the time a final rule is issued, much of the information required to support an application may be obtained from previously published research on similar products. FDA also estimates that it would take an additional 4 hours to meet with FDA about investigational plans and 12 hours to prepare an environmental assessment, for a total of 5,016 hours per application.

The number of premarket tobacco applications that would be submitted for electronic cigarettes or other novel tobacco products is highly uncertain. Given the current size and potential growth of the market for these products, and given that most applications are not expected to require costly randomized clinical trials, the market will justify the costs of submitting many premarket tobacco applications. These costs, however, would be high enough to expect additional product exit, consolidation, and reduction in variety compared with the baseline. We assume for this analysis that 20 to 80 premarket applications would be submitted

within the first 24 months and an average of 10 to 20 would be submitted each subsequent year. We request comment on this assumption.

The estimated cost of premarket tobacco applications for electronic cigarettes is summarized in Table 21. We assume in this analysis that there will not be any premarket applications for other types of products subject to the proposed rule.

Table 21 Costs for Premarket Tobacco Applications (Electronic Cigarettes or Other Novel Tobacco Products)

	First 24 months Lower Bound	First 24 months Medium	First 24 months Upper Bound	Years 3-20 Lower Bound	Years 3-20 Medium	Years 3-20 Upper Bound
Number of applications	20	50	80	10	15	20
Time for submission (hours)	5,016	5,016	5,016	5,016	5,016	5,016
Total cost ($)	**6,671,079**	**16,677,698**	**26,684,317**	**3,335,540**	**5,003,310**	**6,671,079**

We recognize that premarket tobacco applications would be significantly costlier, per product, than the other pathways for introducing new products. If the premarket tobacco application pathway is more widely used than we currently expect, the total cost for marketing new tobacco products would be substantially higher than we currently estimate. We request comment on the number of premarket tobacco applications FDA might receive on an annual basis and the cost of preparing them.

iii. Grandfathered Products

Although not required by chapter IX of the FD&C Act, tobacco product manufacturers may submit information to demonstrate that a product was commercially marketed in the U.S. as of February 15, 2007, and therefore is a grandfathered product. FDA published a draft guidance, "Draft Guidance for Industry and FDA Staff: Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007," for public comment on April 22, 2011 (Ref. 105). It is uncertain how frequently manufacturers would submit this information and ask the agency for a determination, but they would be most likely to do so when they intend to use a grandfathered product as the basis for introducing a new product. We estimate that requests for grandfathered product determinations would be coupled with 25 to 75 percent of new cigar and pipe tobacco products on the market 24 months after a final rule becomes effective (excluding products expected to exit the market). In subsequent years, we estimate only a trickle of these submissions (equal to 5 percent of new products introduced) because there will be no new grandfathered products, although manufacturers may still be interested in using some existing grandfathered products as the basis for introducing new products. Experts in FDA's Center for Tobacco Products estimate that it would take 10 hours to submit the requested information. The cost to establish that products are grandfathered is summarized in Table 22.

Table 22 Cost for Establishing that Products are Grandfathered

	First 24 months	First 24 months	First 24 months	Years 3-20	Years 3-20	Years 3-20 Upper

	Lower Bound	Medium	Upper Bound	Lower Bound	Medium	Bound
Machine-Made Cigar	98	324	614	3	5	8
Premium Cigar ()	0	564	1,828	5	13	25
Non-Premium Handmade Cigar ()	0	1,003	3,251	8	23	44
Pipe and Hookah Tobacco	83	275	521	2	5	7
Total number of products	**181**	**2,166**	**6,214**	**18**	**46**	**84**
Time for submission (hours)	10	10	10	10	10	10
Total Cost						
Machine-Made Cigars ($)	65,168	215,454	408,298	1,995	3,325	5,320
Premium Cigars () ($)	0	375,049	1,215,583	3,325	8,645	16,625
Non-Premium Handmade Cigars () ($)	0	666,975	2,161,850	5,320	15,295	29,259
Pipe and Hookah Tobacco ($)	55,193	182,870	346,455	1,330	3,325	4,655
Total Cost ($)	**120,361**	**1,440,347**	**4,132,186**	**11,970**	**30,589**	**55,858**

iv. Substantial Equivalence Exemptions

Because the substantial equivalence exemption pathway would be the least burdensome way to introduce products that satisfy the criteria for an exemption, we assume that as many products as possible will be introduced through this pathway. Tobacco products may be eligible for an exemption if they are formed by adding or deleting a tobacco additive or increasing or decreasing the quantity of an existing additive, and if several specific findings can be made. Since the August 2011 effective date of the regulation implementing the exemption pathway, approximately 8 percent of substantial equivalence or substantial equivalence exemption submissions have been exemption requests. (As noted below, there need not be a one-to-one correspondence between exemptions granted and new products introduced on the basis of exemptions.) Because procedures for using this product marketing pathway were established subsequent to the availability of other pathways, we expect industry's use of it to grow over time, but the statutory criteria will limit the extent to which it may be used. Therefore, we estimate that between 5 and 40 percent of new cigar and pipe tobacco products would use the exemption pathway.

Before citing an exemption in a 905(j) report, a tobacco product manufacturer must first request and be granted an exemption according to procedures established in the substantial equivalence exemptions final rule (76 FR 38961). This pathway is less burdensome than demonstrating substantial equivalence because it does not require the use of a predicate product with a detailed side-by-side description and analysis of product characteristics. The requirements of an exemption request are described in the final rule and, based on estimates for currently regulated tobacco products (76 FR 38971 and 76 FR 38973), are expected to take 12 hours to complete. FDA estimates that for 30 percent of exemption requests, manufacturers would need to spend 3 hours responding to a request from FDA for additional information. An environmental assessment is also required and is estimated to take 12 hours to prepare.

A 905(j) report citing one or more exemptions must include the basis for the determination that the tobacco product is modified within the meaning of the exemption provision. Also, the modifications must apply to a product that is commercially marketed and in

compliance with the requirements of the FD&C Act, with all of the modifications covered by exemptions granted under the exemption provision.[40] Based on our estimate for currently regulated tobacco products, this submission is expected to take 3 hours to prepare (76 FR 38971 and 76 FR 38973). [41]

Because a granted exemption can serve as the basis for the introduction of more than one new tobacco product, FDA estimates that the number of exemption requests (and associated environmental assessments) will equal two-thirds the number of products introduced through the exemption pathway. Taking this into account, FDA estimates that the average time cost of introducing a new tobacco product through the exemption pathway is 19.6 hours [=12*(2/3) +3*(2/3)*(3/10) +12*(2/3) +3]. Table 23 summarizes the cost of Substantial Equivalence Exemptions.

Table 23: Cost of Marketing Products Through Substantial Equivalence Exemptions

	First 24 months Lower Bound	First 24 months Medium	First 24 months Upper Bound	Years 3-20 Lower Bound	Years 3-20 Medium	Years 3-20 Upper Bound
Machine-Made Cigars	157	146	41	21	24	8
Premium Cigar ()	0	254	122	36	57	25
Non-Premium Handmade Cigar	0	451	217	65	102	44
Pipe and Hookah Tobacco	133	124	35	18	20	7
Total Number of Products	**290**	**975**	**415**	**140**	**203**	**84**
Time for submission (hours)	19.6	19.6	19.6	19.6	19.6	19.6
Total Cost						
Machine-Made Cigars	204,628	190,291	53,438	27,371	31,281	10,427
Premium Cigars ($)	0	331,054	159,010	46,921	74,292	32,584
Non-Premium Handmade Cigars ($)	0	587,816	282,829	84,718	132,943	57,348
Pipe and Hookah Tobacco	173,347	161,617	45,618	23,460	26,067	9,124
Total Cost ($)	**377,975**	**1,270,777**	**540,895**	**182,471**	**264,582**	**109,482**

Note we use assume 40 percent of substantially equivalent products qualify for an exemption in our lower bound, and 5 percent in our upper bound, because total premarket costs are lower when more products qualify for an exemption.

v. Substantial Equivalence

We assume that, for all new cigar and pipe tobacco products that do not qualify for an exemption, manufacturers would seek to introduce them into interstate commerce by filing a substantial equivalence report. A 905(j) report demonstrating substantial equivalence must provide sufficient information to enable FDA to determine whether the new tobacco product is substantially equivalent to an appropriate predicate product.[42,43] For every identified design

[40] The exemption provision is Section 905(j)(3) of the FD&C Act.
[41] We do not have sufficient data on the time and costs spent by manufacturers of currently regulated tobacco products to update these estimates based on their actual experiences with obtaining a substantial equivalence exemption.
[42] Substantially equivalent is defined in Section 910(a)(3) of the FD&C Act.

feature, ingredient, material and harmful or potentially harmful constituent, the report must provide a comparison of the new tobacco product with its predicate tobacco product. The heating source and composition of the product are also to be described. The report must also summarize health information related to the tobacco product or state that such information will be made available to any person upon request. Based on experience with currently regulated tobacco products, FDA's Center for Tobacco Products estimates that it will take on average 140 to 220 hours to prepare and submit such a substantial equivalence report.

In addition to the requirements above, an environmental assessment is required with a substantial equivalence report. Based on FDA's estimates for substantial equivalence exemption requests for currently regulated tobacco products, we expect this to take 12 hours (76 FR 38961 at 38971).[44] Summing the two components yields a cost of 152 to 232 hours for marketing a product through the substantial equivalence pathway. In the case of a product that has different characteristics from its predicate, it may be necessary to submit clinical data to demonstrate that the new product does not raise different questions of public health. It is uncertain how frequently this would occur, and our estimate does not include any potential cost for conducting clinical studies. We request comment on this issue. Table 24 summarizes the cost of marketing products through the substantial equivalence pathway.

Table 24: Cost of Marketing Products Through Substantial Equivalence Reports

	First 24 months Lower Bound	First 24 months Medium	First 24 months Upper Bound	Years 3-20 Lower Bound	Years 3-20 Medium	Years 3-20 Upper Bound
Machine-Made Cigars	236	502	777	32	82	151
Premium Cigar	0	873	2,316	55	198	466
Non-Premium Handmade Cigar	0	1,555	4,117	97	351	829
Pipe and Hookah Tobacco	200	426	659	27	70	128
Total Number of Products	**436**	**3,356**	**7,869**	**211**	**701**	**1,574**
Time for submission (hours)	152	192	232	152	192	232
Total Cost						
Machine-Made Cigars	2,385,416	6,409,343	11,987,195	323,446	1,046,945	2,329,558
Premium Cigars () ($)	0	11,146,129	35,723,385	555,923	2,527,988	7,189,232
Non-Premium Handmade Cigars ($)	0	19,853,643	63,521,954	980,447	4,481,433	12,789,427
Pipe and Hookah Tobacco	2,021,539	5,439,004	10,166,746	272,908	893,733	1,974,725
Total Cost ($)	**4,406,955**	**42,848,119**	**121,399,281**	**2,132,724**	**8,950,099**	**24,282,942**

vi. Summary of Requirements for New Tobacco Products

[43] See FDA guidance entitled "Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products" (Ref. 106 [2011]).

[44] We do not have sufficient data on the time and costs spent by manufacturers of currently regulated tobacco products to update these estimates based on their actual experiences with the substantial equivalence pathway.

As shown in Table 25, summing the costs estimated in sub-sections ii through v above, the total cost of complying with provisions governing the introduction of new tobacco products is estimated to be $11.6 to $152.8 million in the first 24 months and $5.6 to $31.1 million in subsequent years. If new products are introduced at a slower rate in the future as a result of these requirements, actual costs could be lower.

Table 25: Total Costs for Marketing New Tobacco Products

	First 24 months Lower Bound	First 24 months Medium	First 24 months Upper Bound	Years 3-20 Lower Bound	Years 3-20 Medium	Years 3-20 Upper Bound
Machine-Made Cigars($)	2,655,212	6,815,087	12,448,931	352,812	1,081,550	2,345,305
Premium Cigars ($)	0	11,852,231	37,097,979	606,169	2,610,924	7,238,440
Non-Premium Handmade Cigars ($)	0	21,108,434	65,966,633	1,070,485	4,629,671	12,876,034
Pipe and Hookah Tobacco ($)	2,250,080	5,783,491	10,558,818	297,698	923,125	1,988,503
Electronic Cigarettes ($)	6,671,079	16,677,698	26,684,317	3,335,540	5,003,310	6,671,079
Total Cost ($)	**11,576,371**	**62,236,941**	**152,756,679**	**5,662,704**	**14,248,580**	**31,119,362**

f. Miscellaneous Costs

The proposed rule would lead to a variety of small potential costs for which FDA has not produced separate estimates. These costs would include administrative set-up costs for every newly covered entity that must register or submit information to FDA. FDA expects that most submissions will be made electronically, so the set-up cost would include time to download and become familiar with the e-submitter software and time to obtain a DUNS number if a manufacturer or importer does not already have one. FDA estimates that the administrative set-up costs would be 5 hours per reporting manufacturer or importer. There would also be modest annual costs for health document submission and costs for satisfying regulations governing the import and export of FDA-regulated products. We estimate these costs to be 11 hours per year for each manufacturer or importer. In valuing the time for complying with this provision, we use the administrative hourly labor cost of $38.32 per hour.

Table 26 shows the miscellaneous costs.

Table 26: Miscellaneous Costs for Manufacturers and Importers

	Year 1 Lower Bound	Year 1 Upper Bound	Years 2-20 Lower Bound	Years 2-20 Upper Bound
Establishment Set-ups				
Machine-Made Cigars	121	121	12	12
Premium Cigars	80	80	6	8
Non-Premium Handmade Cigars	142	142	11	14
Pipe and Hookah Tobacco	121	121	12	12
Electronic Cigarettes	not estimated	not estimated	not estimated	not estimated
Total Establishment Set-Ups[1]	**464**	**464**	**42**	**46**
Set-up cost per establishment (hours)	5	5	5	5
Set-up cost ($)[1]	**88,902**	**88,902**	**8,047**	**8,890**

Continuing establishments[2]				
Machine-Made Cigars			121	121
Premium Cigars			64	80
Non-Premium Handmade Cigars			114	142
Pipe and Hookah Tobacco			121	121
Electronic Cigarettes			not estimated	not estimated
Total continuing establishments			**420**	**464**
Annual cost per establishment (hours)			11	11
Annual cost ($)			**177,038**	**195,585**
Total Cost ($)	**88,902**	**88,902**	**185,086**	**204,476**

1 See table 14. Existing establishments incur the set-up cost in the first year, but only new establishments incur it in subsequent years. We assume an establishment turnover rate of 10 percent per year. Some cigar importers may not continue to operate in the U.S. past the first year. For analytical convenience, we assume in our calculations that 80 to 100 percent of cigar importers would continue to operate in the U.S. market.
2 See table 14.

g. Prohibition of Free Samples

As discussed above, current regulations banning the distribution of free samples would automatically apply to newly-regulated tobacco products. Prohibiting this practice reduces industry costs but could also reduce total economic profits in the tobacco industry if it reduces total sales. Prohibiting free samples may, however, not reduce total economic profits if the primary effect is to induce brand switching and change the distribution of profits rather than total profits. Any effect of eliminating free samples would likely be small because the baseline levels are small. (The Federal Trade Commission reports that in 1997, the dollar value of cigar samples was $423,000 (Ref. 58 [U.S. Federal Trade Commission, 1999])).

Free samples encourage consumers to try new types of tobacco products, enabling them to learn about their own preferences and possibly change their purchasing behavior as a result. Although we are unable to quantify it here, losing this low-cost opportunity to sample different products would raise search costs.

4. Private Sector Labeling Costs

All products affected by this proposed rule would be required to undergo a labeling change.[45] The labeling change for proposed deemed products would satisfy both the requirements of chapter IX of the FD&C Act (discussed in section II.A above) and the warning statement provisions. The labeling change for cigarette tobacco and roll-your-own tobacco would satisfy the required warning statement provisions. Under the warning statement provisions, cigarette tobacco, roll-your-own tobacco, and proposed deemed products other than cigars would be required to carry a single addiction warning. Cigars would be required to

[45] We assume that the package size stays the same and the non-warning information is compressed to fit the reduced allotment of space. We assume that there are minimal costs to consumers from this compression of information. Expanding package size is a possibility, but we have not observed this in other jurisdictions that have implemented large warning labels.

display 5 rotating warnings, four of which are currently displayed on a sizable segment of the cigar market at a result of FTC consent decrees. For cigars sold individually without a product label, the required warning statement would be displayed on a sign or placard at the point of sale. The compliance period for these requirements would be two years after the effective date of the rule. We do not estimate labeling change costs for products expected to exit.[46]

In order to estimate the cost of tobacco product labeling changes, FDA relies primarily on the FDA labeling cost model developed by RTI International (Ref. 108 [RTI, 2011]). The UPC and product formulation counts in the model are largely based on scanner data from AC Nielsen that only cover sales in grocery stores, drug stores, and mass merchandisers (excluding Wal-Mart). The model adjusts the annual tobacco product sales units to reflect total sales at all retail outlets. However, it assumes that tobacco product UPCs and formulations are not seriously underrepresented in outlets covered by Nielsen and does not adjust these counts. While this assumption should be reasonably accurate for cigarettes, it is not likely to be accurate for other tobacco products, especially premium cigars. Therefore, we use our own estimates (described in section II.B.a above) of the number of UPCs affected by this proposed rule.

a. Products Other Than Cigars

The FDA labeling cost model incorporates three potential cost components of a labeling change: label design costs, inventory costs, and testing costs. Because the sources we use to develop expanded estimates of the number of UPCs do not allow us to identify private label products, we assume all products are branded. This assumption eliminates costs for discarded inventory because only private label products would be expected to have label inventory on hand after one year.[47] Additionally, we assume few tobacco product manufacturers would conduct market testing for the required labeling changes.

For a compliance period of two years, the labeling cost model assumes that labeling changes for 78 percent of branded UPCs cannot be coordinated with a previously scheduled, non-regulatory labeling change. Coordination of a regulatory change with a non-regulatory change reduces the incremental burden of the regulatory change.

The changes required for cigarette tobacco, roll-your-own tobacco and proposed deemed products other than cigars align with what the FDA labeling cost model defines as a major change. The required warning statement would occupy 30 percent of the two principal display panels of all these products. Additionally, chapter IX of the FD&C Act would require at least two new statements to be added to the proposed deemed-product labels, not just minor

[46] For simplicity, we assume throughout the analysis that products that exit will do so at the end of the first year, halfway through the compliance period for labeling requirements and premarket submissions.
[47] If we could estimate the inventory cost, however, we would expect it to be small.

alterations of existing text.[48] Satisfying one or both of these sets of requirements requires the layout of a label to be changed to accommodate additional text.

Table 27 summarizes the model's estimated cost per UPC. The cost of a coordinated labeling change is not zero because there will still be some administrative labor and recordkeeping associated with coordinating a regulatory change with a previously-scheduled, non-regulatory change.

Table 27: Per UPC Label Design Costs

	Low	Medium	High
Per-UPC Cost For Uncoordinated Changes ($)	4,962	8,200	13,294
Per-UPC Cost For Coordinated Changes ($)	347	602	858

Table 28 summarizes the label change costs for products other than cigars. The average cost over all UPCs ranges from $3,946 to $10,550 with a medium estimate of $6,525.

Table 28: Label Change Costs for Products Other Than Cigars

	Low	Medium	High
Number of uncoordinated pipe and hookah tobacco changes	924	924	924
Number of coordinated pipe and hookah tobacco changes	261	261	261
Cost for pipe tobacco ($)	**4,675,358**	**7,733,701**	**12,507,719**
Number of uncoordinated E-cigarette changes	16	39	62
Number of coordinated E-cigarette changes	4	11	18
Cost for E- cigarettes ($)	**80,778**	**326,413**	**839,680**
Number of uncoordinated Cigarette Tobacco and RYO Tobacco changes	130	130	130
Number of coordinated Cigarette Tobacco and RYO Tobacco changes	37	37	37
Cost for cigarette tobacco and RYO tobacco ($)	**657,885**	**1,088,243**	**1,759,983**
Total Cost ($)	**5,414,022**	**9,148,357**	**15,107,383**

b. Cigars

All labels for small and large cigars must be changed to satisfy requirements under chapter IX of the FD&C Act and the warning statement provision, which requires the use of 5 rotating warning statements. Cigars covered by the FTC consent orders already have 5 rotating warning statements, 4 of which are the same as statements required by this proposed rule. However, the portion of the labels devoted to warnings must increase to occupy 30 percent of the two principal display panels. Therefore, each cigar UPC will undergo a major labeling change and will need 5 versions of its new label, regardless of whether it currently has a single label or 5 versions as needed to accommodate the FTC warnings. Because different printing plates will be needed for each version of a label, materials costs for printing plates and prepress activities would be larger for a label with 5 versions than for a single-variant label. However, once the initial major change is made (adding or enlarging the warning statement and including new text

[48] Neither a statement of the percentage of the tobacco contained in the product that is domestically grown tobacco and the percentage that is foreign grown nor a statement that sale is only allowed in the United States is currently included on tobacco product labels.

required under the FD&C Act), altering the black or white text for 4 additional versions of the warning would be 4 minor changes. Therefore, we estimate the cost of materials needed for producing the extra versions of the label to be 4 times the materials cost of a minor labeling change. We add this additional incremental cost for both a coordinated and an uncoordinated labeling change. This adjustment should account for all of the additional label design costs that arise from the requirement to use 5 warnings.[49]

Table 29 summarizes the total label design costs per UPC, accounting for the need to have 5 versions of each new label. Table 30 shows the cost of changing cigar labels when 5 versions of every new label are needed. The average cost over all UPCs would be between $5,200 and $14,100, with a medium estimate of $8,600.

Table 29: Total Per UPC Label Design Costs (5 Versions of Each New Label)

	Low	Medium	High
Per-UPC Cost For Uncoordinated Changes ($)	6,207	10,257	16,863
Per-UPC Cost For Coordinated Changes ($)	1,593	2,660	4,426

Table 30: Cigar Labeling Changes (5 Versions of Each New Label)

	Low Cost	Medium Cost	High Cost
Number of uncoordinated machine-made cigar changes	897	897	897
Number of coordinated machine-made cigar changes	253	253	253
Cost for machine-made cigars ($)	5,971,074	9,873,639	16,245,802
Number of uncoordinated premium cigar changes	1,446	2,024	2,603
Number of coordinated premium cigar changes	408	571	734
Cost for premium cigars ($)	9,625,856	22,279,321	47,142,822
Number of uncoordinated non-premium handmade cigar changes	2,571	3,599	4,627
Number of coordinated non-premium handmade cigar changes	725	1,015	1,305
Cost for non-premium handmade cigars ($)	17,114,171	39,615,363	83,800,584
Total Cost ($)	**32,711,101**	**71,768,323**	**147,189,208**

The provisions covering equal random display and special rules for cigars sold singly generate additional costs. Equal and random display of the 5 cigar warning statements would be new for those cigar UPCs not already carrying warning labels under the FTC consent orders. Although the initial design and implementation of a system for equal and random display would be part of the upfront label change, continued operation of such a system in subsequent years would have incremental ongoing administrative and recordkeeping costs. FDA assumes that the ongoing yearly administrative labor cost per UPC would be equal to 10 percent of the (non-rush) administrative labor cost of an uncoordinated labeling change, and the yearly recordkeeping cost would be equal to 50 percent of the (non-rush) recordkeeping cost of an uncoordinated labeling change. FDA estimates that 56 percent of machine-made cigar UPCs currently carry FTC warnings, leaving 44 percent that do not, while 18 percent of premium and non-premium

[49] Some of the subcomponents of other cost categories might increase due to the 5-warning requirement, but there is far less reason to believe there will be a direct, proportional relationship between those cost categories and the number of warnings. For example, the non-warning part of the label only has to be designed once because the same design will be paired with all five warning statements.

handmade cigar UPCs currently carry FTC warnings, leaving 82 percent that do not.[50] Under Option 1, all cigars would carry these warning labels. Under Option 2, only certain cigars would carry the labels. Table 31 shows the incremental annual costs of equal random display.

Table 31--Incremental Annual Costs for Equal Random Display of Cigar Warnings

	Low Cost	Medium Cost	High Cost
Ongoing Admin. Costs per UPC	63	112	161
Ongoing RK Costs per UPC	26	41	46
Total Administrative and Recordkeeping Costs per UPC	**89**	**153**	**207**
Number of Machine-Made UPCs Affected	506	506	506
Cost for Machine-made Cigars	**44,946**	**77,494**	**104,875**
Number of Premium UPCs Affected	1,521	2,128	2,736
Cost for Premium Cigars	**135,106**	**325,903**	**567,072**
Number of Non-Premium Handmade UPCs Affected	2,702	3,784	4,864
Cost for Non-Premium Handmade Cigars	**240,011**	**579,520**	**1,008,127**
Total Cost	**420,063**	**982,917**	**1,680,074**

The required warning statements would have to be displayed where cigars are sold individually without a package. Signs carrying the 5 warnings would therefore be displayed in every point-of-sale location in every retail establishment that sells cigars individually without a package. The upfront costs include the administrative and set-up costs and material costs (sign and holder). The time of retail clerks is valued at the average total compensation in the retail sector as reported by the Bureau of Labor Statistics, or $17.77.[51] Each retail establishment selling cigars singly without packaging would need at least one sign, although many establishments would likely use multiple signs. We therefore adjust our estimate of the number of signs upward to account for those establishments that sell cigars at more than one counter or register. We include an annual cost, equal to 15 percent of the upfront cost, to account for both retail establishment turnover and replacement of worn signs and sign holders. The costs for this provision are shown in Table 32.

Table 32: Costs for Point-of-Sale Warnings

	Low	Medium	High
Number of Retail Establishments	119,089	211,718	304,346
Number of displays per retail establishment	1.2	1.2	1.2
Printing cost per sign	0.05	0.05	0.05
Cost per display stand	7.5	10	12.5
Time required for each retailers' administrative set-up (min)	60	60	60
Retail wage	17.77	17.77	17.77
Upfront costs for signs, display stands, and set-up	**3,195,167**	**6,315,546**	**9,991,695**
Annual refresh cost (15% of Upfront Cost)	**479,275**	**947,332**	**1,498,754**

[50] This was estimated using raw data indicating the presence or absence of a warning label, by product, for a sample cigars listed in Thompson Cigar's "All Cigar" directory (http://www.thompsoncigar.com/category/CIGARS/ALL-CIGAR-BRANDS/8336/pc/8335.uts). The manufacturers not covered by the FTC consent orders tend to be much smaller than those that are covered, and their products tend to have lower sales volume. Therefore, the proportion of cigar UPCs that have warnings is much lower than the proportion of cigar units sold that have warnings.

[51] Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Private industry workers, by industry group, for December 2013. < http://www.bls.gov/news.release/pdf/ecec.pdf >

5. Additional Private Sector Costs

a. Warning Statement Provisions: Removal of Noncompliant Point-of-Sale Advertising

Retailers and manufacturers of products covered by the warning statement provisions would be required to remove any existing point-of-sale advertising that fails to conform to the new requirements. In the analysis of FDA's 1996 final tobacco rule[52], we based much of our estimate of the cost of removing noncompliant point-of-sale advertising on a report from the Barents Group that used average removal costs for seven types of retail establishments, calculated using in-store surveys conducted by A.T. Kearney, Inc. (61 FR 44396 at 44580). We retain our estimates from 1996 about the level of effort that would be required to remove point-of-sale cigarette advertising and adjust that level downward to reflect the size of the cigar market (the most prevalent newly-regulated tobacco product) relative to the size of the cigarette market. We acknowledge, however, that this approach may overstate or understate the costs for a particular action or type of business.

Appendix Table A6 shows that 358,255 establishments selling tobacco products would be covered by the point-of-sale advertising requirements of the proposed rule. (Because we consider only the removal of noncompliant point-of-sale advertising from physical retail locations, we do not include non-store establishments or vending machines.) FDA estimates that sales of cigars in 2011 were 8.6 percent of expenditures for cigarettes.[53] Assuming that the amount of point-of-sale advertising is proportional to sales, we estimate that the one-time per-establishment costs to remove noncompliant cigar advertising would range from an average of about $1 for "other establishments" to $18 for convenience stores, with a weighted average of $12.29, as shown in Appendix Table A7. The total one-time cost of complying with restrictions on point-of-sale advertising is then estimated to be approximately $4.4 million (=358,255*$12.29). Assuming this cost is split between machine-made and handmade cigars in the same proportion as the dollar value of sales, $2.3 million is attributable to machine-made cigars and $2.1 million is attributable to handmade cigars.[54] We further assume that 64 percent of handmade cigar point-of-sale advertising, or $1.36 million, is for non-premium handmade cigars, while 36 percent, or $0.77 million, is for premium cigars.[55] We do not have sufficient data to estimate costs for removal of noncompliant point-of-sale advertising for tobacco products other than cigars; removal of cigar advertising likely accounts for the most of this cost.[56]

b. Minimum Age and I.D. Restrictions

[52] The majority of the 1996 final tobacco rule did not go into effect until it was reissued (in large part) in 2010, as directed by the Tobacco Control Act.
[53] Sales of cigars totaled $7,772.5 billion in 2011, while sales of cigarettes totaled $90,421.2 billion in 2011 (Ref. 49 [Euromonitor, 2012]).
[54] Data from 2011 show that 48.3 percent of the dollar value of cigar sales comes from handmade cigars while 51.7 percent comes from machine-made cigars (Ref. 49 [Euromonitor, 2012]).
[55] This follows our estimate above of the proportion of handmade cigars that are premium cigars.
[56] If our assumption is correct that point-of-sale advertising is proportional to sales, cigars would account for the majority of the costs associated with this provision.

We expect that the minimum age and identification provision would impose a negligible incremental cost because nearly all retailers should already be conducting identification checks for purchases of newly-regulated tobacco products. We reach this conclusion because, under state laws currently in place, all states except for Alabama prohibit the sale of most types of tobacco product to minors (Ref. 24 [ERG, 2011]). (However, as described previously, the definition of "tobacco products" varies among the states and generally does not cover all proposed deemed products derived from tobacco, which are included in the Tobacco Control Act's definition of "tobacco product" and the Agency's proposed definition of "covered tobacco product.") Moreover, under current federal regulations (21 CFR § 1140.14), no retailer in any state may sell cigarettes or smokeless tobacco to any person under 18 years of age, and retailers must verify the age of cigarette and smokeless tobacco purchasers aged 26 or younger by means of photographic identification containing the bearer's date of birth. Given both state and federal requirements, we expect that most retailers already treat all tobacco products in a similar manner.

c. Vending Machine Restrictions

Sales of tobacco products from vending machines have been in decline for many years. In 1996, the National Automatic Merchandising Association estimated that there were only 141,000 cigarette vending machines in use, and that the number was falling rapidly (61 FR 44396 at 44600). The Vending Times reports higher levels (166,000 cigarette vending machines in 2000) but confirms that a rapid decline took place, as 30,000 cigarette vending machines were reported in 2010 (Ref. 115 [Vending Times 2011 Census of the Industry, 2011]). Similarly, census data show a decline in sales of tobacco products from vending machines. Vending machine sales of tobacco products totaled $452 million in 1992 but were only $46.9 million in 2007 (Ref. 116 [U.S. Census, 1995]; Ref. 90 [2007 U.S. Census Retail Trade Product Lines]). Tobacco products accounted for 7.1 percent of vending machine establishment sales in 1992 but only 0.7 percent of sales in 2007. Sales of newly-regulated tobacco products (such as cigars and pipe tobacco) would have been at most a small proportion of all tobacco product vending machine sales in 2007. Likewise, the number of machines devoted to sales of such products would only have been a small proportion of the number of machines devoted to the sale of cigarettes.

The Barents Group estimated that tobacco product revenues in retail locations would be about 30 percent less than from vending machines because vending machine operators charged a premium to account for their higher operating costs (61 FR 44595). Furthermore, the Barents Group estimated an average pretax profit margin of 2.9 percent for vending machine operators and convenience stores (61 FR 44595). We therefore estimate that annual sales revenues for all tobacco products sold from vending machines in 2007 would decrease by $14.2 million (=$46.9 million x 30.3 percent) if those sales could no longer take place through vending machines. The pretax profit margin of 2.9 percent implies that removing all tobacco product vending machines would have cost the vending machine industry a maximum of $412,000 (=14.2 million x 2.9 percent) annually, or $439,000 annually in current dollars.[57]

[57] We inflate profits to 2011 dollars using the GDP deflator, rather than the tobacco component of the Consumer Price Index, because taxes paid to government make up a large and increasing share of tobacco prices paid by consumers.

We do not quantify the expected effect of the vending machine restrictions contained in this proposed rule on the profits of vending machine operators but it is expected to be small in absolute value and only a small fraction of the $439,000 annual value calculated above. First, products affected by the new restrictions make up a small proportion of the market for tobacco products, and the same should have held for vending machine sales in 2007. Second, most of the $46.9 million in tobacco product vending machine sales in 2007 would have taken place in adult-only establishments because of product and state restrictions already in place. Finally, to extent that vending machine sales of tobacco products still took place in non-adult establishments in 2010, the restrictions on cigarette (and smokeless) vending machine sales that went into effect in 2010 would also have likely reduced vending machine sales of other tobacco products in non-adult establishments as many establishments would have removed vending machines, switched to adult-only policies, or converted to selling tobacco products in a face-to-face exchange.

6. Administration and Enforcement Costs Borne by Government (Costs to FDA)

FDA tentatively projects that 55 full-time-equivalent employees (FTEs) would be needed to implement and enforce option 1 of this proposed rule. These FTEs represent a social opportunity cost, but they would not affect the total amount of user fees or the size of the federal budget because FDA's regulation of tobacco products is fully funded by industry user fees, which are fixed by statute. Fully loaded employee costs vary with the type of employee (e.g., field inspectors versus administrative), but an average of $253,918 per FTE places the dollar cost at approximately $14 million per year. Because a considerable portion of FDA costs would be attributable to the review of new product submissions (substantial equivalence reports, premarket tobacco applications, etc.), we attribute FDA costs to option 2, the regulatory alternatives, and specific products by assuming FDA costs are a constant proportion of annualized private sector premarket submission costs.[58]

7. Summary of Costs

Tables 34A and 34B summarize the undiscounted costs of options 1 and 2 of the proposed rule. For option 1, the total upfront quantified costs are estimated to range from $74.3 to $347.0 million, with a primary estimate of $171.1 million. The annual costs range from $20.8 to $49.0 million, with a primary estimate of $30.6 million. For option 2, the total upfront quantified costs are estimated to range from $60.5 to $258.5 million, with a primary estimate of $132.8 million. The annual costs range from $17.4 to $38.4 million, with a primary estimate of $25.0 million. Table 1 in Section I.A. summarizes present and annualized values of costs.

Unquantified costs include the loss of consumer choice when product exit occurs, the cost of testing for harmful or potentially harmful constituents (which will be estimated when testing

[58] $14 million is 85 percent of the best estimate of annualized premarket submission costs under option 1, calculated with a 3 percent discount rate. We assume this ratio holds for option 2, all regulatory alternatives, and all products.

and reporting regulations are promulgated), and the cost of any clinical testing that may be potentially conducted to support substantial equivalence reports.

Table 34A: Summary of Undiscounted Costs Option 1 ($mill)

	Upfront[1] Lower Bound	Upfront Primary	Upfront Upper Bound	Annual[1] Lower Bound	Annual Primary	Annual Upper Bound
Deeming-Specific Requirements						
Registration and Product Listing[2]	0.10	0.31	0.52	0.03	0.09	0.15
Ingredient Listing[2]	2.81	2.88	2.95	0.07	0.20	0.33
Costs to Market New Tobacco Products	11.58	62.24	152.76	5.66	14.25	31.12
Miscellaneous[2]	0.09	0.09	0.09	0.19	0.19	0.20
Subtotal for deeming-specific	**14.58**	**65.52**	**156.32**	**5.95**	**14.74**	**31.81**
Labeling Changes						
Deeming and Warning Label Changes	41.32	87.23	172.29	0.90	1.93	3.18
Additional Provisions						
Point-of-sale advertising	4.40	4.40	4.40			
Private Sector Subtotal	**60.30**	**157.16**	**333.01**	**6.85**	**16.67**	**34.99**
FDA	13.97	13.97	13.97	13.97	13.97	13.97
Total Cost	**74.27**	**171.12**	**346.98**	**20.81**	**30.63**	**48.96**

1 In general, upfront cost are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions and labeling, upfront costs are incurred in the first 24 months, while annual costs are incurred in years 3-20.
2 We use the midpoint of the estimated lower and upper bounds as our primary estimate.

Table 34**B**: Summary of Undiscounted Costs Option 2 ($mill)

	Upfront[1] Lower Bound	Upfront Primary	Upfront Upper Bound	Annual[1] Lower Bound	Annual Primary	Annual Upper Bound
Deeming-Specific Requirements						
Registration and Product Listing[2]	0.09	0.24	0.40	0.03	0.07	0.12
Ingredient Listing[2]	2.07	2.12	2.17	0.05	0.15	0.24
Costs to Market New Tobacco Products	11.58	50.38	115.66	5.06	11.64	23.88
Miscellaneous[2]	0.07	0.07	0.07	0.16	0.16	0.17
Subtotal for deeming-specific	**13.80**	**52.82**	**118.30**	**5.30**	**12.02**	**24.40**
Labeling Changes						
Deeming and Warning Label Changes	31.69	64.95	125.15	0.76	1.60	2.61
Additional Provisions						
Point-of-sale advertising	3.64	3.64	3.64			
Private Sector Subtotal	**49.14**	**121.41**	**247.08**	**6.06**	**13.62**	**27.02**
FDA	11.38	11.38	11.38	11.38	11.38	11.38
Total Cost	**60.52**	**132.79**	**258.47**	**17.44**	**25.00**	**38.40**

1 In general, upfront cost are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions and labeling, upfront costs are incurred in the first 24 months, while annual costs are incurred in years 3-20.
2 We use the midpoint of the estimated lower and upper bounds as our primary estimate.

8. Summary of Costs by Product Category

We quantify costs for six categories of tobacco products: 1) premium cigars, 2) non-premium handmade cigars, 3) machine-made cigars, 4) pipe and hookah tobacco, 5) electronic cigarettes, and 6) cigarette tobacco and roll-your-own tobacco. We are unable to quantify the

costs for other novel tobacco products (such as nicotine gels) due to data limitations and the relatively small size of their markets.

Costs that are determined by the number of manufacturers or importers, such as establishment registration and miscellaneous costs, are not quantified for electronic cigarettes. We note, however, that these make up a small portion of total costs. The cost for removal of noncompliant point-of-sale advertising under the warning statement provisions is only quantified for cigars.

Table 35 shows the present value of costs by product category.

Table 35: Present Value of Quantified Costs by Product Category ($mill)

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Premium Cigars[1]						
New product submission requirements	8.1	46.5	133.2	5.7	36.0	103.9
Labeling	11.3	26.3	54.0	10.6	24.6	50.9
Total, including not otherwise listed	**61.2**	**115.6**	**231.0**	**47.6**	**92.6**	**187.6**
Non-Premium Handmade Cigars[1]						
New product submission requirements	14.3	82.6	236.9	10.1	63.9	184.9
Labeling	29.6	65.6	125.9	26.4	58.8	114.3
Total, including not otherwise listed	**118.1**	**224.2**	**440.5**	**92.0**	**179.5**	**357.2**
Machine-made Cigars[1]						
New product submission requirements	7.3	21.2	43.6	5.9	16.8	34.1
Labeling	6.5	10.8	17.4	6.2	10.3	16.7
Total, including not otherwise listed	**35.5**	**53.8**	**83.1**	**28.7**	**43.8**	**67.7**
Pipe and hookah tobacco						
New product submission requirements	6.2	18.0	37.0	5.0	14.3	28.9
Labeling	4.6	7.6	12.3	4.5	7.5	12.1
Total, including not otherwise listed	**27.4**	**42.5**	**66.4**	**21.8**	**34.2**	**53.7**
Electronic Cigarettes						
New product submission requirements	51.1	83.2	115.4	37.8	63.2	88.5
Labeling	0.1	0.3	0.8	0.1	0.3	0.8
Total, including not otherwise listed[2]	**122.4**	**154.8**	**187.5**	**90.6**	**116.3**	**142.2**
Cigarette and Roll-your-own tobacco						
New product submission requirements[3]	NA	NA	NA	NA	NA	NA
Labeling	0.6	1.1	1.7	0.6	1.1	1.7
Total, including not otherwise listed	**0.6**	**1.1**	**1.7**	**0.6**	**1.1**	**1.7**
All quantified, Option 1						
New product submission requirements	87.0	251.6	566.1	64.4	194.2	440.3
Labeling	78.3	165.8	319.7	74.7	158.1	307.1
Total, including not otherwise listed	**365.2**	**592.0**	**1,010.1**	**281.4**	**467.6**	**810.2**

All quantified, Option 2						
New product submission requirements	78.9	205.0	432.9	58.7	158.1	336.4
Labeling	41.4	85.4	158.2	37.8	77.9	145.6
Total, including not otherwise listed	**304.0**	**476.4**	**779.2**	**233.8**	**375.0**	**622.6**

1 In our analysis of cigars, we separate machine-made from handmade cigars, as does the data source we use (Ref. 98 [Perelman, 2010]). We note that the distinction can be blurred in the case of cigars that are made partially by hand.
2 Costs that are determined by the number of manufacturers or importers, such as establishment registration and miscellaneous costs, are not quantified for electronic cigarettes. Note that these make up a small portion of total costs.
3 For cigarette tobacco and roll-your-own tobacco, costs of new product submission requirements (and other requirements stemming from the deeming action) are not attributable to this proposed rule because these products are already regulated under chapter IX of the FD&C Act and its implementing regulations.

9. Summary of Costs and Benefits by Combustible and Non-Combustible Product Categories

Table 36 shows costs broken out by provision and by whether the affected products are combustible products or electronic cigarettes. We have made preliminary qualitative statements about likely benefits for many provisions. Provisions with direct benefits can have an independent effect on public health and welfare. Provisions with indirect benefits contribute to the overall effectiveness of FDA's tobacco program. Other effects, such as many of those associated with electronic cigarettes, are unknown.

Table 36: Costs and Benefits of the Proposed Deeming Rule

	Present Value of Costs, Combustible Products Option 1($mill) (7%)	Present Value of Costs, Combustible Products Option 2 ($mill) (7%)	Present Value of Costs, E-Cigarettes ($mill) (7%)	Benefits (Combustible)	Benefits (E-Cigarettes, other novel)
Deeming-Specific Requirements					
Registration and Product Listing	1.2	0.6	0.1	Indirect	Unknown
Ingredient Listing	4.6	3.2	0.4	Indirect	Unknown
Costs to Market Tobacco Products	131.0	95.0	63.2	Direct	Unknown
Adulteration and Misbranding	NQ (Small)	NQ (Small)	NQ (Small)	Direct	Direct
Miscellaneous	2.1	1.8	NQ (Small)	Indirect	Unknown
Free Samples	NQ (Small)	NQ (Small)	NQ (Small)	Direct	Unknown
Labeling Changes					
FD&C Act Label Requirements	102.2	77.6	0.3	Indirect	Unknown
Warning Label Requirements				Direct	Unknown
Additional Provisions					
Advertising (point-of-sale)*	4.3	3.5	NQ	Direct	Unknown
Vending Machines	NQ (small, probably 0)	NQ (small, probably 0)	NQ (Small, probably 0)	Direct	Unknown
Youth Access Restrictions	NQ (very small)	NQ (very small)	NQ (very small)	Direct	Direct
FDA Cost	105.9	76.6	52.4		
Total Cost	**351.3**	**257.8**	**116.3**		

NQ: Not quantified
Indirect benefits contribute to the overall effectiveness of FDA's tobacco program.
Direct benefits can have an independent effect on public health and welfare.
* Quantified for cigars only

The lack of direct evidence and uncertainty associated with the indirect evidence prevented quantification of the benefits and some part of the costs of the proposed rule. After the proposed rule becomes final, its operation will generate direct evidence. Once the rule is in operation for several years, we plan to do a retrospective review of its effects, a review that will include quantification of the benefits and costs.

C. Break-Even Calculation for the Proposed Rule

Much of the proposed rule's benefits are likely to come from years of life saved. The years of life saved would be from reducing the number of cigar smokers, changes in the consumption of other tobacco products, and from other changes in consumer behavior, such as compensating health behaviors. We do not quantify the benefits of this proposed rule here because we lack sufficient evidence to estimate with acceptable levels of certainty the change in usage and other behavioral responses. We do, however, perform an exercise in which we determine the number of life-years that must be saved for the benefits to outweigh the costs.

The primary estimate of the present value of costs for option 1 of this proposed rule is 592 million with a 3 percent discount rate and 468 million with a 7 percent discount rate; the primary estimate of the present value of costs for option 2 is 476 million with a 3 percent discount rate and 375 million with a 7 percent discount rate. Three life-year values (also known as values of a statistical life-year, or VSLY) used frequently in the literature and in previous FDA analyses are $100,000, $200,000 and $300,000 (Ref. 74 [Cutler, 2008]; Ref. 76 [Murphy and Topel, 2006]; 74 FR 33030, July 9, 2009), which we update to $101,776, $223,551 and $335,327 in 2012 prices. For this break-even calculation, we use a point estimate of 335,327 for the value of a statistical life-year, which constitutes our estimate of willingness-to-pay for a year of life preserved in the present. (Recent studies of the value of statistical life imply the higher end of the range we have used previously (Ref. 146 [Cropper at al., 2011]).)

Incorporating a welfare gain ratio of 30 percent, which is within the range described above in section II.A.1.b, if (over the years the rule is in effect) if option 1 of this proposed rule leads to behavioral changes that save a total of 5,885 discounted life-years and quality-adjusted life-years, the benefits would equal the costs at a 3 percent discount rate; if option 1 of this proposed rule leads to behavioral changes that save a total 4,648 discounted life-years and quality-adjusted life-years, the benefits of the proposed rule would equal the costs at a 7 percent discount rate. Under option 2, benefits would equal the costs at a 3 percent discount rate if this proposed rule leads to behavioral changes that save a total 4,735 discounted life-years and quality-adjusted life-years; at a 7 percent discount rate, benefits would equal costs if this proposed rule leads to behavioral changes that save a total 3,727 discounted life-years and quality-adjusted life-years

D. Distributional Effects

This proposed rule would have effects that would be experienced as losses by some segments of U.S. society but as equal and offsetting gains by other segments of society; as such, these effects do not constitute net social costs or benefits and have not yet been discussed in detail. In general, sectors affiliated with tobacco and tobacco products would lose sales revenues as a result of this proposed rule. Simultaneously, non-tobacco-related industries would gain sales, because dollars not spent for tobacco products would be spent on other commodities.

1. Collection of User Fees from Cigar and Pipe Tobacco Manufacturers

Chapter IX of the FD&C Act provides for the collection of quarterly user fees from each manufacturer and importer of cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, or roll-your-own tobacco.[59] In the event that any of these product classes are not subject to FD&C Act—as is currently the case for cigars and pipe tobacco—the amount that would be paid by their manufacturers would be reallocated to manufacturers of classes that are subject to the FD&C Act (cigarettes, snuff, chewing tobacco and roll-your-own tobacco). Therefore, if cigars and pipe tobacco are deemed subject to the FD&C Act, cigar and pipe tobacco manufacturers and importers would start to pay user fees and the amount paid by other tobacco product manufacturers would decrease accordingly.

Table 37 shows how much cigar and pipe tobacco manufacturers would be charged in user fees from fiscal year 2014 through 2019, and how much other product manufacturers' fees would decrease. After 2019, the total amount of user fees will remain constant. It is assumed that the allocation to each tobacco product class follows the same percentages currently in effect for fiscal year 2013 (Ref. 118 [USDA, 2012]), though the actual percentages will change each year according to market share. Cigar manufacturers would pay more in user fees than pipe tobacco manufacturers. Cigarette manufacturers would experience the largest reduction in user fees.

Table 37: Reallocation of User Fees to Cigars from Other Tobacco Product Manufacturers

Year	Total Tobacco Product User Fees ($1,000)	Percentage Allocated to Cigars (%)	Total Amount Allocated to Cigars ($1,000)	Percentage Allocated to Pipe Tobacco (%)	Total Amount Allocated to Pipe Tobacco ($1,000)	Reduction in Fees to be Paid By Cigarette Manuf. ($1,000)	Reduction in Fees to be Paid by Snuff Manuf. ($1,000)	Reduction in Fees to be Paid by Chewing Tobacco Manuf. ($1,000)	Reduction in Fees to be Paid by Roll-Your-Own Manuf. ($1,000)
2014	534,000	9.79	52,296	0.60	3,220	54,831	582	46	56
2015	566,000	9.79	55,430	0.60	3,413	58,117	617	49	59
2016	599,000	9.79	58,661	0.60	3,612	61,506	653	52	63
2017	635,000	9.79	62,187	0.60	3,829	65,202	692	55	67
2018	672,000	9.79	65,810	0.60	4,052	69,001	732	58	71
2019	712,000	9.79	69,728	0.60	4,293	73,109	776	62	75

[59] See Section 919.

2. Consumers of Tobacco Products

This proposed rule puts a framework for future regulation into place and requires labels to be changed in accordance with chapter IX of the FD&C Act and the required warning statement provisions. These actions entail social costs, as calculated above in Section II.B. The majority of the costs of this proposed rule are fixed, but a portion of the costs are variable. Most of the variable costs would be would be passed on to consumers in the form of higher prices. The average increase in the price of proposed deemed tobacco products would be very small relative to current prices.

3. Tobacco Manufacturers, Distributors, and Growers

The proposed warning labels and other provisions may reduce tobacco product use. This may reduce revenues of tobacco manufacturers, distributors, and growers.

According to USDA's 2007 Census of Agriculture (Ref. 122), there are 16,234 tobacco farms. Upon implementation of the rule, these farms may shift some of their acreage from growing tobacco to producing other agricultural products.

4. National and Regional Employment Patterns

Several studies estimate the contribution of tobacco product to the U.S. economy or, alternatively, the losses to the U.S. economy that would follow a decline in tobacco-related consumption. Economists have shown both theoretically and empirically that, for the nation as a whole, employment gains from spending on other products would offset any employment losses from reduced spending on tobacco products (Ref. 124 [Chaloupka and Warner, 2000]). Any income and employment effects associated with a potential reduction in tobacco product consumption would be small.

5. Retail Sector

Like tobacco growers, distributors and manufacturers, tobacco retailers would be affected by any decrease in tobacco product sales. Retailers would, however, be in a position to shift shelf space and promotional activities to non-tobacco products, in order to take advantage of the increase in demand for other products that would be expected to accompany the decrease in spending on tobacco products. If some retailers who rely heavily on tobacco sales are not be able to fully offset their reduction in tobacco sales with sales of other products, other retailers would then experience some of the gain in sales associated with an increase in demand for those other products.

6. Excise Tax Revenues

This proposed rule would decrease government tobacco product tax revenues to the extent that consumption of taxed tobacco products is reduced by this proposed rule. Sales tax revenues generated through tobacco sales would also fall as a result of the proposed rule, but those changes would be much smaller than the changes in excise tax collections.

Leaving aside potential deadweight loss, there are two principal effects of tax reductions: gains to former payers and losses to former recipients. Because these transfers exactly offset each other, there is no net social cost or benefit associated with the reduction in excise tax collections induced by the proposed rule.

7. Government-Funded Medical Services, Insurance Premiums and Social Security

Cigarette smokers use more medical services over their life cycles than do comparable nonsmokers; in 2013 dollars and discounted at a 3 percent rate, specific net costs are estimated to be $5,822 per female 24-year-old smoker and $4,056 per male 24-year-old smoker (Ref. 68 [Sloan et al., 2004] Smokers bear a portion of these net costs themselves, but a portion equaling $2,911 per female smoker or $2,028 per male smoker is borne by the general public through increased private insurance premiums or taxes used to fund government health care programs; hence, a reduction in the U.S. smoking population would transfer value from smokers (who receive medical services paid partially by the general public) to the general public. The financial effects of using other tobacco products would differ but may be qualitatively similar.

E. International Effects

The Bureau of Economic Analysis reports that $96.1 billion worth of tobacco products were consumed in the United States in 2011. Of this amount, U.S. Census Bureau's USA Trade Online (Ref. 136) reports that $1.5 billion consisted of imported Tobacco and Manufactured Tobacco Substitutes. Of this total, cigarettes accounted for $180.6 million and cigars and similar products accounted for $536.1 million. Small cigar imports were $7.8 million and large cigar imports were $528 million. US Trade Online does not contain explicit estimates for the value of hand-made cigars. Our best estimate for the value of these imports is about $316 million, which includes all large imported cigars valued at $0.23 or higher. The number of imported handmade cigar products is 9,101. Smoking tobacco and homogenized or reconstituted tobacco (a subset of which would be affected by this rule) imports were valued at $50.2 million. [60]

As with domestic manufacturers, foreign manufacturers would experience an increase in costs as a result of this deeming action. The average value of imports of a handmade cigar product is $34,721 (=$316 million/9,101). As shown in Table 29 in section II.B.4.b above, the

[60] The 2-digit Harmonized System Code for Tobacco and Manufactured Tobacco Substitutes is 24. The 4-digit codes are 2401 for Tobacco, Unmanufactured and Tobacco Refuse, 2402 for Cigars, Cigarettes, Etc. of Tobacco or Tobacco Substitutes, and 2403 for Smoking Tobacco, Homogenized or Reconstituted Tobacco, and Manufactured Tobacco Products and Substitutes Not Elsewhere Specified or Indicated. HS-4 code 2402 is further broken down into HS-6 code 240210 for Cigars, Cheroots, Cigarillos containing Tobacco, 240220 for Cigarettes Containing Tobacco, and 240290 for Cigars, Cigarettes, Etc. of Tobacco Substitutes. HS-4 code 2403 is broken down into HS-6 codes 240310 for Smoking Tobacco, 240391 for Homogenized or Reconstituted Tobacco, and 240399 for Other Manufactured Tobacco, Tobacco Substitutes, Tobacco Extracts, and Essences. Small cigars are defined as those in HS-10 code 2402103030 and 2402108030. Large cigars are defined as those in HS-10 codes 2402103070, 2402106000, 2402108070, and 2402108080. Hand-made cigars are defined as those in HS-10 code 2402108080.

estimated cost of a cigar labeling change when the change cannot be coordinated with a previously-scheduled non-regulatory labeling change, ranges from $6,209 to $16,900. Substantial equivalence reports are estimated to take 152 hours to 232 hours to prepare, at a cost of $10,100 to $15,400. Adding these costs together, we see that for a product sold under a single UPC, the combined cost of submitting a substantial equivalence report and undergoing an uncoordinated labeling change is estimated to be $16,300 to $32,300.

The increase in costs, and corresponding reduction in profits, for participating in the U.S. market would encourage foreign manufacturers and U.S. importers to cease selling relatively low-volume products in the U.S. or consolidate products. Exit from the U.S. market could result in U.S. consumers paying higher prices for the remaining products. In addition, exit from the market and product consolidation would reduce product variety in the U.S. market and thus consumer utility. The degree to which consumer utility decreases is unknown as is the scope to which cigar smokers switch to other cigar brands or tobacco products or quit smoking.

F. Regulatory Alternatives and Proposed Options

We have identified and assessed several alternatives to the proposed rule. We note that not all of these regulatory alternatives are necessarily legally permissible. We use proposed rule option 1 as the baseline for comparisons among the alternatives.

1. Deeming only; exempt proposed deemed products from all labeling changes and premarket submission requirements

This alternative would extend FDA's authority under chapter IX of the FD&C Act to all tobacco products except accessories of a proposed deemed tobacco product, but would exempt the proposed deemed products from enforcement of the labeling change requirements and new product submission requirements that would otherwise apply under the FD&C Act. It would also eliminate (or postpone) the non-deeming provisions of the proposed rule. FDA would have the option to issue regulations in the future. Such regulations could include the extension of labeling change and new product submission requirements under the FD&C Act to proposed deemed products or include provisions such as the non-deeming provisions of this proposed rule.

Exempting newly-regulated tobacco products from all labeling requirements would be virtually identical,[61] from a cost perspective, to postponing enforcement of tobacco product labeling provisions of the FD&C Act until FDA's first (additional) labeling regulations affecting proposed deemed products go into effect. The first labeling regulation for the proposed deemed products would then trigger the statutory requirements as well. This option would enable the

[61] The exact incremental cost of including the statutory requirements with a future rule would depend on the requirements of the future rule. Because the proposed warning statement provisions require a major labeling change, the incremental cost of including statutory requirements would be very small. The incremental cost of including statutory requirements with an otherwise minor labeling change would be larger.

labeling changes required under the FD&C Act to be coordinated in time with future labeling regulations, which reduces costs by not requiring two separate labeling changes.

Because labeling and premarket application submissions account for most of the costs of the proposed rule, costs would be dramatically reduced, as shown in Table 40.

Table 40: Present Value of Quantified Costs for Regulatory Alternative 1 ($ million)

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Total Cost	**7.1**	**10.3**	**13.5**	**6.0**	**8.3**	**10.7**
Change from Proposed Rule Option 1	-358.1	-581.7	-996.6	-275.4	-459.2	-799.4

This alternative would enable us to take further regulatory action in the future; future actions would have their own costs and benefits. Additionally, the proposed deeming action would—via the application of the FD&C Act's registration and product listing, establishment registration, and ingredient listing requirements—enhance FDA's ability to obtain tobacco product data and some types of risk data; this data would be disseminated to consumers and used to inform future policy-making. On the other hand, some benefits that may be associated with the deeming action as proposed—including any reduction in tobacco product consumption brought about by the removal of modified-risk descriptors and any prevention of increased-risk products from entering the market—would be unrealized (or at least delayed, in the case of regulations related to these activities being issued in the future).

2. Enforce Premarket Submission Requirements Only for Machine-Made Cigars

Under this alternative, premarket submission requirements would only be enforced for machine-made cigars; costs of premarket submissions for other products would be eliminated. All other aspects of the rule would remain as proposed. However, we assume that when premarket requirements are not enforced, fewer electronic cigarette products would exit the market because costly premarket submissions would no longer be required. Therefore, in analyzing this alternative, we assume that all electronic cigarette products would incur the cost of changing labels to comply with this rule.[62]

As Table 45 shows, the costs of this alternative are dramatically lower than for the proposed rule due to the reduced costs associated with premarket submissions.

Table 45: Present Value of Costs for Regulatory Alternative 2 ($ million)

	3 percent			7 percent		
	Lower Bound	Primary	Upper Bound	Lower Bound	Primary	Upper Bound
Total Cost	**96.1**	**176.3**	**308.7**	**84.4**	**156.0**	**276.3**

[62] This is a simplification because exit could still occur due to labeling or other regulatory costs.

Change from Proposed Rule Option 1	-269.10	-415.72	-701.46	-196.98	-311.58	-533.89

Under this alternative, benefits associated with potentially preventing increased-risk products from entering the market would be eliminated for products other than machine-made cigars. For electronic cigarettes, the welfare effects of not enforcing premarket requirements are unknown, as described in Section II.A.4.b.

3. Change New Product "Grandfather Date" to the Date of Issuance of a Final Deeming Regulation

Under this alternative, the grandfather date for determining which products are considered new would be moved from February 15, 2007, to the date this rule is finalized. All other aspects of the rule would remain as proposed. This would reduce costs in the first 24 months as new product submissions would not have to be prepared for products introduced into domestic commerce between February 15, 2007, and the date of the final rule; that is, manufacturers would not start with such a large multi-year backlog of new products.[63] However, manufacturers would still bear the substantial costs of preparing new product submissions for the new products introduced each year.

If no valid predicate exists for electronic cigarette products, then changing the grandfather date would have additional implications for electronic cigarettes. In our analysis of the proposed rule, all electronic cigarette products would be new tobacco products and many would exit the market rather than bear the cost of submitting a premarket tobacco application, which would be required in the absence of a valid predicate product. By contrast, if we change the grandfather date, only electronic cigarette products introduced after the issuance of a final rule would be considered new, and a large number of candidate predicates would exist. We assume that new electronic cigarettes would then be marketed through the substantial equivalence (or exemptions) pathway. We would no longer assume that many electronic cigarette products would exit the market, but instead assume that all electronic cigarette labels would be changed to conform with the requirements of the proposed rule.[64]

Table 47 shows what the present value of costs for this alternative. See Appendix Table A9 for the undiscounted costs under this alternative.

Table 47: Present Value of Quantified Costs for Regulatory Alternative 3 ($ million)

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Total Cost	**242.8**	**422.1**	**797.3**	**191.6**	**333.0**	**632.1**
Change from Proposed Rule Option 1	-122.37	-169.89	-212.84	-89.78	-134.63	-178.05

[63] Additional minor changes in costs would occur as we would expect a change in the timing of submissions requesting FDA to make a determination as to whether specific products are grandfathered products.
[64] Some exit, however, could still occur due to labeling or other regulatory costs.

Under this alternative, the benefit associated with potentially preventing increased-risk products from entering the market could be reduced. Instead of having FDA evaluate proposed deemed tobacco products introduced between February 15, 2007, and the date of the final rule, such products would be grandfathered. This alternative would create an incentive for tobacco product manufacturers to rush new products to market before a final rule is issued to ensure that their products would be grandfathered. If some products introduced during that period are riskier than those existing before February 15, 2007, such products (and products found substantially equivalent to them) could be marketed in the absence of other grounds for their removal. For electronic cigarettes, the welfare effects of changing the grandfather date would be unknown (see Section II.A.4.b).

This alternative could be combined with Alternative 3 (exempt handmade cigars from labeling changes). Because they alter different aspects of the rule, the changes in estimated costs would be additive. Combining these alternatives would dramatically reduce the costs of compliance for handmade cigars.

4. Deeming only; exempt proposed deemed products from all labeling changes

This alternative would extend FDA's authority under chapter IX of the FD&C Act to all tobacco products, except accessories of a proposed deemed tobacco product, but explicitly exempt newly-regulated products from enforcement of provisions requiring a labeling change. This alternative would also eliminate (or postpone) the non-deeming provisions of the proposed rule. As discussed above, exempting newly-regulated tobacco products from labeling requirements would be virtually identical in cost to postponing enforcement of tobacco product labeling provisions of the FD&C Act until FDA's first (additional) labeling regulations affecting proposed deemed products go into effect. Aligning labeling changes would enable the labeling changes required under the FD&C Act to be coordinated in time with future labeling regulations, which reduces costs by not requiring two separate labeling changes.

The costs of all labeling changes required by the proposed rule and the cost of removing noncompliant point-of-sale advertising would be eliminated, leading to substantially lower costs than option 1 of the proposed rule. See Table 42.

Table 42: Present Value of Quantified Costs for Regulatory Alternative 4 ($ million)

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Total Cost	**308.1**	**475.9**	**793.6**	**228.7**	**360.8**	**609.4**
Change from Proposed Rule Option 1	-57.07	-116.07	-216.57	-52.68	-106.78	-200.80

This alternative would enable us to take further regulatory action in the future; future actions would have their own costs and benefits. This alternative preserves the potential benefits associated with prevention of increased-risk products from entering the market. Additionally, the proposed deeming action would—via the application of the FD&C Act's registration and product listing, establishment registration, and ingredient listing requirements—enhance FDA's ability to obtain tobacco product and risk data; this data would be disseminated to consumers and

used to inform future policy-making. On the other hand, some benefits that may be associated with the deeming action as proposed—including any reduction in tobacco product consumption brought about by the removal of modified-risk descriptors—would be unrealized (or at least delayed, in the case of regulations related to these descriptors being issued in the future).

5. Exempt handmade cigars from labeling changes.

Under this alternative, premium cigars and non-premium handmade cigars would be exempted from all new labeling requirements. Because labeling costs are largely determined by the number of universal product codes (UPCs), and there are an estimated 10,299 handmade cigar UPCs (of which we estimate 50 to 90 percent would continue to be marketed), exempting these products from the labeling changes would dramatically reduce the labeling costs associated with this rule.

We calculate the cost of this alternative by eliminating handmade cigar UPCs from the labeling cost calculations. This alternative reduces costs compared with option 1 of the proposed rule because of the costs associated with labeling changes for handmade non-premium cigars. See Table 43.

Table 43: Present Value of Quantified Costs for Regulatory Alternative 5 ($ million)

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Total Cost	**324.3**	**500.0**	**830.2**	**244.4**	**384.2**	**644.9**
Change from Proposed Rule Option 1	-40.91	-91.95	-179.93	-36.99	-83.40	-165.22

Under this alternative, benefits associated with reductions in handmade cigar smoking due to labeling changes would be unrealized. Any potential benefits associated with reduction in handmade cigar smoking brought about by the removal of modified-risk descriptors from handmade cigars—would also be unrealized (or at least delayed, in the case of regulations related to these descriptors being issued in the future).

6. Deeming only

This alternative would eliminate all non-deeming provisions of this rule, including the warning statement requirements for packages and advertisements, minimum age and identification requirements, and vending machine restrictions. Costs for removing noncompliant point-of-sale advertising would be eliminated, as would costs of changing cigarette tobacco and roll-your-own tobacco labels (which are affected by the required warning statement provision but not the deeming provision). Eliminating the warning statement provision would reduce the costs associated with the cigar labeling changes, but not the costs associated with changing labels of other proposed deemed products. Ongoing incremental costs for rotation and display (for cigar packages that do not already carry the FTC warnings) and the costs associated with single sales would be eliminated. Costs for changing cigar package labels would also be reduced because only the UPCs currently carrying the 5 FTC warnings would need 5 versions of

the new label designed to comply with chapter IX of the FD&C Act; the other UPCs would only need a single-variant new label.

The present value of costs under this alternative are shown in Table 46; see Appendix Table A8 for the undiscounted costs under this alternative.

Table 46: Present Value of Quantified Costs for Regulatory Alternative 6 ($ million)

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Total Cost	**339.2**	**541.6**	**923.3**	**259.2**	**425.3**	**736.7**
Change from Proposed Rule Option 1	-25.95	-50.42	-86.87	-22.14	-42.34	-73.49

This alternative would enable us to take further regulatory action in the future; future actions would have their own costs and benefits. The benefits of this alternative would include the removal of potentially misleading modified-risk descriptors and the potential prevention of increased-risk products from entering the market. Additionally, the proposed deeming action would—via the application of the FD&C Act's registration and product listing, establishment registration, and ingredient listing requirements—enhance FDA's ability to obtain tobacco product and risk data; this data would be disseminated to consumers and used to inform future policy-making.

7. Change the labeling compliance period of the rule.

a. Extend to 36 months.

b. Reduce to 12 months

The cost of a labeling change is very sensitive to the compliance period. Because manufacturers change their labels regularly, a longer compliance period enables a greater proportion of the labeling changes to be coordinated with changes that would have been made for non-regulatory reasons, which reduces the incremental costs.

A shorter compliance period reduces the proportion of labeling changes that can be coordinated with changes that would have been made for non-regulatory reasons, increasing incremental costs. For most costs, the labeling cost model adds rush charges equal to 40 percent for compliance periods shorter than 18 months.

Table 48 shows the present value of costs of this rule under 36-month and 12-month labeling change compliance periods and the change in cost, compared with the option 1 of the proposed rule. See Appendix Table A10 for the total undiscounted costs under this alternative.

Table 48: Present Value of Costs for Regulatory Alternative 7 ($ million)

	3 percent			7 percent		
	Lower Bound	Primary	Upper Bound	Lower Bound	Primary	Upper Bound
36-Month	**355.8**	**572.3**	**971.7**	**271.6**	**447.1**	**770.1**
Change from Proposed Rule	-9.40	-19.68	-38.41	-9.83	-20.50	-40.01

Option 1						
12-Month	**390.8**	**646.1**	**1,117.6**	**307.7**	**523.2**	**920.7**
Change from Proposed Rule Option 1	25.6	54.1	107.5	26.3	55.6	110.5

Extending the compliance period would delay removal of potentially misleading descriptors, prevention of the misbranding of proposed deemed tobacco products, and the accrual of benefits attributable to the warning statement provision. Shortening the compliance period would hasten removal of potentially misleading descriptors, prevention of the misbranding of proposed deemed tobacco products, and the accrual of benefits attributable to the warning statement provision.

8. Summary of Alternatives

Table 50 summarizes the present value of costs of the proposed rule under options1 and 2 and several regulatory alternatives.

Table 50.--Summary Quantified Costs of Regulatory Alternatives (Present Values, $ million)

Alternative		**3%**	**7%**
1 – Deeming only; exempt from labeling changes and new product submissions	**Total**	**7 to 14**	**6 to 11**
2 --Enforce premarket requirements only for machine-made cigars	Incremental	89 to 295	78 to 266
	Total	**96 to 309**	**84 to 276**
3 -- Change grandfather date to date of regulation	Incremental	147 to 489	107 to 356
	Total	**243 to 797**	**192 to 632**
4-- Deeming only; exempt from labeling changes	Incremental	65 to -4	37 to -23
	Total	**308 to 794**	**229 to 609**
Proposed Rule Option 2: Exempt Premium Cigars from Regulation	*Incremental*	-4 to -14	5 to 13
	Total	***304 to 779***	***234 to 623***
5--Exempt handmade cigars from labeling changes	Incremental	20 to 51	11 to 22
	Total	**324 to 830**	**244 to 645**
6 -- Deeming only; no additional provisions	Incremental	15 to 93	15 to 92
	Total	**339 to 923**	**259 to 737**
7a-- 36-month compliance period for labeling changes	Incremental	17 to 48	12 to 33
	Total	**356 to 972**	**272 to 770**
Proposed Rule Option 1 – 24-month compliance period for labeling changes	*Incremental*	9 to 38	10 to 40
	Total	***365 to 1,010***	***281 to 810***
7b--12-month compliance period for labeling changes	*Incremental*	26 to 108	26 to 111
	Total	**391 to 1,118**	**308 to 921**

Note: incremental costs and benefits are relative to previously-listed alternative. Benefits are not quantified but are described in the text.

III. Small Entity Effects

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

A. Description and Number of Affected Small Entities

This proposed rule would primarily affect domestic tobacco product manufacturers and importers. Although U.S. Census data are not ideal for estimating the total number of such entities that would be affected, they offer the best available insight into the proportion that may be small.[65] Manufacturers of tobacco products covered by this proposed rule would be designated under the North American Industry Classification System (NAICS) as "other tobacco product manufacturers" or "tobacco product manufacturers," depending on the classification system year. Importers may be designated as wholesalers or retailers. Most tobacco product-importing wholesalers would be classified as "tobacco and tobacco product merchant wholesalers." Although many different categories of retailers (such as grocery and convenience stores) may sell tobacco products covered by this proposed rule, those most likely to import them are specialty tobacco shops and non-store retailers operating electronically or through the mail. Table 52 shows the Small Business Administration (SBA) size thresholds for small businesses in each of these categories, as well as the most comparable size categories available from the U.S. Census (Ref. 140 [SBA, 2013]; Ref. 94 [Statistics of U.S. Businesses, 2008]; Ref. 142 [U.S. Census, 2010b]).[66] For other tobacco product manufacturers and potential tobacco product retailers, the proportion found to be small will be underestimated because the Census size categories are lower than the SBA threshold.

[65] The Census data categories for tobacco product manufacturing are tobacco stemming and redrying, cigarette manufacturing, and other tobacco product manufacturing. Other tobacco product manufacturing would include a mixture of currently-regulated and proposed deemed products. Additionally, the Census establishment count for other tobacco product manufacturing should be viewed as an approximation since many of these establishments have fewer than 20 employees, and such establishments are not counted as accurately as larger establishments (Ref. 138 [U.S. Census, 2007]).

[66] Tobacco product manufacturers (and importers) are considered small under chapter IX of the FD&C Act if they employ fewer than 350 people. This definition is used in the enforcement of certain requirements under the FD&C Act. However, the Small Business Administration's definition of small is applicable to the small entity analysis required under the Regulatory Flexibility Act.

Table 52: SBA Size Standards and Census Size Categories for Tobacco Product Manufacturers and Importers

	NAICS	Description of NAICS Category	SBA Size Standard (employees or $million)	Census Size Category (employees or $million)
Potential Tobacco Product Manufacturers				
	312229	Other Tobacco Product Manufacturing		500
	312230	Tobacco Manufacturing	1,000	
Potential Tobacco Product Importers				
Wholesalers				
	424940	Tobacco and Tobacco Product Merchant Wholesalers	100	100
Retailers				
	453991	Tobacco Stores	$7.0	$5.00
	454111	Electronic Shopping	$30.0	$25.00
	454113	Mail-Order Houses	$35.5	$25.00

Table 53 shows the number of businesses with employees in each of the categories described above, the number qualifying as small according to the census size standard, and the percent qualifying as small. Statistics of U.S. Businesses data from 2008 indicate 89 percent of "other tobacco product manufacturing" businesses with employees are small (Ref. 94). These data also show that 91 percent of "tobacco and tobacco product merchant wholesalers" qualify as small. Data from the 2007 Economic Census show that 94 percent of tobacco shops with payroll are small, while 98 percent of "electronic shopping" and 94 percent of "mail-order" retailers are small (Ref. 142 [U.S. Census, 2010b]).

Table 53: Estimated Percentage of Small Firms Among Firms With Employees

NAICS	Description of NAICS Category	Number of Firms	Number of Firms Below Census Size Standard	Percentage of Small Firms (%)
312229	Other Tobacco Product Manufacturing	44	39	89%

424940	Tobacco and Tobacco Product Merchant Wholesalers	1,118	1,019	91%
453991	Tobacco Stores	4,025	3,793	94%
454111	Electronic Shopping	11,646	11,374	98%
454113	Mail-Order Houses	5,645	5,281	94%

If the percentage of tobacco product manufacturing establishments affected by this rule that are small is the same as the percentage of other tobacco product manufacturing firms that are small, then 173 (=194*0.89) proposed deemed small manufacturing establishments and 20 (=23*0.89) currently regulated small manufacturing establishments would be affected by this proposed rule. For several reasons, these numbers are only an approximation: (1) the "other tobacco manufacturing" Census category includes many firms that are not affected by this proposed rule, and those firms that would be affected may not necessarily be representative; (2) because the Census manufacturing category excludes manufacturers without payroll, which would by definition be small, the Census understates the percentage of manufacturing firms that are small; and (3) large firms are more likely to have multiple establishments, so the percentage of establishments belonging to small firms would be smaller than the percentage of firms that are small.

Based on Table 53, we also expect that most of the importers affected by this rule would be small. Using the proportion of tobacco and tobacco product merchant wholesalers that are small, 246 (=0.91*270) small importers of proposed deemed products and 19 (=0.91*21) small importers of currently regulated products would be affected by this rule.

B. Economic Effect on Small Entities

Small tobacco product manufacturers would be most affected by this rule because they are more likely than importers to be completely specialized in a newly-regulated product. Specifically, we expect small cigar manufacturers to be more adversely affected under option 1 because of the handmade segment of the market, which is characterized by a large number of low-volume products. Therefore, the quantitative analysis in this section focuses on cigar manufacturers. However, we note that most pipe and hookah tobacco manufacturers are also small, and we expect the impact on them to be similar to that for handmade cigar manufacturers, though perhaps less substantial. Most electronic cigarette manufacturers are also small, though the number of small domestic manufacturers is uncertain. Premarket tobacco applications, discussed above in section II.B, are expected to be the most burdensome requirement for electronic cigarettes. We expect to see adjustment through additional product consolidation and exit from the U.S. market, compared with what we would expect without regulation.

Because most cigar manufacturing firms are small and there are few multi-establishment firms, we assume that the typical manufacturing establishment is approximately equivalent to the typical small manufacturing firm. We estimate the average compliance cost per domestic cigar manufacturing establishment by calculating costs for a single typical establishment that operates for an entire year. The number of products, number of UPCs, and dollar sales of the establishment are equal to the domestically produced total divided by the number of domestic cigar manufacturing establishments.

Even though user fees are a transfer payment and not a societal cost, they are a cost from the standpoint of the manufacturers and importers who must pay them. Therefore, we also include user fees in the estimated burden for small cigar manufacturers. In estimating the proportion of cigar user fees that would be paid by domestic cigar manufacturers, we use the proportion of domestically consumed units that is manufactured domestically.[67] The total amount paid by domestic cigar manufacturers is then divided by the number of domestic cigar manufacturing establishments. User fees would increase each year through 2019, after which they would remain constant. We use the maximum (2019) value as the ongoing user fee cost.

Our estimate of the total number of domestic cigar manufacturing establishments may be too high due to counting the same establishment twice if it manufactures both large and small cigars. To use this number as the denominator in calculating the average product counts per domestic establishment might understate the proposed rule's effect. Therefore, we use our main cigar establishment count of 121 in calculating the lower bound estimates. To calculate the upper bound estimates we assume that all 14 manufacturers of small cigars also manufacture large cigars, reducing our estimate of the number of manufacturers to 107.

Table 54 summarizes the estimated cost per small domestic cigar manufacturer under Option 1, which is assumed to be equivalent to the cost per domestic cigar manufacturing establishment. In general, upfront costs are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions, upfront costs are incurred in the first 2 years, while annual costs are incurred in years 3-20.

Table 54: Estimated Costs per Small Domestic Cigar Manufacturer—Option 1

	Upfront Costs[1]		Annual Costs[1]	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Deeming-Specific Requirements				
Registration and Product Listing	639	600	143	249
Ingredient Listing	2,880	3,415	99	448
Costs to Market Tobacco Products	14,412	172,325	3,285	33,165
Miscellaneous	192	192	422	422
User Fees	316,212	357,585	445,828	504,160
Subtotal for deeming-specific	**334,334**	**534,117**	**449,777**	**538,444**
Labeling Changes				
Deeming and Warning Label Changes	55,181	224,958	561	2,145
Total Cost	**389,515**	**759,076**	**450,338**	**540,589**

1 In general, upfront costs are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions, upfront costs are incurred in the first 2 years, while annual costs are incurred in years 3-20.

[67] Because the class allocation for cigars would be determined based on sub-calculations for small and large cigars, we determine the proportion of cigar sticks consumed in the U.S. that are domestically produced within each subcategory. We then multiply the subcategory's share of user fees by this proportion and sum to get the total amount of user fees that would be paid by domestic cigar manufacturers. This calculation is inexact because the manufacturer or importer's share would actually be determined based on their share of excise taxes paid. This could differ from their share of unit volume because large cigars are taxed on an ad valorem basis (up to a maximum).

Because the costs of the proposed rule depend more on the number of distinct products than the number of units (or value of units) sold, FDA is unable to estimate how costs would vary between larger and smaller firms. The estimated upfront costs range from $390,000 to $759,000; the average costs after the first year are estimated to range from $450,000 to $541,000. As a point of comparison, the average value of shipments for all "other tobacco product manufacturing" establishments captured by the Economic Census was $68.4 million in 2007 (Ref. 144 [U.S. Census, 2010c]). Although sufficient data are not available to conduct a detailed analysis of how this varies by size, the average value of shipments for all establishments covered by administrative records was $4.0 million (Ref. 144 [U.S. Census, 2010c]). These establishments are generally among the smallest (Ref. 138 [U.S. Census, 2007]). Because it is difficult to estimate how much lower than average the smallest establishments' costs may be, we are unable to rule out the potential for them to be significantly affected by this proposed rule; some firms may exit the market.

Option 2 of the proposed rule, which would exempt premium cigars from the regulation, would provide regulatory relief to all manufacturers of such products. Small firms that completely specialize in premium cigars would be exempt from all provisions and bear no costs.

We request comments on the specific challenges and costs unique to small business in complying with the proposed rule.

C. Additional Flexibility

Because approximately 90 percent of domestic entities affected by this rule are estimated to be small, the regulatory alternatives analyzed in section II.E that would reduce costs for all affected manufacturers 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. Although we only cover the alternatives that would offer regulatory relief and list them in the order relevant for this section, we refer to the alternatives by the same numbers used in section II.E.

1. Deeming Only; Exempt Proposed deemed Products from All Labeling Changes and Premarket Submission Requirements [Regulatory Alternative 1]

Choosing Alternative 1 would eliminate the non-deeming provisions of the proposed rule and exempt proposed deemed tobacco products from premarket submissions and all labeling changes required under chapter IX of the FD&C Act. Table 55 shows costs for the typical domestic cigar manufacturer under this alternative.

Table 55: Deeming Only; Exempt Proposed deemed Products from All Labeling Changes and Premarket Submission Requirements [Regulatory Alternative 1]

	Upfront Costs[1]		Annual Costs[1]	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Deeming-Specific Requirements				
Registration and Product Listing	639	600	143	249
Ingredient Listing	2,880	3,415	99	448

Miscellaneous	192	192	422	422
User Fees	316,212	357,585	445,828	504,160
Total Cost	**319,922**	**361,792**	**446,492**	**505,279**
Change From Proposed Rule Option 1	-69,592	-397,284	-3,846	-35,310

1 In general, upfront costs are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions, upfront costs are incurred in the first 2 years, while annual costs are incurred in years 3-20.

2. Deeming Only; Exempt Proposed deemed Products from All Labeling Changes [Regulatory Alternative 4]

Choosing Alternative 4 would eliminate the non-deeming provisions and exempt proposed deemed tobacco products from all labeling changes required under chapter IX of the FD&C act. This would eliminate all labeling costs. Table 57 shows costs for the typical domestic cigar manufacturer under this alternative.

Table 57: Deeming Only; Exempt Proposed deemed Products from All Labeling Changes [Regulatory Alternative 4]

	Upfront Costs[1]		Annual Costs[1]	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Deeming-Specific Requirements				
Registration and Product Listing	639	600	143	249
Ingredient Listing	2,880	3,415	99	448
Costs to Market Tobacco Products	14,412	172,325	3,285	33,165
Miscellaneous	192	192	422	422
User Fees	316,212	357,585	445,828	504,160
Total Cost	**334,334**	**534,117**	**449,777**	**538,444**
Change From Proposed Rule Option 1	-55,181	-224,958	-561	-2,145

1 In general, upfront costs are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions, upfront costs are incurred in the first 2 years, while annual costs are incurred in years 3-20.

3. Deeming Only; No Additional Provisions [Regulatory Alternative 6]

Choosing Alternative 6 would eliminate the non-deeming provisions of the proposed rule, including the warning statement provision. However, manufacturers would still need to change product labels to comply with the requirements of chapter IX of the FD&C Act. Table 58 shows upfront and annual costs for the typical domestic cigar manufacturer under this alternative.

Table 58: Deeming Only; No Additional Provisions [Regulatory Alternative 6]

	Upfront Costs[1]		Annual Costs[1]	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Deeming-Specific Requirements				
Registration and Product Listing	639	600	143	249
Ingredient Listing	2,880	3,415	99	448
Costs to Market Tobacco Products	14,412	172,325	3,285	33,165
Miscellaneous	192	192	422	422
User Fees	316,212	357,585	445,828	504,160
Subtotal	**334,334**	**534,117**	**449,777**	**538,444**
Labeling Changes				
Deeming Label Changes	47,310	188,027		
Total Cost	**381,644**	**722,144**	**449,777**	**538,444**
Change From Proposed Rule Option 1	-7,871	-36,931	-561	-2,145

1 In general, upfront costs are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions, upfront costs are incurred in the first 2 years, while annual costs are incurred in years 3-20.

4. Change New Product "Grandfather Date" to the Date of Issuance of a Final Deeming Regulation [Regulatory Alternative 3]

This alternative would change the grandfather date for determining which products are new from February 15, 2007, to the date this rule is finalized. Therefore, new product submissions would not be required for products introduced between February 15, 2007, and the date of a final rule. As shown in Table 56, upfront costs would fall.[68]

Table 56: Change New Product "Grandfather Date" to the Date of Issuance of a Final Deeming Regulation [Regulatory Alternative 6]

	Upfront Costs[1]		Annual Costs[1]	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Deeming-Specific Requirements				
Registration and Product Listing	639	600	143	249
Ingredient Listing	2,880	3,415	99	448
Costs to Market Tobacco Products	3,895	53,558	3,301	33,239
Miscellaneous	192	192	422	422
User Fees	316,212	357,585	445,828	504,160
Subtotal for deeming-specific	**323,817**	**415,350**	**449,793**	**538,519**
Labeling Changes				
Deeming and Warning Label Changes	55,181	224,958	561	2,145
Total Cost	**378,998**	**640,308**	**450,354**	**540,664**
Change From Proposed Rule	-10,517	-118,768	17	75

1 In general, upfront costs are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions, upfront costs are incurred in the first 2 years, while annual costs are incurred in years 3-20.

The table shows the reduced burden for cigar manufacturers but this alternative would provide even greater relief for small businesses producing electronic cigarettes.

5. Extend the Rule's Compliance Period for Labeling Changes to 36 Months [Regulatory Alternative 7a]

Choosing Alternative 7a and allowing 36 months to comply with all labeling would reduce upfront (labeling change) costs and would also allow small firms to spread the cost of labeling out over the 36-month period. Costs in subsequent years would be unchanged except that ongoing costs for random display would only be incurred after the compliance period for labeling changes ended. Table 59 shows costs under these alternatives.

Table 59: Change the Labeling Compliance Period of the Rule [Regulatory Alternative 7]

	Upfront Costs[1]		Annual Costs[1]	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound
36-Month Compliance Period				

[68] Ongoing costs would be affected slightly, to the extent that there would be a change in the timing of submissions requesting a determination of grandfathered status.

Deeming and Warning Label Changes[2]	43,930	179,396	561	2,145
Total Cost	**378,264**	**713,514**	**450,338**	**540,589**
Change From Proposed Rule Option 1	-11,251	-45,562	0	0

1 In general, upfront costs are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions, upfront costs are incurred in the first 2 years, while annual costs are incurred in years 3-20.
2. Upfront labeling costs would be spread over the first 3 years. Annual labeling costs would be incurred in years 4 through 20.

6. Exempt Handmade Cigars from Labeling Changes [Regulatory Alternative 5]

Choosing Alternative 5 would exempt all handmade cigars from the labeling changes required by this proposed rule. This option would not provide relief to all small newly regulated tobacco product manufacturers, but it would provide relief to the smallest and most affected firms.

Although we have an estimate of the number of domestically produced handmade cigar UPCs, there is considerable uncertainty regarding the number of small handmade cigar manufacturers in the U.S. This uncertainty would make any analysis of the typical domestic handmade cigar manufacturer subject to a great deal of error. Therefore, we evaluate the effect this alternative would have on each uncoordinated handmade cigar UPC and for a hypothetical manufacturer of 10 such UPCs.

Handmade cigars are distinctive products and the FDA labeling cost model may not accurately represent the costs of changing their labels. The direction of the possible error is, however, uncertain: the model could over- or underestimate costs. While small firms could use a less costly labeling alternative than assumed by the model, we also know that many handmade cigars come in collectible cigar boxes that could be even more expensive to change than a standard product label.

With these caveats in mind, we see from Table 29 that the estimated cost of an uncoordinated labeling change with 5 versions of the new label is $6,207 to $16,863. Additionally, we see in Table 31 that the ongoing yearly costs for equal random display are estimated to be $89 to $207 per UPC. If a handmade cigar manufacturer had 10 uncoordinated UPCs, the firm's reduction in costs would be $62,000 to $169,000 in the first year. If those 10 UPCs were not already displaying a rotating FTC warning, costs would be reduced by $890 to $2,100 annually.

7. Enforce Premarket Submission Requirements Only for Machine-Made Cigars [Regulatory Alternative 2]

Choosing Alternative 2 would exempt products except for machine-made cigars from premarket submission requirements. This option would not provide relief to all small newly regulated tobacco product manufacturers, but it would provide relief specifically to firms that specialize in proposed deemed products other than machine-made cigars, including firms that specialize in producing handmade cigars.

Although we have an estimate of the number of domestically produced handmade cigar products, there is considerable uncertainty regarding the number of small handmade cigar manufacturers in the U.S. This uncertainty would make any analysis of the typical domestic

handmade cigar manufacturer subject to a great deal of error. We note, however, substantial equivalence reports are estimated to take 152 hours to 232 hours to prepare, at a cost of $10,100 to $15,400.[69] Substantial equivalence exemptions would be less costly to prepare, while premarket tobacco applications would be more costly. The cost savings for each small handmade cigar manufacturer would depend on the number of products and the type of premarket submissions that would be most appropriate under the proposed rule.

[69] See table 24. We use a technical composite labor cost of $66.50 per hour to value the time spent on all premarket submissions.

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V. Appendix

Table A1.--Summary of Benefits, Costs and Distributional Effects: Option 1

Economic Data: Costs and Benefits Statement							
				Units			
Category	Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate	Period Covered	Notes
Benefits							
Annualized Monetized $ millions/year							
Annualized Quantified							
Qualitative							Health improvements from reduced tobacco use attributable to warning labels, free samples prohibition, content of warnings on advertisements. Reduction in passive smoking. Potentially improved enforcement, removal of potentially misleading descriptors, possible prevention of marketing of more harmful products through new product application review.
Costs							
Annualized Monetized $ millions/year	41.2	24.8	71.5	2012	7%	2015-34	Registration, listing and various submissions; labeling changes performed to simultaneously satisfy deeming and warning statement requirements; one-time costs to remove point-of-sale promotions that do not comply with warning statement provisions; ongoing costs for government activities.
	38.6	23.8	65.9	2012	3%	2015-34	
Annualized Quantified					7%		All quantified costs are also monetized.
					3%		
Qualitative							Potential enforcement costs; harmful and potentially harmful constituent testing; any potential clinical testing for substantial

							equivalence reports; compliance costs for components and parts; discarded inventory costs for private label products.
Transfers							
Federal Annualized Monetized $ millions/year							
From/To							
Other Annualized Monetized $ millions/year							
From/To							
Effects							
State, Local or Tribal Government: Each year, state governments would lose excise tax revenue. There would be additional changes in Medicaid and other government health insurance receipts and outlays.							
Small Business: The proposed rule would affect small entities in several industries, from tobacco farming to tobacco product manufacturing and importing to the retail industry. Domestic tobacco product manufacturers are expected to be most affected. Most (89%) are small, and the first-year costs of this proposed rule could be a substantial share of annual receipts.							
Wages: No Estimated Effect							
Growth: No Estimated Effect							

Table A2.--Summary of Benefits, Costs and Distributional Effects: Option 2

Economic Data: Costs and Benefits Statement							
				Units			
Category	Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate	Period Covered	Notes
Benefits							
Annualized Monetized $ millions/year							
Annualized Quantified							
Qualitative							Health improvements from reduced tobacco use attributable to warning labels, free samples prohibition, content of warnings on advertisements. Reduction in passive smoking. Potentially improved enforcement, removal of potentially misleading descriptors, possible prevention of marketing of more harmful products through new product application review.
Costs							
Annualized Monetized $ millions/year	33.1 31.1	20.6 19.8	54.9 50.8	2012 2012	7% 3%	2015-34 2015-34	Registration, listing and various submissions; labeling changes performed to simultaneously satisfy deeming and warning statement requirements; one-time costs to remove point-of-sale promotions that do not comply with warning statement provisions; ongoing costs for government activities.
Annualized Quantified					7% 3%		All quantified costs are also monetized.
Qualitative							Potential enforcement costs; harmful and potentially harmful constituent testing; any potential clinical testing for substantial equivalence reports; compliance costs for

							components and parts; discarded inventory costs for private label products.
Transfers							
Federal Annualized Monetized $ millions/year							
From/To							
Other Annualized Monetized $ millions/year							
From/To							
Effects							
State, Local or Tribal Government: Each year, state governments would lose excise tax revenue. There would be additional changes in Medicaid and other government health insurance receipts and outlays.							
Small Business: The proposed rule would affect small entities in several industries, from tobacco farming to tobacco product manufacturing and importing to the retail industry. Domestic tobacco product manufacturers are expected to be most affected. Most (89%) are small, and the first-year costs of this proposed rule could be a substantial share of annual receipts.							
Wages: No Estimated Effect							
Growth: No Estimated Effect							

Table A6.--Estimated Number of Establishments Selling Tobacco Products Covered by the Proposed Rule

Kind of Business	Establishments With Payroll [a]	Nonemployer Establishments[a]	Total
AT Kearney Category			
General Merchandise	7,626	5,428	13,054
Supermarket & Grocery	77,969	66,455	144,423
Convenience Stores	25,670		25,670
Convenience Stores with Gas	87,432		87,432
Service Stations	5,668	2,683	8,351
Drug Stores	16,331	25,289	41,620
Specialty Tobacco Stores	6,463		6,463
Other establishments [c]	18,887	12,354	31,241
Total	**246,045**	**112,209**	**358,255**

[a] Source Table 9 of the regulatory impact analysis.

[c] Includes miscellaneous retail establishments and accommodation and food services establishments (including drinking places) but excludes nonstore retailers and vending machine operators.

Table A7--Estimated Average Per-Establishment Costs to Remove Noncompliant Point-of-Sale Advertising

AT Kearney Business Category	Remove Cigarette Promotional Materials ($)		Remove Cigar Promotional Materials ($)
	1996 dollars[a]	Current dollars[a]	Current dollars
General Merchandise	23.42	32.50	2.79
Supermarket & Grocery	125.14	173.64	14.93
Convenience Stores	150.02	208.16	17.90
Convenience Stores with Gas	146.43	203.18	17.47
Service Stations	36.09	50.08	4.31
Drug Stores	11.72	16.26	1.40
Specialty Tobacco Stores	123.21	170.96	14.70
Other establishments [b]	9.37	13.00	1.12
Weighted Average [c]	103.03	142.96	12.29

a Sources: 61 FR 44585, Table 8; 1996 to 2012 (most recent) GDP-deflator = 38.8%

b Includes miscellaneous retail establishments and accommodation and food services establishments (including drinking places) but excludes nonstore retailers and vending machine operators.

c Weights are the proportion of total establishments belonging to each type.

Table A10: Total Costs Under 36-Month and 12-Month Labeling Change Compliance Periods

	Upfront Costs ($mill)[1]			Annual Costs ($mill)[1]		
	Lower Bound	Primary	Upper Bound	Lower Bound	Primary	Upper Bound
36-Month[2]	**66.13**	**154.08**	**313.10**	**20.81**	**30.63**	**48.96**
Change from proposed rule	-8.14	-17.04	-33.88	0.00	0.00	0.00
12-Month[3]	**98.4**	**222.1**	**448.9**	**20.8**	**30.6**	**49.0**
Change from proposed rule	24.1	51.0	101.9	0.0	0.0	0.0

1. In general, upfront costs are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions, upfront costs are incurred in the first 2 years, while annual costs are incurred in years 3-20.
2. Upfront labeling costs would be spread over the first 3 years. Annual labeling costs would be incurred in years 4 through 20.
3. Upfront labeling costs would be spread over the first 2 years. Annual labeling costs would be incurred in years 3 through 20.

Table A9: Change Grandfather Date to Date of Regulation

	Upfront Costs[1] ($ mill)			Annual Costs[1] ($ mill)		
	Lower Bound	Primary	Upper Bound	Lower Bound	Primary	Upper Bound
Deeming-Specific Requirements						
Registration and Product Listing	0.10	0.31	0.52	0.03	0.09	0.15
Ingredient Listing	2.81	2.88	2.95	0.07	0.20	0.33
Costs to Market Tobacco Products	2.46	7.28	43.18	2.89	11.00	28.21
Miscellaneous	0.09	0.09	0.09	0.19	0.19	0.20
Subtotal for deeming-specific	**5.47**	**10.56**	**46.74**	**3.18**	**11.49**	**28.90**
Labeling Changes						
Deeming and Warning Label Changes	48.01	98.11	189.57	0.90	1.93	3.18
Additional Provisions						
Point-of-sale advertising	4.40	4.40	4.40			
Private Sector Subtotal	**57.89**	**113.07**	**240.72**	**4.08**	**13.42**	**32.08**
FDA	8.55	8.55	8.55	8.55	8.55	8.55
Total Cost	**66.43**	**121.62**	**249.26**	**12.63**	**21.96**	**40.63**
Change from Proposed Rule	-7.84	-49.50	-97.71	-8.19	-8.67	-8.33

* In general, upfront costs are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions, upfront costs are incurred in the first 2 years, while annual costs are incurred in years 3-20.

Table A8: Deeming Only; No Additional Provisions

	Upfront Costs[1] ($ mill)			Annual Costs[1] ($ mill)		
	Lower Bound	Primary	Upper Bound	Lower Bound	Primary	Upper Bound
Deeming-Specific Requirements						
Registration and Product Listing	0.10	0.31	0.52	0.03	0.09	0.15
Ingredient Listing	2.81	2.88	2.95	0.07	0.20	0.33
Costs to Market Tobacco Products	11.58	62.24	152.76	5.66	14.25	31.12
Miscellaneous	0.09	0.09	0.09	0.19	0.19	0.20
Subtotal for deeming-specific	**14.58**	**65.52**	**156.32**	**5.95**	**14.74**	**31.81**
Labeling Changes						
Deeming Label Changes	31.58	66.63	131.61			
Private Sector Subtotal	**46.16**	**132.14**	**287.93**	**5.95**	**14.74**	**31.81**
FDA	13.97	13.97	13.97	13.97	13.97	13.97
Total Cost	**60.12**	**146.11**	**301.89**	**19.91**	**28.70**	**45.78**
Change from Proposed Rule	-14.15	-25.01	-45.08	-0.90	-1.93	-3.18

* In general, upfront costs are incurred in year 1, while annual costs are incurred in years 2-20. For premarket submissions, upfront costs are incurred in the first 2 years, while annual costs are incurred in years 3-20.