

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

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Office of Policy, Planning, Legislation and Analysis
Office of the Commissioner

May 2016

I. INTRODUCTION.....	4
II. RESPONSES TO COMMENTS ON THE PRELIMINARY ECONOMIC ANALYSIS OF IMPACTS 7	
A. GENERAL COMMENTS ABOUT BENEFIT-COST ANALYSIS AND THE PROPOSED REGULATORY IMPACT ANALYSIS (PRIA)	7
B. COMMENTS ABOUT THE NEED FOR THE RULE	10
C. COMMENTS ABOUT BENEFITS	10
D. COMMENTS ABOUT COSTS	21
1. <i>Comments About the Number of Entities and Products Affected</i>	24
2. <i>Comments About the Costs of Manufacturing and Importing Deemed Products</i>	31
3. <i>Labeling Costs</i>	40
4. <i>Comments About Other Industry Costs</i>	41
5. <i>Administration and Enforcement Costs Borne by Government</i>	42
6. <i>Other Comments About Costs</i>	43
E. COMMENTS ABOUT THE BREAK-EVEN CALCULATION	44
F. COMMENTS ABOUT DISTRIBUTIONAL AND INTERNATIONAL EFFECTS.....	45
G. COMMENTS ABOUT THE ANALYSIS OF ALTERNATIVES:	51
H. COMMENTS ABOUT THE SMALL ENTITY ANALYSIS.....	52
I. OTHER COMMENTS	58
III. FINAL REGULATORY IMPACT ANALYSIS.....	58
A. NEED FOR THE FINAL RULE	58
B. BENEFITS.....	62
1. <i>Youth access restrictions, prohibition on free samples, and vending machine restrictions</i>	63
2. <i>Addition of health warning Statements to newly-deemed and certain other tobacco products and restrictions against making false or misleading product claims</i>	64
3. <i>Premarket authorizations</i>	65
4. <i>Changes in demand across and within categories of tobacco products</i>	65
5. <i>Willingness to pay for benefits of rule</i>	67
C. COSTS.....	68
1. <i>Number of Affected Entities</i>	68
a) <i>Manufacturers and Importers</i>	68
b) <i>Retailers</i>	70
2. <i>Number of Affected Products</i>	72
a) <i>Baseline Number of Products</i>	72
b) <i>Potential Product Consolidation</i>	78
c) <i>Changes in Products over time</i>	80
3. <i>Compliance costs for Manufacturing, Importing or Selling Newly Deemed Products</i>	80
a) <i>Regulation Review and Administrative Setup</i>	80
b) <i>Marketing Authorizations for Newly Deemed Tobacco Products</i>	81
(1) <i>Compliance Policy for Premarket Review Requirements</i>	82
(2) <i>Number of Newly Deemed Tobacco Products Seeking Marketing Authorization</i>	83
(3) <i>Description and Cost of Each Marketing Pathway</i>	85
(a) <i>Premarket Tobacco Application (PMTA)</i>	85
(b) <i>Substantial Equivalence (SE)</i>	92
(c) <i>Substantial Equivalence Exemptions (Exemptions)</i>	93
(d) <i>Summary of Application Types</i>	94
(4) <i>Newly Deemed Tobacco Products Use of the Marketing Pathways</i>	95
(5) <i>Costs for Complying with Premarket Requirements for Marketing Tobacco Products</i>	97
c) <i>Annual Registration and Product Listing</i>	98
d) <i>Ingredient Listing</i>	100
e) <i>Harmful or Potentially Harmful Constituents</i>	101
f) <i>Tobacco Health Documents</i>	102
g) <i>Prohibition of Free Samples</i>	103
4. <i>Other Costs Associated with Newly Deemed Products</i>	103

a)	Consumer Costs	103
b)	Costs of Market Adjustment	104
5.	<i>Labeling Costs</i>	105
(1)	Pipe Tobacco, Waterpipe Tobacco and RYO Tobacco.....	106
(2)	Cigars.....	107
(3)	ENDS.....	109
6.	<i>Additional Private Sector Costs</i>	110
a)	Warning Statement Provisions: Removal of Noncompliant Point-of-Sale Advertising	111
b)	Minimum Age and I.D. Restrictions	112
c)	Vending Machine Restrictions.....	112
7.	<i>Administration and Enforcement Costs Borne by Government (Costs to FDA)</i>	113
8.	<i>Summary of Costs</i>	113
9.	<i>Summary of Costs by Product Category</i>	114
D.	BREAK-EVEN CALCULATION FOR THE FINAL RULE.....	115
E.	DISTRIBUTIONAL EFFECTS.....	116
1.	<i>Collection of User Fees from Cigar and Pipe Tobacco Manufacturers</i>	116
2.	<i>Consumers of Tobacco Products</i>	117
3.	<i>Tobacco Manufacturers, Distributors, and Growers</i>	118
4.	<i>National Employment Patterns</i>	118
5.	<i>Regional and Local Impacts</i>	119
6.	<i>Retail Sector</i>	119
7.	<i>Excise Tax Revenues</i>	120
8.	<i>Government-Funded Medical Services, Insurance Premiums and Social Security</i>	120
F.	INTERNATIONAL EFFECTS.....	121
G.	ASSESSMENT OF REGULATORY ALTERNATIVES	122
1.	<i>Exempt Premium Cigars, As Defined in the Notice of Proposed Rule Making, from Regulation.</i> 122	
2.	<i>Change the Labeling Compliance Dates</i>	123
a.	Extend the Compliance Period for Labeling Changes to 36 Months	123
b.	Reduce the Compliance Period for Labeling Changes to 12 months	123
3.	<i>Do Not Extend the Premarket Review Compliance Policy to New Flavored Tobacco Products.</i> 124	
4.	<i>Summary of Regulatory Alternatives</i>	126
IV.	SMALL ENTITY EFFECTS.....	128
A.	DESCRIPTION AND NUMBER OF AFFECTED SMALL ENTITIES	128
B.	ECONOMIC EFFECT ON SMALL ENTITIES	131
C.	REGULATORY ALTERNATIVES FOR SMALL ENTITIES.....	133
1.	<i>Extend the Compliance Period for Labeling Changes to 36 Months [Regulatory Alternative 2a]</i> 133	
2.	<i>Exempt Premium Cigars From Regulation [Regulatory Alternative 1]</i>	134
V.	REFERENCES	135
VI.	APPENDIX 1	143
VII.	APPENDIX 2: PREMARKET TOBACCO APPLICATION ANALYSIS	148
VIII.	APPENDIX 3: SEARCH, MARKET ADJUSTMENT, AND PRODUCER SURPLUS COSTS UNDER REGULATORY ALTERNATIVE 3 (DO NOT EXTEND THE PREMARKET REVIEW COMPLIANCE POLICY TO NEW FLAVORED PRODUCTS)	152
A.	SEARCH AND MARKET ADJUSTMENT COSTS DUE TO EXPECTED EXIT OF NEWLY DEEMED FLAVORED NEW TOBACCO PRODUCTS	152
B.	ESTIMATING THE LOSS OF PRODUCER SURPLUS IN THE MARKET UNDER THIS REGULATORY ALTERNATIVE.....	153

I. INTRODUCTION

We have examined the impacts of the final 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 us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We find that the final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "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 \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This final rule would result in a 1-year expenditure that meets or exceeds this amount.

This final rule finalizes option 1 of the proposed rule, which deems all products meeting the statutory definition of "tobacco product," except accessories of a newly deemed tobacco product, to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This final rule also finalizes additional provisions that would apply to certain newly 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 will apply to newly deemed products include establishment registration and product listing, ingredient listing, submissions prior to the introduction of new products, and labeling requirements. Free samples of newly deemed tobacco products will also be prohibited. The additional provisions of this final rule include minimum age and identification requirements, vending machine restrictions, and required warning statements for packages and advertisements.

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, under the final rule, all additional tobacco products that meet the statutory definition, except accessories of those newly deemed tobacco products, will be subject to chapter IX of the FD&C Act and its implementing

regulations.¹ These products include cigars, pipe tobacco, waterpipe tobacco, electronic nicotine delivery systems (ENDS) (including e-cigarettes), and other novel tobacco products such as certain dissolvable products and gels. These products further include components and parts of the newly deemed products, including pipes, e-liquids, atomizers, batteries, cartomizers (atomizer plus replaceable fluid-filled cartridge), tank systems, flavors for e-liquids, vials that contain e-liquids, programmable software, flavor enhancers for waterpipe tobacco, waterpipe cooling attachments, water filtration base additives, flavored waterpipe tobacco charcoals, and waterpipe bowls, valves, hoses, and heads.

The final deeming action differs from most public health regulations in that it is an enabling regulation. In addition to directly applying the substantive requirements of chapter IX of the FD&C Act and its implementing regulations to newly deemed tobacco products, it enables FDA to issue further regulations related to such products that are appropriate for the protection of the public health. 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 require manufacturers to provide, for example, 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 newly deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify, and we cannot predict the size of these benefits at this time. Among other effects, new products will be subject to an evaluation to ensure they meet the appropriate public health standard for the pathway before they can be marketed, labeling cannot contain misleading statements, and FDA will be made aware of the ingredients in newly deemed tobacco products. If, without the final rule, new products would pose substantially greater health risks than those already on the market, the premarket requirements made effective by this final rule would keep such products from appearing on the market and worsening the health effects of tobacco product use. The warning statements required by this final rule will help consumers better understand and appreciate the risks and characteristics of tobacco products.

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

¹ As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part, a tobacco product: (1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and (2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)), or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)).

The primary estimate for the present value of total quantified costs over 20 years is approximately \$988 million at a 3 percent discount rate and \$817 million at a 7 percent discount rate. The quantified costs of the final rule can also be expressed as annualized values, as shown in Table 1. Unquantified costs which may be attributable to this final rule include: some consumer costs for users of the newly deemed products due to loss of product variety or higher prices; recordkeeping costs for exporters of deemed tobacco products; compliance costs for components and parts other than complete pipes, waterpipes, and ENDS delivery systems; the cost of testing and reporting for harmful and potentially harmful constituents; the cost of any clinical testing that may potentially be conducted to support substantial equivalence reports; market adjustment (friction) costs and lost producer surplus associated with product consolidation, exit of manufacturers (including some vape shops currently engaged in manufacturing activities), and the switch to pure retailing among retailers such as vape shops who currently engage in manufacturing activities.

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 of Private Sector Costs	517.7	783.7	1,109.8	450.4	670.9	939.8
Present Value of Government Costs ¹	204.6	204.6	204.6	145.7	145.7	145.7
Present Value of Total Costs	722.3	988.2	1,314.4	596.1	816.5	1,085.4
Annualized Value of Private Sector Costs	34.8	52.7	74.6	42.5	63.3	88.7
Annualized Value of Government Costs ¹	13.8	13.8	13.8	13.8	13.8	13.8
Annualized Value of Total Costs	48.5	66.4	88.3	56.3	77.1	102.5

¹ FDA costs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the federal budget, or the total amount of tobacco industry user fees.

Because it is not possible to compare benefits and costs directly when the benefits are not quantified, we employ a breakeven approach. For the reasons provided in the preamble and elsewhere in this analysis of impacts, FDA has concluded that the benefits of the final rule justify the costs.

In addition to the benefits and costs of this final rule, we assess the benefits and costs of four different approaches. These approaches consist of regulatory alternatives (i.e., alternatives to the rule) as well as enforcement options (i.e., periods of time during which FDA does not intend to enforce certain requirements). First, we assess the regulatory alternative of exempting premium cigars from regulation. Second, we assess two hybrid regulatory alternatives/enforcement options of providing either a 36-month or 12-month compliance period for labeling changes. Lastly, we assess the enforcement option of not extending the premarket review compliance policy to new flavored tobacco products (other than tobacco flavored products).² For the sake of simplicity only, we have referred to these four approaches as “alternatives to the rule.”

² Throughout the final RIA, any reference to “flavored tobacco products” means flavored products other than tobacco flavor.

In addition to the above alternatives, comments discussed changing the grandfather date as an alternative. FDA has decided not to include this option in the analysis of alternatives because we determined that the Agency lacks the authority to change the grandfather date.

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

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

Alternative	Present Value (3%)	Present Value (7%)	Annualized Value (3%)	Annualized Value (7%)
1 -- Exempt Premium Cigars from Regulation	959	794	64	75
2a-- 36-month compliance period for labeling changes	968	797	65	75
<i>Final Rule and Compliance Period</i>	988	817	66	77
2b--12-month compliance period for labeling changes	1,043	871	70	82
3 – Do not extend the premarket review compliance policy to new flavored tobacco products	1,141	961	77	91

¹ Nonquantified benefits are described in the text.

In addition to the social costs described above, the final rule would lead to distributional effects, such as: reduced revenues for firms in affected sectors, payment of user fees, and potential changes in tax revenues. Appendix Table 1 summarizes the costs, benefits, and distributional effects of the final rule.

II. RESPONSES TO COMMENTS ON THE PRELIMINARY ECONOMIC ANALYSIS OF IMPACTS

Most comments referred to “e-cigarettes” when discussing electronic nicotine delivery systems, or ENDS. FDA summarizes comments on the economic analysis of impacts using “e-cigarettes (or ENDS).” When not further specified (e-liquid or delivery systems), we use ENDS to refer to any or all types of products or components, such as cigalikes, e-liquid, delivery systems, hardware components, etc.

A. GENERAL COMMENTS ABOUT BENEFIT-COST ANALYSIS AND THE PROPOSED REGULATORY IMPACT ANALYSIS (PRIA)

[Comment]: We received comments on the application of welfare economics, or cost-benefit analysis, to assess public health in general and tobacco policy in particular. Several comments objected to the idea of cost-benefit analysis of regulations when dealing with public health. Some objected to the use of welfare economics tools in general because they are based on the economic notions of consumer utility and opportunity cost.

[Response]: FDA disagrees with these comments. The benefit-cost analysis of public health regulations remains the accepted method of estimating changes in economic welfare due to policy interventions. When it is not possible to conduct a benefit-cost analysis to measure changes in economic welfare, other tools are used to evaluate regulations, such as break-even calculations.

[Comment]: One commenter put forth that use of consumer surplus in analyses of proposed rules is unlawful under the Tobacco Control Act. The commenter noted the extensive Findings of Fact section of FSPTCA, particularly with respect to youth initiation and addictiveness, and argued that, as a matter of law, equating cigarette consumption with a benefit, and taking regulation-induced reduction of tobacco products to represent a reduction in consumer surplus, contradicts the express findings of Congress. The commenter concluded that “Counting reduced tobacco product consumption as lost consumer surplus is unlawful under the [Act]” (capitalization altered).

[Response]: We need not address the merits of the comment’s argument in this rulemaking, because the analysis of the final rule uses a different approach to characterizing the potential value of the rule which does not estimate consumer surplus.

[Comment]: Some comments raised questions about the requirements for the preliminary regulatory impact analysis of regulations and its relationship with the rule itself.

[Response]: The PRIA is an analysis intended to provide information to decision makers about the expected benefits and costs of a proposed rule. The regulation is issued on consideration of many factors, including costs and benefits. Executive Order 12866, for example, states that, “recognizing that some costs and benefits are difficult to quantify,” adoption of a regulation must be based upon a “reasoned determination that the benefits of the intended regulation *justify* its costs” (emphasis ours).

[Comment]: Comments stated that FDA should consider risk tradeoffs, such as whether proposed deemed products pose equal harm. For example, a comment stated that “Given the enormous costs and the ‘unquantifiable’ benefits of imposing the requirements of Option 1 on premium cigar manufacturers, it is difficult to understand how FDA can reach a ‘reasoned determination’ that the benefits of Option 1 justify its costs.” Other comments stated that FDA’s regulatory impact analysis should consider whether electronic cigarettes are beneficial to public health.

[Response]: The preambles to both the proposed and final rules (79 FR 23141-23207 and 81 FR 28973-29106) provide in-depth discussions of the evidence of the risk associated with various tobacco products. FDA concluded that it is appropriate to deem premium cigars and determined that the benefits of regulating premium cigars and other newly regulated products justified the costs. Recognizing that there may be differences between combusted and non-combusted products, both the PRIA and Final Regulatory Impact Analysis (FRIA) contain a discussion of the welfare implications of the emergence and regulation of electronic cigarettes (or ENDS products). We note in both the PRIA and FRIA that our discussion of the health and welfare effects of ENDS would also apply to other novel non-combusted tobacco products, but we focus on ENDS because they are the most widely used novel non-combusted tobacco product.

[Comment]: One comment stated that the purpose of the regulatory impact analysis was to maximize benefits.

[Response]: The regulatory impact analysis analyzes the effects of the proposed rule. The intent of the requirement for regulatory impact analysis is to help inform decision makers and the public. Benefit-cost analysis is a primary tool used for regulatory analysis, a purpose of which is to identify regulatory options that maximize net benefits. It is not always possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate (see OMB Circular A-4 at 2).

[Comment]: Several comments questioned whether the non-quantified benefits could justify the costs of the proposed rule. For example, one comment asserted that because benefits were not quantified, FDA “has not selected and cannot select” the regulatory alternative that maximizes net benefits. Another commenter stated that the benefits analysis is “enormously incomplete, speculative, and incapable of supporting the proposed regulations” and “does not comply with the EO.”

[Response]: Executive Order 12866 makes the following statement: “Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.” Additionally, “[c]osts and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider.”

FDA has described the expected impacts of this rule, including a qualitative and quantitative assessment of costs and the inherent uncertainties and a qualitative assessment of benefits and the inherent uncertainties. FDA’s detailed review of the non-quantified benefits concludes they would justify the costs.

[Comment]: One comment stated that FDA failed to prepare an adequate Regulatory Impact Analysis. Specifically, the comment stated that “the FDA did not analyze any significant alternatives to their proposed rule, they did not perform a reasonable cost/benefit analysis, and they did not examine the impact of the proposed rule on small businesses in the United States.” The commenter has included what they suggest is “a proper analysis using FDA’s own assumptions wherever possible,” following OMB guidelines. The commenter’s analysis includes estimates of both the benefits and costs of the rule, regulatory alternatives, and the effects of alternatives on small businesses.

[Response]: FDA disagrees that we have failed to prepare an adequate Regulatory Impact Analysis. While benefits of the rule are difficult to quantify, analyses of both the proposed and final rule estimate the costs of the rule, qualitatively describe the benefits, estimate the costs and describe the benefits of several regulatory alternatives, and consider the impacts of the rule (or its alternatives) on small business. Specific suggestions from the commenter’s alternative RIA will be addressed in later sections, where they are grouped with other comments by topic.

[Comment]: A commenter stated that a long time horizon, such as 100 years, should be used to estimate the impacts of this rule because the benefits are seen far in the future.

[Response]: We do not quantify the benefits of this final rule, but we agree that the benefits of the regulation would stretch out for decades into the future.

[Comment]: Some comments stated that the analysis should start with a better characterization of the industry. One commenter provided an alternate regulatory impact analysis with a section on the baseline in the newly deemed tobacco product industries.

[Response]: Most of the suggested baseline information was presented by FDA in its analysis of the proposed rule, though not in the same organizational format as the commenter provided. We include updated information about baseline usage of newly deemed tobacco products in section III.A. We include updated information about the baseline number of products and entities in section III.C.

B. COMMENTS ABOUT THE NEED FOR THE RULE

[Comment]: A comment stated that premium cigars do not pose health risks comparable to other tobacco products, and that premium cigar retailers strictly apply age requirements for entering their establishments. The comment further stated that the Regulatory Impact Analysis (RIA) is deficient because “FDA has not demonstrated a compelling public need for regulation of premium cigars based on general public health considerations or on youth access issues.”

[Response]: The preambles to both the proposed and final rules (79 FR 23141-23207 and 81 FR 28973-29106) provide in-depth discussions of the evidence of the risk associated with various tobacco products. FDA has concluded that the benefits of regulating premium cigars and other newly regulated products justified the costs.

Additionally, there are several reasons government regulatory action may be warranted, including failures of private markets or public institutions. The FRIA describes the market and institutional failures existing in the markets for tobacco products covered by this rule, as required by Executive Order 12866 and Circular A-4.

C. COMMENTS ABOUT BENEFITS

[Comment]: Several comments on the analysis of the proposed rule questioned how we estimated benefits. Some of these comments included detailed discussions of the method used to estimate benefits.

[Response]: While we did not estimate benefits in the proposed rule, we did provide a detailed description of the qualitative benefits that may accrue to a dissuaded smoker. The breakeven analysis included in the PRIA estimated the number of life-years that would need to be saved in order to break even with the costs of the proposed rule. In the FRIA, we again include a detailed qualitative discussion of the benefits of the rule. A breakeven analysis is included, but updated to evaluate how much the rule’s beneficiaries would need to be willing to pay for the information and market corrections provided in the rule in order to break even with the costs of the rule.

[Comment]: Some comments noted that the preliminary RIA analysis did not include an estimate of benefits, and suggested that FDA should be able to estimate benefits. Many of these comments described the negative health effects of cigarette smoking, including both direct and second-hand effects of cigarette smoking. Some of these comments included data on the number of cigarette smokers, exposure to second-hand tobacco smoke, when people have their first cigarette, and the health costs of smoking, both direct and second-hand.

[Response]: The proposed rule does not apply to cigarettes; cigarettes are already subject to the FD&C Act.

As explained in the preliminary RIA, the direct benefits of making each of the newly deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify, and we cannot predict the size of these benefits. Among other effects, new products will be subject to evaluation to ensure they meet the appropriate public health standard for the pathway before they can be marketed, labeling cannot contain misleading statements, and FDA will be made aware of the ingredients in newly deemed tobacco products. If, without the final rule, new products would pose substantially greater health risks than those already on the market, the premarket requirements made effective by this final rule would keep such products from appearing on the market and worsening the health effects of tobacco product use. The warning statements required by this final rule will help consumers understand and appreciate the risks of using tobacco products. To provide perspective, we divide the total rule costs by the number of people expected to benefit from it. This procedure estimates the average amount that beneficiaries of the rule would need to be willing to pay for the benefits of the rule to equal the costs.

[Comment]: Many comments suggested that FDA's welfare gain ratio, used to estimate the net gain in consumer surplus, was incorrect.

[Response]: The welfare gain ratio was used as an input for the breakeven arithmetic in which FDA calculated the number of net life-years that would need to be saved through dissuading use of deemed products (and other behavioral changes) and changing product characteristics in order for the monetized benefits of the proposed rule to equal monetized costs. The ratio used in the breakeven calculation was based on a range that was in turn based on limited evidence.

Estimating the change in welfare associated with behavioral changes that improve or worsen health remains a difficult problem that is the subject of ongoing research. If the non-quantified benefits or costs of a rule are likely to be important, standard principles of regulatory analysis call for conducting a "threshold" analysis, also called a "break-even" analysis. In this context, a break-even analysis evaluates the quantified costs of the rule, and asks how small the rule's non-quantified benefits would have to be to cancel out the costs—in other words, for the rule to yield zero net benefits. Because we do not quantify the benefits of this final rule, and because the methods we would use are the subject of ongoing research, we have determined that it is appropriate to describe the benefits of this final rule in terms of people's willingness to pay for the provisions of the rule itself, which is one standard form of break-even analysis. FDA emphasizes that a breakeven calculation is neither a benefit-cost analysis nor a measure of welfare gain.

[Comment]: Some comments on the PRIA referenced terms, such as “lost consumer surplus”, “lost pleasure”, “discounted health benefits” and variations on those terms.

[Response]: These various terms all refer to the practice of estimating benefits in terms of the net increase in consumer surplus – which includes the monetized value of all effects on consumers rather than just the monetary value of health and longevity effects. While FDA does not estimate the benefits of this rule, we continue to interpret the impacts of the rule as most appropriately measured by the overall change in societal welfare, as discussed elsewhere.

[Comment]: Several commenters objected to the use of “lost consumer surplus” in FDA’s analyses of how tobacco regulation affects consumers. In these comments, the idea of lost utility or lost consumer surplus was criticized on a number of grounds.

First, a number of comments argued that the concept of lost utility or lost consumer surplus is not applicable to addictive products because addiction imparts strong involuntary elements to consumer demand. Second, some argued that utility offsets for tobacco products are unlikely to be negative and may even be positive on balance, given that there are potential utility gains from breaking an addiction (reduced self-loathing, improved sense of self-efficacy, etc.). Third, some argued that many or most users of tobacco products use them not because they get pleasure from consumption, but because it staves off withdrawal symptoms. Fourth, some argued that the potential for utility loss should be disregarded because almost all people start consuming tobacco products when they are teens or young adults, when they have only the emerging ability to make decisions that rationally balance benefits, costs, and risks. Fifth, some comments objected to the specific multiple used for the utility offset to health benefits, pointing out that it came from a highly stylized theoretical model calibrated using assumptions about key behavioral parameters (Gruber and Köszegi, 2001), rather than empirical work using actual data on consumer behavior; as such, the comment stated that it falls short of the standard required for quantitative analysis in RIAs. Some comments also offered extended comments on how FDA estimated benefits in the analysis of a previous rule. At the same time, a few comments agreed that lost utility should be factored into the analysis because, even if people’s tastes are distorted by addiction, they reflect the satisfactions from consumption that people feel.

[Response]: FDA agrees that application of the concept of lost utility is complicated for products that are addictive or habitually consumed, and accepts that the approach taken in the PRIA warrants reconsideration. In general, FDA disagrees with the view that lost utility is not an appropriate concept for analyzing regulations addressing addictive goods. Consumer surplus is central to the welfare economics framework that FDA and numerous outside experts (including many commenters) believe serves as a useful guide to assessing efficiency of policy. The Office of Management and Budget’s Circular A-4 on regulatory impact analysis includes gains and losses in consumer surplus among the issues that agencies should evaluate when relevant.

Yet the comments raise many valid points about the difficulties of applying the concept in the case of addictive or habitually consumed goods.³ For most consumer products, people make consumption choices that match their preferences and that reflect good information about the product's benefits, costs and risks. In that case, the quantities of the good they buy and the prices they are willing to pay contain useful information for inferring how their welfare would change if their consumption fell. With addictive and habitually consumed goods, however, there are many reasons to be concerned that the usual assumptions do not hold. A large body of economic research across many areas of economic behavior finds that consumers tend to overweight short-run costs of adjusting their consumption downward while underweighting the long-run benefits (Angeletos et al., 2001). This problem is compounded in the case of addictive goods, as high short-run disutilities of curbing consumption tend to keep people consuming at higher levels than they may prefer. Information on health risks of addictive goods may not be freely available. It may be costly to acquire or difficult to interpret. It may be intentionally distorted by producers in the interests of selling their products. Even when information is available, it may be insufficiently salient at decision points. This is particularly a problem for initiation of cigarette smoking, as most cigarette smoking starts when people are under 18 (U.S. Department of Health and Human Services, 2012), when they are known to have problems processing risk information. Thus, even if adult cigarette smokers do some weighing of the benefits, costs and risks in making decisions about continuing to smoke, most express regret that they ever started (Fong et al., 2004) -- suggesting potential for welfare gains from deterring initiation.

While it is widely accepted in the economics discipline that consumption of addictive and habitually-consumed goods departs from the standard model of consumer behavior, to date there has been limited work establishing how such departures should be accommodated within the welfare economics framework generally and in the specific case of cost-benefit analyses of federal regulations. Valuable general references on welfare analysis in the presence of departures from the standard model of consumer behavior include Bernheim and Rangel (2005) and Chetty (2009, 2015); Robinson and Hammitt (2011) provide an overview of issues relevant to cost-benefit analysis. Contributions to the newly-emerging literature on conducting cost-benefit analysis in cases of addictive and habitually-consumed goods include Ashley et al. (2015) and Jin et al. (2015).

To meet the need for guidance in this area, over the past year FDA has worked closely with the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the Department of Health and Human Services (HHS) and a number of outside experts, to develop a conceptual framework for analyzing benefits of proposed regulations affecting addictive and habitually-consumed goods and assess possible ways in which its principles could be used in applied cost-benefit work. The approach was developed by first reviewing the literature from behavioral economics and the psychology of addiction as applied to cigarette smoking. HHS and FDA reached out to prominent health and behavioral economists who focus on smoking (including some of the authors that have been critical of FDA's approach), aiming to solicit a broad range of

³ Although both addictive and habitually-consumed goods are discussed in this response, FDA notes that tobacco products are addictive, so "addictive goods" is the relevant category in the analysis of tobacco regulations and the present rule.

opinions on conceptually rigorous and empirically feasible methods of quantifying possible utility offsets to health benefits of proposed regulations. ASPE retained expert consultants to work with FDA and ASPE economists to develop an approach that could be broadly used across the range of addictive and habitually consumed goods for which FDA and other HHS agencies may propose regulations. Feedback on the approach was solicited from academics, FDA economists, FDA tobacco experts, and staff of the Centers for Disease Control, National Institutes of Health, Office of Information and Regulatory Affairs, and the Council of Economic Advisors. This collaborative work between FDA, HHS and academics has resulted in a White Paper issued by ASPE and two peer-reviewed articles that offer broad guidance on sound theoretical and empirical approaches to accounting for such offsets in cost-benefit analysis (Office of the Assistant Secretary for Planning and Evaluation 2015; Cutler et al. 2015, 2016).

The White Paper uses the standard economic model of addictive consumption, extended to include the possible divergences between consumers' behavior and their underlying preferences, to identify three possible sources of utility loss from regulations that curb tobacco use.⁴ First, withdrawal costs may be a major source of lost utility for cigarette smokers who quit. Cigarette withdrawal symptoms include irritability, headaches, anxiety, insomnia, and difficulty concentrating (Hughes 2007); these can be severe and explain the fact that most quit attempts by cigarette smokers fail within a week (Hughes, Keely, and Naud 2004). This disutility is a cost borne by smokers who quit, and cost-benefit analyses need to take this cost into account. However, the disutility of withdrawal is time-delimited. Studies show cigarette withdrawal symptoms are most acute in the first month, declining progressively over the course of a year (Hughes, Keely, and Naud 2004); by one year post-quitting, few physiological symptoms of withdrawal remain (Hughes 2006). The White Paper uses alternative methods to estimate the magnitude of short-term utility loss from a regulation that induces 10% of existing cigarette smokers to quit. Its estimates suggest the short-term utility loss to eventual quitters is on the order of 5-10% of the value of the health benefits smokers would realize from quitting.

Second, the standard economic model of addictive consumption predicts that, to the extent that people who discontinue use of an addictive good experience ongoing utility loss after quitting, this can be expected to decline over time as addiction fades out of their preferences. In this model, utility is specified as a function of both current consumption and the "stock of past consumption", such that the more of the good the person has consumed in the past, the higher the good's utility will be in the present. After a person stops consuming the good, the addictive stock decumulates, and the marginal utility that would result from consuming the good declines. Whether the lost utility of an average smoker induced to quit by a regulation falls to zero or tapers down to a positive level may depend on the regulation being analyzed. For many regulations related to cigarette smoking, quitting can be expected to be concentrated among smokers whose utility loss will be minimal after withdrawal passes. Yet some regulations may induce quitting among smokers who transition into sustained abstinence, yet may "miss" smoking in an ongoing way. There is limited research relevant for determining the extent to which former smokers who quit as a result of a regulation may get less utility from a consumption bundle without cigarettes than they would from a bundle containing them, years

⁴ Chaloupka and Warner (2000) and Cawley and Ruhm (2011) provide valuable reviews.

after quitting. However, the declining stock of addictive consumption implies that possible longer-term per-period utility losses will be much below the short-term disutility experienced by people who quit.

Third, the standard model of addictive consumption suggests that utility losses will be minimal for people deterred from starting to consume an addictive good as a result of a regulation, to the extent that they should be taken to be zero in applied cost-benefit analysis of regulations reducing initiation of cigarette smoking. In the model, a person who does not accumulate a stock of addictive consumption has a low marginal utility of consuming the addictive good; in effect, if their preferences never shift towards smoking because they never start, they can get as much utility from a consumption bundle that omits cigarettes as one that includes them. Thus, a rule that dissuades people from starting to smoke cigarettes is unlikely to make them worse off utility-wise (and likely to make them much better off health-wise) than they would have been in the absence of the rule.⁵

The White Paper also developed an empirical approach for estimating utility offsets that can be used when information on product demand is available, as is the case with cigarettes. The paper finds that the 70% utility offset ratio used in the PRIA will be too high for most regulations affecting cigarette consumption, and will often be too high for regulations affecting other tobacco products as well. Based on a calculation reported in Gruber (2002-03) for cigarette smoking, the PRIA estimated that consumers of newly deemed products would value only 30% of the quality-adjusted life years (QALYs) the proposed rule would save;⁶ implicitly consumers would benefit from the rule, but in effect, the PRIA estimated, would “discount” these by 70% due to utility losses. The White Paper points to two key reasons why this offset ratio is likely to be too high in the case of cigarette smoking. First, low elasticity of demand for cigarettes and the presence of withdrawal costs mean that smokers may experience relatively large utility losses at the time that they quit, but the losses begin to decline within the first year after a person quits and can be expected to trail down to a low or negligible level for the typical smoker who quits in the years thereafter. In the case analyzed in the White Paper of a regulation that causes 10% of existing smokers to quit, estimated lifetime utility losses amount to 5-20% of the value of the lifetime health benefits they receive. Second, if some important part of the effect of the regulation is to deter initiation, it will not be appropriate to calculate an offset ratio relevant to existing users only. Rather the ratio needs to factor in the minimal utility losses from deterred use, which could affect many future cohorts of youth who would otherwise start to smoke. For regulations, like this final rule, that have provisions to reduce youth initiation, the minimal offset

⁵ In principle, a well-rounded analysis should consider whether reduced consumption of a given health-harming addictive good may be associated with increased consumption of some other harmful good, for example, if a regulation reduced consumption of cigarettes but increased consumption of small cigars. While lack of data and the evolving character of demand for tobacco products make it difficult to address this issue in the case of deeming, the RIA discusses available evidence on substitution patterns across tobacco products relevant to this case.

⁶ Note that some ambiguity in the language in the PRIA may have made it unclear whether the break-even number of statistical life-years saved was quality-adjusted or not. As the intention was to provide numbers in quality-adjusted terms, the text here uses that language to describe the PRIA’s calculations. The updated numbers shown in Table 3 are quality-adjusted.

for deterred initiation implies the overall offset ratio – which is a weighted average of the ratios for the different users in the beneficiary pool – would be accordingly low.

In the case of the deeming rule, lack of data on usage patterns and health risks for deemed products means the empirical approach used in the White Paper cannot be used to quantify utility offsets that may be associated with the deeming rule. Nonetheless, insights from the White Paper framework are helpful for identifying the range in which the offset may fall. First, deterred users represent an important part of the pool of people potentially affected by the rule, as its provisions aim to reduce youth initiation of certain tobacco products for which use among young people is currently rising rapidly (ENDS and waterpipe) (Arrazola et al. 2015). If the rule's provisions curb this growth relative to what it would have been without deeming, this will contribute to a relatively low overall offset ratio. Second, several of the newly deemed products are used more incidentally than is the case for cigarette smoking (U.S. Centers for Disease Control 2014). This suggests that shifting away from them may cause smaller losses in utility than would be expected for cigarettes, as the difference in utility from a consumption bundle without the deemed product and one that includes it may be smaller as well. Third, greater incidental use of these products also implies that average health benefits of deterring use may be lower than they would be for a similar rule deterring use of cigarettes. This makes it unclear whether the utility offset *ratio* – the ratio of utility losses to health benefits from a rule – would be higher or lower than a ratio for cigarettes. Fourth, compliance costs of the rule to producers, such as costs of submitting applications for pre-market review, may reduce the number of suppliers in markets for newly-deemed products and increase their costs. If this increases product prices or alters valued product attributes, ongoing utility losses may result for continuing users. Fifth, some loss of product variety can be expected from subjecting newly-deemed new tobacco products to the requirements of premarket review. The extent to which this loss may reduce utility from consuming newly deemed products depends on the extent of the decline in variety and the extent to which consumers value having a wide range of products available. While we cannot predict how these five effects add up, we expect the overall offset-ratio to be much below the 70% ratio used in the preliminary RIA – both because the 70% ratio used in the preliminary RIA likely overstated losses to continuing users of deemed products, and because the minimal offset for potential users deterred from initiating use pulls down the overall ratio for the full pool of people potentially affected by the rule.

In part because an offset ratio cannot be reliably estimated for the final rule, the FRIA uses a different approach to quantifying how high the benefits of the rule to consumers would have to be to cover the rules' costs to industry and government. As discussed below (Section III.D), the FRIA estimates what people who will be potentially affected by the rule would need to be willing to pay for its provisions in order for the rule to break even. This provides a direct estimate of the monetary value that potential beneficiaries would have to be willing to pay for the rule's provisions – including new warning labels, prohibitions against false or misleading claims, premarket review, and enforcement actions against firms selling products that are adulterated or misbranded -- for the rule to be worthwhile.

Nonetheless, to illustrate how the choice of offset ratio affects results of the breakeven method used in the PRIA, Table 3 shows how the breakeven numbers change when smaller

offset ratios – 0%, 10%, 20% and 50% -- are used.⁷ For reasons given above, our expectation is that a correctly-calculated offset ratio for the final rule would fall at the lower end of this range, but the degree of uncertainty associated with the estimate warrants considering a relatively wide range.

As the table shows, even at a relatively high offset ratio of 50%, the rule would need to save only between 2,080 and 4,187 QALYs to breakeven depending on the discount rate. These numbers can be compared to the estimated 34.9 million adults and youth who currently use the tobacco products to be deemed and roll-your-own tobacco (see Section III.D below). Breakeven numbers of QALYs decline as the offset ratio falls. Assuming no offset at all, the breakeven numbers are 1,040 and 2,094 depending on the discount rate. Thus, even if the PRIA’s estimate of the breakeven number of QALYs was too high relative to what more recent estimates of the offset ratio suggest, it remains true that the final rule only needs to produce modest amounts of gains in terms of health and longevity in order to break even.

Table 3. Number of quality-adjusted life years-required for the rule to break even

Discount rate	3%	7%	3%	7%	3%	7%	3%	7%
Present Value of the Rule’s Total Costs (Primary Estimate in \$ millions) [from Table 1]	988.2	816.5	988.2	816.5	988.2	816.5	988.2	988.2
Utility offset ratio	0%	0%	10%	10%	20%	20%	50%	50%
Value per QALY (\$	472	785	472	785	472	785	472	785

⁷ In addition to the use of lower offset ratios, the estimates given in Table 3 are not directly comparable to the estimates in the PRIA because they are based on estimated costs of the final rule, and because they use estimates of values of a quality-adjusted life-year (based on Robinson and Hammitt, 2015) that have been revised up. For comparison, using the same value per QALY as was used in the PRIA (\$335,327) and the PRIA’s assumption of a 70% offset ratio, the breakeven number of QALYs for the final rule would be 9,824 at a 3% discount rate. Using the updated value per QALY of \$472,000 and the PRIA’s assumption of a 70% offset ratio, the breakeven number of QALYs for the final rule would be 6,979 at a 3% discount rate. These numbers are given for comparison with the PRIA only; as mentioned in the text, reconsideration of the question of utility offsets leads us to expect a much lower offset ratio for the deeming rule. (As mentioned, some ambiguity in the language in the PRIA may have made it unclear whether the break-even number of life-years saved were quality-adjusted or not. The intention was to provide numbers in quality-adjusted terms).

thousands):								
QALYs Needed to break even	2,094	1,040	2,326	1,156	2,617	1,300	4,187	2,080

[Comment]: Some comments pointed out that we did not include the effects of reductions in second-hand smoke from cigars and pipe tobacco in our assessment of benefits.

[Response]: While FDA did not quantify benefits in the preliminary impact analysis, the effects of second-hand exposure are important when considering the impacts of tobacco products. The literature concerning the extent to which individuals are exposed to second-hand cigar and pipe tobacco smoke is limited, as is the research on second-hand exposure to ENDS products. Because we agree that the second-hand exposure health effects should be included in any qualitative and quantitative assessment of benefits, we have included a short discussion of this literature in the final RIA. We are unable to include any quantitative assessment due to lack of data.

[Comment]: Some comments stressed the effects of the regulation on the prices of newly-deemed tobacco products. The premarket application requirements and the labeling requirements, according to these comments, would reduce the supply of covered tobacco products. The comments further contended that reduced supply would increase costs and prices, which would reduce consumption of those newly-deemed products. The comments also discussed the size of potential changes in consumption. Some comments focused on combusted tobacco products such as cigars and pipe tobacco, while other comments focused on electronic cigarettes and similar products.

[Response]: Most of the costs of the proposed rule are fixed costs, which affect prices through product exit. FDA predicts product consolidation or exit but not its effect on price. If product exit were sufficiently large to lead to an increase in prices, we could see a corresponding decline in consumption of the affected tobacco products. We do not predict the effects of this rule on price, partly because estimating the price increase of newly deemed products due to product consolidation or exit is not straightforward. If price changes do occur, the effects could be quantified using estimates of price elasticities. One recent estimate based on an analysis of tobacco products sold through mass-market channels (Zheng et al., 2014) found price elasticities of demand of -1.8 for little cigars and -1.3 for large cigars. These estimated elasticities imply that a rise in the price of cigars in these channels will lead to declines in sales of cigars in these channels. Such declines could have implications for public health. A reduction in cigar use, without an increase in the use of other tobacco products, could yield public health benefits. Nevertheless, the implications of these estimated elasticities are not straightforward given that the substitutions that occur when many tobacco products' prices rise would be highly uncertain, with the public-health implications impossible to predict.

The welfare implications of changes in the prices of electronic tobacco products may be different from those of traditional combusted products. The recent estimate (Zheng et al., 2014) of the price elasticity of demand for electronic tobacco products sold through mass-market channels (taken together) is approximately -2, which indicates a large responsiveness to changes in price, holding all else (including the prices of other tobacco products) constant. There is limited research to help answer the question of whether traditional cigarettes and other combusted tobacco products are substitutes for electronic cigarettes. To the extent that this final rule raises prices of electronic cigarettes, it is possible that cigarette or cigar consumption could increase in response. Zheng et al. (2014) found that although increased cigarette prices lead to considerable switching by consumers to electronic cigarettes (i.e., electronic cigarettes are substitutes for combusted cigarettes), the elasticity of combusted cigarette consumption with respect to the price of electronic cigarettes is quite low, 0.007. This number indicates little or no response of current cigarette smoking to changes in the price of electronic cigarettes. The interpretation of this finding is difficult but does appear to indicate that changes in the prices of ENDS products have, at most, modest effects on the consumption of other tobacco products. Empirical research in this area, however, is in its early stages, and subsequent studies may generate different results.

[Comment]: A comment pointed out that delaying implementation of the rule would have welfare costs.

[Response]: We agree that delaying implementation of the rule would lead to forgone benefits during the time of the delay, but we also note that delaying implementation may also reduce some costs. While this tradeoff exists for various provisions included in the final rule, we explicitly discuss it in the context of alternative implementation dates for labeling changes in the alternatives section of the final regulatory impact analysis. We note that this tradeoff exists for other provisions as well.

[Comment]: A few comments asserted that ENDS are a perfect substitute for regular cigarettes, generating as much pleasure but no health costs. We also received comments stating that electronic cigarettes and other non-combusted nicotine products are preferred by cigarette smokers to existing nicotine replacement products, such as patches and gum. The commenters stated that, by deeming these products to be covered by the Act, the manufacturers must submit a PMTA to remain on the market and bear other regulatory costs, such as warning labels. These costs, the commenters noted, will lead to exit of many existing products and forms as well as reduced entry.

[Response]: As explained in the preamble, there is uncertainty regarding the long-term health effects of using ENDS. Whether ENDS products are on balance used as substitutes or complements to traditional tobacco products is also uncertain and possibly changing over time. Evidence on the relationships among the various products is still emerging and long run relationships may differ from what has been observed in the short run. Whether consumers will turn to ENDS products for long-term use (for consumption experience or for nicotine) or use them as an alternative to traditional nicotine replacement products for quitting (and with what effectiveness) is also uncertain. Therefore the welfare effects of including ENDS in this final rule are uncertain.

The purpose of the review of PMTAs is to ensure that new tobacco products are appropriate for the protection of the public health. However, FDA acknowledged in the PRIA that premarket submission requirements could lead to significant product exit and reduced entry. As we note in Table 12 of the PRIA and the associated discussion, a reduction in the supply of electronic cigarettes could under some conditions yield negative health benefits. In particular, if, going forward, electronic cigarettes are proven safer than other tobacco products and are substitutes for other tobacco products, and if the effect of premarket requirements on the supply and price of electronic products were large enough, then the welfare effects of a reduction in supply of electronic cigarettes due to the rule could potentially be negative. Counterbalancing this, however, is that the PMTA requirement helps ensure that new tobacco products are appropriate for the protection of the public health.

[Comment]: A commenter asserted that FDA overestimated benefits by not treating the regulation and user fees as a tax on an ordinary consumption good. The commenter further stated that, with ordinary goods, regulation can often work like a tax, reducing both consumer surplus and producer surplus.

[Response]: FDA disagrees with this comment on the grounds that the market for tobacco products has market failures, including intrapersonal market failures (or externalities) and information asymmetry. Where such market failures exist, the final rule may increase total economic welfare. In this instance, we agree that a reduction in producer surplus would occur to the extent that resources flowing out of production of newly-deemed products earn lower returns in their next-best uses; however, changes in consumer welfare may offset the loss in producer surplus.

[Comment]: A commenter (presuming that premium cigars carry little to no health risk) stated that if consumers change their smoking behavior, especially with regard to premium cigars, they may mistakenly feel safer and take new risks that more than offset the risks of smoking premium cigars.

[Response]: As discussed in the preamble to this final rule, premium cigars carry health risks. The final RIA provides a qualitative discussion of the benefits of the rule and does not quantify the effects the rule may have on consumers. We cannot estimate the extent to which consumers who may cease smoking or reduce their use of premium cigars would feel safer and engage in new, riskier activities. While it is possible that consumers who cease or reduce using any tobacco product could theoretically then feel justified in engaging in other unhealthy behaviors, thus reducing the benefits of this rule, it is also possible that consumers who cease or reduce using any tobacco products may do so as part of a shift toward an overall healthier lifestyle. Moreover, cigar and pipe smokers generally are not motivated to use these products because they are risky, so if they stop or reduce their usage they are not likely to seek high risk as a defining characteristic of substitute consumption products.

[Comment]: A comment argued that FDA should offset the benefits of the proposed rule by the costs that would arise from unintended consequences such as current consumers of cigars or e-cigarettes (or ENDS) switching to cigarette use and the costs from “the rise of a black market, a DIY industry, a trade in unregulated additives and high strength nicotine liquids, criminal enterprise, illegal imports and cross-border shopping.”

[Response]: We note that we have not quantified the benefits of the proposed or final rule, and we are unable to quantify any possible unintended offsetting effects. There may be some incentive to obtain illegal (noncompliant) versions of newly deemed products if they can be obtained at lower cost than legal products. We note, however, that FDA is not banning any type of tobacco product, so we expect current classes of products to be available under the final rule, although there may be some loss of product variety and price increases for some products. If substantial enough, this may induce some users to switch to black market products or, in the case of e-liquids, to mix their own liquids. Potential substitution towards black market or do-it-yourself products could affect the public health benefits of this final rule. We are unable to predict the likelihood or size of this effect.

See our discussion above of how regulation-induced increases in the price of tobacco products might affect consumer behavior.

D. COMMENTS ABOUT COSTS

[Comment]: One comment stated there were “obvious errors,” in Table 1: Summary of Quantified Costs Over 20 Years, and that the annualized values at a 7 percent discount rate are larger than the annualized values at 3 percent. The comment stated, “These relationships are clearly in error since higher discount rates of necessity produce lower Annualized Values, unless the costs being annualized were incurred in the past or unless for some strange reason the undiscounted values differ before discount rates are applied. Unfortunately, a mistake in something this fundamental raises questions about the entire cost analysis.”

[Response]: Higher discount rates do not of necessity produce lower annualized values; whether higher discount rates produce lower or higher annualized values depends on the timing of the costs. In this case, we predict that the bulk of the costs will be in the early years. We can illustrate this point with a simple numerical example. Assume all cash flows occur at the end of the time period in which they occur. Consider a one-time cost in year 1 of \$100,000. The annualized value, over 30 years, is \$4,953 at a 3 percent discount rate or \$7,531 at a 7 percent discount rate. Next, consider a one-time cost in year 30 of \$100,000. The annualized value, over 30 years, is \$2,102 at a 3 percent discount rate or \$1,059 at a 7 percent discount rate. Finally, consider any annual cost of X dollars per year. The annualized value at 3 percent, 7 percent, or any other discount rate, is X dollars per year.

[Comment]: Comments objected to the fact that the economic analysis only quantified the compliance costs for entities and products that are expected to comply rather than exit from the market. One comment objected that over 99 percent of electronic cigarette products would be eliminated based on the costs of paperwork rather than public health concerns, and asserted that in the most extreme case, FDA could design requirements so burdensome that nobody could comply but claim the burden is 0. Another comment asked FDA to estimate the impacts on producers that exit the market.

[Response]: Products are withdrawn from the market in response to a regulation only if the cost of complying with the regulation exceeds the cost of exiting (including foregone profits). To avoid underestimating the cost impact of new regulations, we therefore often estimate the

cost for all producers to comply with the regulation, noting that this overestimates actual industry costs because compliance costs are not incurred for products taken off the market. When the amount of exit is expected to be modest, that approach leads to only a modest overestimate of actual industry costs.

Some of the industry segments affected by this final rule consist of very large numbers of products with very low sales, relative to the costs of premarket authorization; substantial amounts of product consolidation and exit, as well as firm exit, can be expected to occur within those segments. For this reason, the cost estimates in the proposed rule assumed the share of products for which compliance costs would be incurred was below 100 percent. However, uncertainty about the effects of premarket authorization requirements on the magnitude of exit across market segments made it difficult to quantify with confidence the number of products that would be taken off the market. Our lack of quantification of the incidence or level of exit and forgone producer surplus in the PRIA was a source of understatement of the costs. Exit costs per entity will depend upon the levels of investment in specialized capital and skills; if these investments are relatively low in certain market segments, exit costs will be small relative to the costs of compliance.

In the final RIA, we have added a discussion of the market adjustment costs (friction costs and lost producer surplus) associated with product or firm consolidation and exit. See section III.C.4.b.

[Comment]: Commenters stated that FDA's analysis "conceptually accounts for the fact that some foreign producers will exit the US market as a result of these regulations. To operationalize this construct, it assumes that 10 to 50 percent of the products of these foreign producers will not continue to be marketed in the United States." Commenters stated that FDA estimates costs for fewer products than currently exist, "but the implications of this exit are never really traced in subsequent portions of the analysis."

[Response]: FDA estimated for the proposed rule that 10 to 50 percent of handmade cigar products would not continue to be marketed in the U.S. and that 80 to 100 percent of cigar importers would continue to operate in the U.S. This estimated exit carried through all of the calculations in the PRIA. The implications of this exit were discussed in the cost, distributional, and international sections of the PRIA. In the analysis of the final rule, we have changed our assumptions about product consolidation and exit as we updated related estimates of baseline product counts, proportions of products that are grandfathered, and compliance costs. We also do not estimate potential entity exit. See sections III.C.1 and III.C.2. Our assumptions about product exit are again carried through all the calculations and discussed in the cost, distributional, and international sections of the FRIA where appropriate.

[Comment]: A commenter stated that FDA's estimates are difficult to evaluate because of inadequate information regarding the sources of its estimates. The commenter also stated that the PRIA did not justify whether implementation costs would be similar for all affected tobacco products.

[Response]: We often lack published information that would feed directly into needed estimates of the costs (or benefits) of a regulation. In this situation, we build our estimates using a combination of public information about similar actions or requirements as well as the

experience and judgment of FDA experts. By definition, FDA does not have experience regulating newly deemed products. However, FDA's growing experience with currently regulated tobacco products provides the closest parallel, both in terms of product characteristics and regulatory requirements, to regulation of newly deemed tobacco products. Therefore, we continue to forecast that per-entity and per-product costs for each requirement will be similar for newly deemed products as for currently regulated tobacco products. To the extent that newly regulated tobacco products differ, this approach could over- or under-estimate costs. We note that commenters did not generally submit the kind of detailed information that could be used to build alternate estimates of per-entity and per-product costs.

[Comment]: Because the Bureau of Labor Statistics did not publish wage estimates for legal occupations in the tobacco manufacturing industry in 2013, a commenter uses a general wage for legal occupations in calculating a composite wage for complying with provisions requiring technical rather than purely administrative work.

[Response]: The comment does not state exactly which rate is used as a "general wage rate," but we agree that using a general wage rate is a possible solution. However, the Bureau of Labor Statistics published 2013 and 2014 wage estimates for legal occupations in the broader industry category covering both beverage and tobacco product manufacturing. We use this wage to estimate of the cost of legal labor hours utilized in complying with this final rule.

[Comment]: A commenter stated that the RIA underestimates unit costs of compliance activities and consequently the cost of the regulation. According to the comment, for "ingredient listing and for premarket tobacco applications, FDA assumes a labor mix to perform the activity and then applies an occupation specific unit cost from BLS [Bureau of Labor Statistics] to develop a unit cost for the activities." As an example, the comment stated that the labor cost for ingredient listing and premarket tobacco applications is underestimated because FDA assumed 30 percent of the necessary labor comes from life, physical, and social science occupations; 20 percent from architecture and engineering occupations; 30 percent from office and administration occupations; and 20 percent from legal occupations. The comment argued that this is incorrect because industry participants state that at least 40 percent of the labor would come from legal occupations and 20 percent from executive management. Second, because a lot of legal work is hired from outside the tobacco company, the comment stated that an hourly cost of \$42.15 is far too low. The commented stated that the hourly rate for executive management is about \$100 per hour, before overhead. Third, the comment stated that a factor of only two for overhead is low based on the commenter's experience. The correct hourly labor cost is therefore at least \$125 per hour.

[Response]: Given the amount of science and engineering work inherent in requirements such as premarket submissions, we find that the comment's estimate that 40 percent of compliance labor would come from legal occupations and 20 percent from executive management overstates the amount of labor from these two categories, while understating the amount of labor required from the science and engineering categories.

The opportunity cost of legal services – the correct concept for cost-benefit analysis -- does not depend on whether the services are hired from outside the company or provided from within the company. While the Bureau of Labor Statistics published \$42.15 as the mean wage rate for legal services in the tobacco product manufacturing industry in 2012, we agree in retrospect that

the wage seems low, possibly due to small sample issues; the Bureau of Labor Statistics did not publish the corresponding wage value in 2014. For the final RIA, we instead use the wage for legal occupations in the broader industry category covering both beverage and tobacco product manufacturing, \$68.12. This wage is similar to the legal wage in other FDA-regulated industries, such as “food manufacturing” and “pharmaceutical and medicine manufacturing”.

Consistent with HHS guidance, we double money wages because we lack data on benefits and overhead in this industry and this is the economy-wide average. Updating to current wages and making the change in the legal wage rate yields a technical composite wage of \$37.98, or \$75.96 after doubling to account for benefits and overhead. We use this technical composite wage in the FRIA, which is somewhat higher than the technical composite wage of \$66.50 used in the economic analysis of the proposed rule.

[Comment]: Many comments imply that the proposed regulation would ban covered products and discussed the distributional effects of removing those products and the harm associated with denying consumers access to covered products.

[Response]: Although FDA expects some product exit and reduced entry as a result of the final rule, no general category of covered product would be banned by this rule. It is likely that some manufacturers within each particular industry segment will be able to bear the burden of complying with the regulation and it is therefore highly unlikely that all entities or products within any segment would choose to exit.

[Comment]: A commenter provided costs tables for every provision of the proposed rule, using different assumptions about numbers of manufacturers or importers, the number of products, the wage rate, and the time horizon of the rule.

[Response]: The main drivers of differences between the commenter’s cost estimates and FDA’s proposed estimates appear to be the number of manufacturers or importers, the number of products, the wage rate, and the time horizon of this rule. We address each of these in other responses. The commenter has not provided alternative estimates of the burden hours (per product, entity, or other unit) for most provisions.

It is difficult to determine what assumptions the commenter made about the timing of costs. The commenter’s summary tables contain initial costs and ongoing (discounted) costs, but the titles and headings of tables for individual provisions fail to state whether the tables cover initial costs, ongoing costs, or both. Based on a comparison of the cost tables for individual provisions to the summary tables, we have concluded that most of the comment’s cost tables for individual provisions contain only upfront costs.

Because final estimates result from the interaction of many inputs to the analysis, we respond below to identifiable differences in inputs, methods, and assumptions rather than to differences in final estimates.

1. COMMENTS ABOUT THE NUMBER OF ENTITIES AND PRODUCTS AFFECTED

[Comment]: A commenter estimates based on Dunn & Bradstreet (D&B) data that there are 202 cigar manufacturers, 231 cigarette manufacturers, and 183 manufacturers of other tobacco products in the US. The commenter stated, however, that these numbers come from self-reported information and likely include importers as well as manufacturers and that the 2013 TTB annual report states that there are 936 tobacco permit holders, which includes manufacturers and importers. The comment further stated that “calibrating the D&B data to the TTB figures suggests that there are a total of 295 cigar manufacturers, and 284 manufacturers of other non-cigarette products,” and that the total number of other non-cigarette product manufacturers is split among pipes, waterpipe, and Electronic Nicotine Delivery Systems (ENDS) based on relative sales volumes.

[Response]: It difficult to evaluate this method based on the information provided by the comment. It is not clear what is meant by “calibrating the D&B data to the TTB figures.” It is not clear if the commenter intends for “manufacturers” to refer to domestic manufacturers or both domestic manufacturers and importers. In splitting the manufacturers of non-cigarette products among pipes, hookah, and ENDS, it is not clear if the commenter accounted for the fact that manufacturers and importers of processed tobacco must also obtain a TTB permit. It is also not clear if the comment considered in the calculation that ENDS manufacturers and importers are not tobacco permit holders. Therefore, we continue to base our estimates of the numbers of manufacturers and importers of products other than ENDS on product-type aggregate totals obtained from TTB. We have obtained updated information from TTB since publication of the proposed rule and use it in this analysis.

[Comment]: Comments asserted that either FDA intends to put most manufacturers of e-cigarette (or ENDS) products out of business, except for the largest companies, or the Agency’s Paperwork Reduction Act (PRA) estimate of the number of manufacturers and importers was egregiously low. Even if most companies do exit, the comments stated that the PRA estimate of 140 is too low to reflect the entities that would remain.

Examples of the specific numbers submitted by the comments are as follows: An individual commenter observes that e-liquid manufacturers outnumber hardware makers by a ratio of at least 5:2. Comments stated an e-cigarette (ENDS) web site works with 542 suppliers (US online merchants), 68 wholesalers (9 based in the U.S.), 5 US service providers, and 30 US accessories suppliers and this yields a total of 589 US businesses the web site owner works with (entities can be counted in multiple categories). A trade association whose web site is cited in many comments estimated that “there are as many as 15,000 vape stores operating currently, 1200 manufacturers of e-liquid and 22 manufacturers of hardware and 13 assemblers of finished products in the United States; representing over 70,000 jobs and that there are as many as 1000 established distributors of vapor products representing thousands of jobs as well.” Other comments stated that there are at least 5,000, and possibly up to 15,000, individual e-liquid manufacturers in the U.S., including vape shops that mix their own products. The comments stated that nearly all these businesses are small, and that they account for 65,000 jobs. A comment also noted that the Electronic Cigarette Forum has nearly 1,700 e-cigarette and e-liquid businesses (including importers) on record, not including the hundreds of manufacturers of hardware components.

Comments pointed out that vape shops have been sprouting up everywhere; some have “vape bars.” Comments state that over 1,000 or over 5,000 such shops are listed on

vaporsearchusa.com. In comments, the CEO of Vape World is cited as saying there are more than 3,500 independent vape shops in the U.S. Comments cited industry analysts estimating that there are 5,000 to 10,000 vape shops in the U.S. In comments, an individual from a trade association is said to estimate that there are 14,000 to 16,000 brick and mortar vape shops in the U.S. The Tobacco Vapor Electronic Cigarette Association estimates that brick and mortar stores will sell more than \$1 billion in vaping equipment and products in 2014.⁸

The comments also state that the e-cigarette (or ENDS) industry in the U.S. has roughly doubled every year since its inception. Although the companies are small, they are growing. Comments cited industry estimates that current U.S. sales of e-cigarette (or ENDS) products were expected to be between \$2.2 and \$3 billion in 2014 and expected to pass \$10 billion by 2017.

[Response]: While an estimate of the number of ENDS manufacturers was developed for the required Paperwork Reduction Act burden analysis, we did not estimate the number of manufacturers for the PRIA due to the high level of uncertainty. As the comments describe, the industry is in a state of flux; during the time that the proposed rule was in review, and since the proposed rule was published, the ENDS industry has grown and additional vape shops have opened. The comments on the number of ENDS manufacturers did not provide concrete data sources, but rather industry estimates for which the bases were not given. In the case of non-retail manufacturers, comments did not always specify whether the cited numbers included both domestic and foreign manufacturers, or only domestic manufactures. Therefore, considerable uncertainty remains as to the number of domestic non-retail manufactures. Similarly, comments did not address the number of non-retail importers. In the RIA for this final rule, based on logo counts from trade association websites and FDA listening sessions, we estimate that there are 168 to 204 manufacturers of ENDS products, other than retailers who mix their own e-liquids, selling goods in the US market. We also estimate that there are 14 importers of ENDS products.

As discussed in the preamble, retailers who mix their own e-liquids are considered manufacturers under the FD&C Act. The comments received on this topic indicate that there are thousands of retail vape shops, many of which mix their own e-liquids. In this RIA, we estimate that there are 5,000 to 10,000 vape shops, approximately 70 percent of which mix their own e-liquids, for a total of 3,500 to 7,000 vape shops that meet the definition of a manufacturer.

[Comment]: Comments expressed concern that the term “manufacturer” could be interpreted very broadly, and, as a result, the RIA would not accurately reflect the number of manufacturers. For example, one comment questioned whether individual hand rollers of premium cigars who sell directly to retailers or consumers would be considered manufacturers. Others questioned whether retailers who blend pipe tobacco would be considered manufacturers, or retailers who mix e-liquids, as discussed above. Some comments offered policy recommendations, which are discussed in the preamble to this final rule.

[Response]: FDA has confirmed that retailers who blend pipe tobacco qualify as manufacturers under the FD&C Act. FDA also notes that individual hand rollers of cigars are considered manufacturers under chapter IX of the FD&C Act, and subject to the same

⁸ www.tveca.com

requirements as other tobacco product manufacturers. We are unable to estimate the number of retailers who blend pipe tobacco or the number of individual hand rollers of premium cigars who sell directly to retailers or consumers. Without knowing baseline numbers of such entities, it is not possible to estimate exit or compliance costs associated with the rule's expectations for manufacturing activities.

[Comment]: A commenter provided estimates of the number of retail establishments of various types selling deemed tobacco products.

[Response]: The commenter's estimates contain some updated information, compared with FDA's estimates published with the proposed rule, but do not appear to be significantly different. We have revised our estimates to reflect the most recent information available at the time of drafting the final analysis.

[Comment]: Numerous comments addressed the number of affected products, asserting that FDA had underestimated the number.

Commenters disagreed with the way FDA estimated the number of e-cigarette (or ENDS) products in the PRIA by relating the size of the market to the size of the market for cigars. One comment stated that there are easily tens of thousands of e-liquid product formulations on the market, and the number is still growing. Others stated that the Consumer Advocates for Smoke Free Alternatives Association estimated there are at least 100,000 electronic cigarette products. Given another association's estimate in their comment that there are 1,200 e-liquid manufacturers in the U.S., if each offered 5 flavors, each available in 5 strengths, they alone would account for 30,000 products. Individual retailers often commented how many products they alone carry. For example, one stated that it carries 7 combinations of nicotine, propylene glycol and vegetable glycerin, and uses 200 different flavors, yielding 4,000 unique product formulations; another stated that it carries 875 products excluding size variations, or 5,250 including size variations (based on 175 flavors, 5 strengths, and 6 sizes). Comments also referenced a peer-reviewed article finding that there were 466 brands and 7,764 unique flavors of e-cigarette (or ENDS) and e-liquid products in the market by January 2014 (Zhu et al., 2014).

Comments stated that FDA underestimated the number of cigars, especially premium cigars. Some comments stated that industry estimates the number of cigars to be as high as 50,000 stock keeping units (SKUs). An industry association stated its data indicate at least 10,000 and maybe as many 20,000 unique cigar SKUs are sold in the U.S., and that the premium hand rolled cigar industry could generate at least 10,000 new product submissions. A single retailer stated that it carried 410 SKUs. Another comment stated that a typical premium cigar manufacturer may have over 100 unique stock keeping units and turn over about 15 percent in a given year. Comments stated that all or virtually all premium cigars would be affected by premarket requirements; each and every artisanal, hand-made cigar would be regarded as "new" because no two are alike. The comments also stated that even brands that were marketed as of the 2007 grandfather date would be considered new due to changes in composition made to ensure consistency.

[Response]: We disagree that our method underestimated the number of cigar products on the market. The market for cigar products is highly differentiated, with thousands of brands and many products per brand. There are also seasonal and special products on the market for limited durations. There are no government statistics covering numbers of cigar products, nor does an

industry trade association collect data of this kind. As a result, estimation of baseline numbers of cigar products and numbers of products expected to submit premarket applications via different channels require use of available data sources that may over- or under-state the number of products currently on the market, because they were compiled for purposes other than providing a full census of cigar products currently available for sale in the U.S. market.

The PRIA's estimate was based on Perelman's 2010 Pocket Cyclopedia of Cigars (Perelman, 2010). This source is now out of date and has discontinued publication. It was a potential source of concern that the Cyclopedia listed products reported by their manufacturers as being actively marketed in the U.S.; this could differ from the number of products currently available for sale to consumers if it includes products that producers offer for sale to retailers or wholesalers that the latter opt not to carry. Although commenters provided higher numbers that they considered to be alternative estimates, it is not possible for us to tell whether these numbers correspond to the number of unique cigar products available for sale to consumers in the U.S., or a count that reflects a broader pool of cigar products such as products produced in the U.S. and abroad but not all sold in the U.S.

Out of concern about the 2010 publication date of the Cyclopedia, staff of FDA's Center for Tobacco Products developed alternative estimates of numbers of cigar product counts, based on counting products available for sale through two Internet retail sites carrying a wide variety of products. From this we estimate the number of cigar brands to be 1,100, the number of cigar products to be 5,000, and the number of product-package combinations to be 7,500. Because cigars are highly differentiated products, it is clear that numbers of actual products are large, and numbers of potential products may be larger still (i.e. adding a new cigar shape or a new tobacco wrapper type to product offerings for a given brand). Data sources like Nielsen, the Cigar Cyclopedia, and large internet retailers provide good coverage of products with medium to high sales volume that are likely to represent a high share of the value of cigar-market sales. Other types of products will be less well-represented in these sources, including products sold only through specialty (non-internet) retailers, small-batch and seasonal products, and other products with low sales values; we expect such products to represent a relatively small share of the value and volume of cigar sales but we have no good way of quantifying their share of the number of products. Therefore, we opt to use the estimate of 7,500 products, acknowledging its potential for undercount but expecting that it provides good representation of the parts of the market for cigar products that are likely grandfathered or for which manufacturers are likely to comply with the requirements of premarket review because the products' sales levels are sufficiently high.

We agree that the PRIA substantially underestimated the number of ENDS products on the market, partly because the ENDS industry experienced rapid growth during the period of time that the proposed rule was under development. We now have information to update our estimate from the proposed rule. Based on examination of 5 major retail websites and Nielsen scanner data, FDA now estimates that there are 5,000 to 10,000 e-liquid product-package combinations and the components to make 800 to 1,000 delivery systems product-package combinations. We note, however, that the market for ENDS is in a state of flux, and without reliable statistical information on numbers of products all estimates are necessarily uncertain.

[Comment]: A commenter estimated that there are 1,394 brands of cigars, 79 brands of little cigars, 152 brands of pipe, waterpipe, or smoking tobacco, and 211 brands of e-cigarette (or ENDS) products.

[Response]: The figures for cigars and little cigar brands in this comment are close to those from Perelman’s Pocket Cyclopedia. We are uncertain how the number of pipe, hookah, or smoking tobacco brands was estimated, and so we cannot respond to that part of the comment. The comment is not explicit about whether brands and manufacturers of ENDS refer to all types of ENDS products (e-liquid, complete delivery systems, hardware components, cigalikes, etc.), or just a subset. The figures are further unclear because a table provided in the comment shows that there are 466 brands of electronic cigarettes (or ENDS), based on Zhu et al. (2014), but subsequent calculations appear to use 211.⁹

[Comment]: A commenter estimated based on Zhu et al. (2014) that there are 60 unique products per electronic cigarette (or ENDS) brand, though the number would be higher if the commenter used the mean rather than median or if each package size constitutes a unique tobacco product. Based on the commenter’s estimate that there are 211 electronic cigarette (or ENDS) brands, the estimated number of current products is $211 \times 60 = 12,660$. Using an 80-20 distribution, the commenter estimates that 600 electronic cigarette (or ENDS) products will be profitable enough to justify incurring premarket and other costs, while more than 12,000 products would be discontinued.

[Response]: As stated above, FDA is unsure why the commenter uses an estimate of 211 unique brands while also presenting information from Zhu et al., which covers 466 brands. We note that the comment is not explicit about whether brands and manufacturers of ENDS refer to all types of ENDS products (e-liquid, complete delivery systems, hardware components, cigalikes, etc.), or just a subset. However, the number of products per brand is derived from information about flavors per brand contained in the Zhu et al. study.¹⁰ The commenter multiplies the number of flavors per brand by the number of strengths in order to estimate the number of unique products per brand. This assumes that every flavor is offered in every strength, which is unlikely to be true in all cases. However, the commenter also estimates the number of products per brand based on the older brands studied by Zhu et al. The newer brands studied by Zhu et al. offer far more flavors.

As described in previous responses and the FRIA, we have updated our estimate of the number of ENDS products currently on the market. We continue to assume a substantial amount of product consolidation and exit will occur as a result of regulation, as described in the final RIA.

[Comment]: A commenter estimated based on Perelman’s Pocket Cyclopedia of Cigars and “the median of a sample of 39 companies” that there are 6 unique cigar products per brand. The

⁹In the Zhu et al. study, a brand corresponds to a website that at a minimum sells some hardware and sells at least one own-brand ENDS-related product. “A website was coded as carrying a brand if it identified at least one e-cigarette related product (such as a cigalike, cartridge, atomizer, or e-liquid) as its own through a distinct name or logo. Sites that sold only e-liquid but no e-cigarette hardware were not considered to have a brand and were excluded. Websites that, in addition to selling their own brand also sold other brands, were counted as having one brand. Thus, one site, one brand” (p. iii4).

¹⁰A brand in the Zhu et al. study refers to a website that identifies “at least one e-cigarette related product (such as a cigalike, cartridge, atomizer, or e-liquid) as its own through a distinct name or logo” and sells some form of ENDS or e-cigarette hardware.

comment stated that this implies there are $1,394 \times 6 = 8,364$ large cigar products and $79 \times 6 = 474$ small cigar products.

[Response]: FDA catalogued the Cyclopedia of Cigars in preparing its analysis of the proposed rule. Sampling the source instead would add sampling error. To compute the total number of products, it would seemingly be appropriate to use the mean rather than median number of unique products per brand. Additionally, it is unclear why the number of products per brand would be computed on the basis of a sample of 39 companies as the sample should be drawn on the basis on the brand. Given these questions, FDA cannot respond in greater detail to the difference in conclusions about the number of cigars.

[Comment]: A commenter estimated the number of pipe tobacco formulations and distinct products based on www.pipesandcigars.com/pipe-tobacco/ and stated that “the median number of products, based on a sample of 30 companies, is 3.” The commenter appears to estimate that there are 462 pipe tobacco products.

[Response]: As described above, estimating the total number of products requires an estimate of the mean rather than median number of unique products per brand. Based on the 152 brands estimated by the commenter and the limited amount of information provided in the comment, FDA assumes that $152 \times 3 = 456$ is what the commenter intended for the number of pipe tobacco products instead of 462. Because FDA has previously cataloged the entire pipe tobacco contents of pipesandcigars.com and obtained a much higher number, we believe this estimate must be low due to sampling error. For the FRIA, staff members at FDA’s Center for Tobacco Products also surveyed numbers of products offered on pipesandcigars.com to ensure that product counts had not changed significantly since the previous analysis. As the updated sample estimates are similar to our original census estimates, we continue to use the original estimates as they are based on a full count of pipe tobacco brands and formulations available on the website.

[Comment]: A commenter suggested that FDA estimate the total amount of nicotine being consumed in the country from e-liquids by taking the total amount of U.S. Pharmacopeia Convention grade nicotine produced or imported into the US and subtracting the amount used in NRT products.

[Response]: While the total amount of nicotine consumed from e-liquids would be interesting background information, current estimates of dollar sales of ENDS products and population usage rates of ENDS products provide baseline information that is more directly relevant to estimating the potential regulatory impacts of the final rule.

[Comment]: Comments pointed out inconsistencies or apparent inconsistencies between the PRIA and the analysis conducted pursuant to the Paperwork Reduction Act (PRA). Comments said the PRIA stated that FDA did not have an estimate of the number of electronic cigarette manufacturers and importers, while the PRA section of the proposed rule estimated 140. Comments stated the PRIA estimated that 168-1,675 electronic cigarettes would be affected by product listing, while PRA estimated 1,675. Comments stated the PRIA estimated that 1,717 to 1,801 electronic cigarette products would be affected by ingredient listing, while PRA estimated 1,675. Finally, comments stated the PRIA contained different estimates of the number of electronic cigarettes affected by grandfathered product submissions, SE reports, SE exemptions, and PMTAs.

[Response]: While we respond to numerous specific points below, we also note that the RIA and PRA analyses are conducted to fulfill different purposes and must adhere to different requirements; as a result, the two analyses would rarely, if ever, be the same. For example, the time horizons for the analyses are typically different. Information collections are approved for a three year period and are reanalyzed every time they are up for renewal, whereas a prospective regulatory impact analysis is conducted before a rule is issued using a time horizon chosen to capture the most important effects of the rule, often 10 or 20 years. If estimates differ from year to year, the regulatory impact analysis will often explicitly identify how the estimates vary, whereas the PRA analysis will most often use an average or the estimate for the current year. Regulatory impact analyses also tend to make more frequent use of ranges rather than point estimates.

For the PRIA, we determined that it was better to omit a count of electronic cigarette (ENDS) manufacturers due to uncertainty. We note that costs estimated for the proposed rule were primarily driven by the number of products rather than the number of manufacturers, so this decision would only have a minor impact on estimated costs.

Product listing information is provided at the time of registration, and currently only domestic manufacturers are required to register. Importers (and other entities) may also be subject to registration and product listing requirements if they repackage or otherwise change the container, wrapper, or labeling of any tobacco product package. Consequently, imported products could be included as part of a product listing if the importer is required to register. The PRIA excluded imported products from the lower bound estimate; the PRA estimate, as with the PRIA upper bound estimate, included all products.

The PRA estimate of the number of electronic cigarettes for which a manufacturer or importer, or agent would be required to submit ingredient listing information is consistent with the PRIA's year 1 estimate except that the PRIA estimate was inflated to account for product churn that may occur between the expiration of the ingredient listing compliance policy period described in the preamble and the end of the first year. Subsequently, only manufacturers or importers, or their agents, of new products would submit ingredient listing information, and therefore, the RIA estimates substantially fewer ingredient listings in the future. The PRA estimate, in aligning with the RIA's first year estimate, is akin to an upper bound.

Finally, subject to differences in time horizon and the use of annual averages, the PRA estimates of the total numbers of grandfathered product submissions, SE reports, SE exemptions, and premarket tobacco applications were within the ranges used in the PRIA. However, the PRIA assumed that all manufacturers of electronic cigarette (or ENDS) products would seek marketing authorization through the PMTA pathway, while the PRA analysis accounted for some SE report submissions by manufacturers of electronic cigarette (or ENDS) products.

2. COMMENTS ABOUT THE COSTS OF MANUFACTURING AND IMPORTING DEEMED PRODUCTS

[Comment]: One commenter stated that the cost analysis is incomplete because it omits the costs of "reading, understanding, and studying the regulations; deciding whether they will exit

the market or remain market participants; and developing implementation and compliance plans and approaches if they remain in the market.” The comment further stated that because these costs will not vary much by size of the business establishment, smaller businesses will be disproportionately affected, raising distributional implications.

[Response]: In the “Miscellaneous Costs” section of the PRIA, we estimated that the administrative set-up cost would be 5 hours for every newly regulated manufacturer that continues to participate in the market. This cost was intended to cover general up-front administrative activities such as reading and understanding the regulation. Upon reexamining this issue, we concluded that the cost of reading and understanding the regulations would be higher. We also agree with the commenter that some upfront cost would be incurred even by entities that respond to the regulation by exiting the market. Therefore, we now estimate a higher regulation review and potential general administrative setup cost that will be incurred by all current manufacturers, importers, and retailers who meet the definition of manufacturers.

While we do not include development of implementation and compliance plans as a separate line item, this cost is included in the estimated cost of specific statutory and regulatory requirements.

We agree that the costs described in this comment do not vary much by establishment size. However, the most costly provisions of this rule are expected to vary directly with the number of products an establishment or entity produces.

[Comment]: A commenter estimated establishment registration costs using estimates of tobacco product brands, by product category, rather than estimates of the number of establishments. The commenter also asserted that there would be a limited number of new tobacco product companies following the implementation of the proposed rule.

[Response]: The number of domestic establishment registrations should coincide with the number of domestic manufacturing establishments, not the number of brands. The comment is unclear whether its estimate of the number of establishments assumes exit of any existing establishments, lack of entry of any future establishments, or a low rate of entry of future establishments. While the total number of establishments will likely fall after the rule is finalized, FDA estimates that there will always be a small amount of entry and exit in the industry, even when the total number of establishments is constant. However, because the compliance costs estimated at the establishment level are small, the incremental effect of accounting for establishment entry due to usual turnover would be very small. Therefore, FDA does not include the incremental costs of such entry in the analysis of this final rule.

[Comment]: A commenter appears to estimate product listing costs by assuming that currently existing products belong to one of two groups: either they list after the rule is finalized, or they delist after the rule is finalized. The commenter also states that based on FDA’s experience with currently regulated products, it is expected to take 0.75 minutes (45 seconds) to list a product. The commenter appears to estimate that one third of cigar, pipe, and waterpipe tobacco products will exit, but this assumption is not explained. Furthermore, the commenter asserts that based on historical marketing authorizations of new tobacco products currently subject to FDA regulation, very few new products will be authorized in the future. Specifically, the commenter states that only 0.67 percent of SE reports have actually received substantial

equivalence determinations, and the commenter assumes a similar rate for newly deemed products in estimating the cost of this and other provisions.

[Response]: Under the rule, every product that remains on the market until the first listing date (December 31 or, if the rule is finalized in the second half of a calendar year, FDA intends to issue a compliance policy with a compliance period that is not later than six months into the subsequent calendar year) would need to be listed. Every product that is subsequently removed from the market would then need to be delisted. It is not necessary to delist a product that was never listed, and neither listing nor delisting would be required for a product that exits from the market before the initial product listing date. The PRIA included assumptions about the timing of exit and the nature of product listing that may have contributed to this confusion. FDA assumed that the cost of product listing was driven by the number of products and also assumed product exit would occur after the initial product listing. This led to our estimate of a large number of products being listed and then delisted a short time later. As described in section III.C.3.c of the final RIA, however, FDA now has determined that the number of establishments is the main driver of product listing costs, so detailed estimates of the number of products being listed or delisted are no longer included in the analysis of this cost.

FDA estimated that it took 0.75 hours to list a product, not 0.75 minutes. This appears to be an error in the commenter's description rather than the commenter's calculation. As described in section III.C.3.c of the final RIA, we now estimate product listing costs on a per-establishment basis.

We disagree that one third of all cigar, pipe, and waterpipe tobacco products will exit, though we have revised our assumptions about exit from the proposed rule. See section III.C.3.b of the final RIA.

It is not clear how the commenter estimates future product entry by assuming a similar authorization rate for newly deemed products. Future entry depends not only on the proportion of premarket submissions ultimately leading to marketing authorization, but also to the number of premarket submissions made in the first place.

It appears that the commenter's calculation in concluding that FDA had acted on a very small number of substantial equivalence applications conflates provisional SE reports (those reports submitted prior to March 23, 2011 for products that were first commercially marketed in the United States between February 15, 2007 and March 22, 2011) and regular SE submissions (those reports submitted on or after March 23, 2011 for products that were not commercially marketed as of February 15, 2007). New tobacco products that are the subject of provisional SE reports may remain on the market until the agency issues a not substantially equivalent (NSE) order. It also appears that the calculation conflates negative and positive decisions. While FDA had decided on less than 0.7 percent of all substantial equivalence reports as of December 31, 2013, all decisions made by that time had been for regular SE reports. As of November 30, 2015, FDA has resolved 59 percent (1193/2029) of all regular SE reports submitted. This measure captures the experience with currently regulated products. Therefore, the number of SE reports which FDA has resolved is actually much higher than the number stated in the comment. Of the portion of regular SE Reports that FDA has resolved, FDA has issued a substantial equivalence order for 36 percent (431/1193); 54 percent (646/1193) were applications for products that received a refusal to accept letter (e.g., were not under CTP's jurisdiction or failed

to include an explanation of actions taken to comply with section 907 that are applicable to the tobacco product) or were voluntarily withdrawn by the company before a determination of SE or NSE was reached; and only 10 percent (116/1193) received not substantially equivalent orders. As of April 2014, FDA no longer has a backlog of regular SE reports, and all regular SE reports received have immediately been entered into review. Therefore, we disagree that these statistics provide accurate long-term estimates of the rate of introduction of new tobacco products under FDA regulation and therefore we do not apply them to newly deemed products.

[Comment]: A commenter estimates the cost of submitting information on harmful and potentially harmful constituents (HPHCs) by assuming the cost would be at least as large as the cost of ingredient listing but acknowledging that the true cost would be substantially higher. Others criticized FDA for not estimating the cost of constituent testing and reporting for premium cigar manufacturers, arguing that due to the large number of products and potentially a higher cost per product, premium cigar manufacturers would be disproportionately affected by the cost of this requirement.

[Response]: We agree that the cost of submitting information on HPHCs would be significantly higher than the cost of ingredient listing unless the product testing has already been conducted for other reasons. As described in our analyses of the proposed and final rule, the Secretary is also required to issue regulations concerning the testing and reporting of constituents. Since we expect the regulations to be in effect before reports are due, and since the content of those regulations will in large part determine the costs of testing, we will include the cost of compliance with testing and reporting for newly deemed products when those regulations are promulgated.

[Comment]: A commenter estimates the cost of tobacco health document submission assuming that the number of submissions for newly deemed products equals the number of brands of newly deemed products.

[Response]: We disagree with this estimate. As stated in our analysis of the proposed rule, we expect this cost to be small. Because most manufacturers of newly deemed products will be small, FDA assumes that very few routinely develop health documents.

Although section 904(a)(4) sets out an ongoing requirement to submit tobacco health documents developed after June 22, 2009 (the date of enactment of the TCA), FDA generally does not intend to enforce the requirement with respect to all such documents at this time, so long as a specified set of documents are submitted by [the effective date + 6 months]. FDA will publish additional guidance that specifies the scope of such documents with sufficient advance time for manufacturers and importers to prepare their submissions.

FDA does intend to collect other tobacco health documents developed after June 22, 2009, but before doing so the agency will publish additional guidance specifying the timing of subsequent submissions. Note that, despite this compliance policy with respect to timeliness of submissions, manufacturers and importers are still to preserve all tobacco health documents developed after June 22, 2009 for future submissions to FDA. Failure to submit tobacco health documents developed after June 22, 2009 because of a failure to preserve them after publication of this rule will constitute a violation of section 904(a)(4).

For these reasons, we continue to expect the cost of this provision to be small (and negligible for small entities) and do not quantify it.

[Comment]: A comment called for FDA to publish a new regulatory impact analysis explicitly reporting FDA estimates of which or how many products would not receive marketing authorization.

[Response]: As described elsewhere, FDA has forecasted the amount of product consolidation and exit that will occur under this rule. FDA is unable to prejudge or forecast specific products that would or would not obtain marketing authorization. Applications submitted to FDA will be evaluated according to the standards set forth in the FD&C Act and applicable implementing regulations. However, we have added to the final RIA an assumption that 90 percent of products for which marketing applications are submitted will ultimately be authorized. We acknowledge that it would not be realistic to expect 100 percent of products seeking marketing authorization to obtain marketing authorization, and incorporate this assumption as a placeholder in order to create a baseline for estimating the number of products that are introduced or modified in later years. This 90% placeholder is comparable to the high end of observed medical product approval rates. The marketing authorization rate for tobacco products, however, may differ, and this placeholder is not a forecast of actual marketing authorization rates or an estimate based on currently regulated tobacco products. Furthermore, this assumption does not imply that marketing authorizations are in any way prejudged. The actual proportion of products that will be successful in obtaining marketing authorization will depend on many factors that are difficult to forecast in advance, such as the characteristics of the products seeking marketing authorization and the quality of the SE exemption requests, SE reports, and PMTAs submitted. This is discussed in more detail in section III.C.2.b.

[Comment]: A commenter states that “[t]here are four ways companies can complete premarket reviews for their products[.]” The commenter proceeds to estimate costs for grandfathered products, SE exemptions, SE, and premarket applications assuming all products must be associated with an application.

[Response]: FDA notes that grandfathered products are not new products and, consequently, are not subject to premarket review. (Because grandfathered products can serve as a predicate product in an SE submission, manufacturers may voluntarily request grandfathered review of a grandfathered product.) New products are required to obtain marketing authorization through one of three pathways— SE exemption request, SE report, or premarket tobacco product application.

[Comment]: A commenter estimates the number of new product submissions that would occur in the future by multiplying the number of tobacco products estimated to remain on the market after initial premarket submissions by 7.8 percent and then 5 percent. Comments stated that, based on the Cigar Cyclopeda, 7.8 percent is the average growth rate in the number of tobacco products (cigars) from 2005 through 2011. The commenter estimates, however, that only 5 percent of the products that would otherwise be introduced would be profitable enough to introduce when regulatory requirements are in place. The commenter further estimates that for cigars, pipe tobacco, and waterpipe tobacco, one third of the new products would be grandfathered, one third would be the subject of substantial equivalence reports, and one third would be the subject of SE exemption requests.

[Response]: We disagree with this estimate. New products enter the market because of product churn or growth in the number of products. The commenter's estimate considers growth only and disregards churn. The estimated growth rate in the number of cigar brands is 7.8 percent over the time period considered. This rate may be different from the growth in the number of products due to product changes within brands; it also measures the net increase in brands after any potential exit. Additionally, while we agree that increasing the cost of product entry will reduce the amount of product entry, we disagree that 95 percent of new product entry that would otherwise occur would be curtailed due to the costs of this rule. In the analysis of impacts, we assume the number of combusted products will remain steady after any exit that occurs during the initial wave of marketing applications and authorizations. For the proposed RIA, we assumed a product churn rate of 5 to 15 percent, both before and after regulation. For the final RIA, we assume a product churn rate of 5 to 10 percent after regulation based on the rate at which marketing applications have been submitted for currently regulated tobacco products. See Section III.C.2.c for additional details.

We also disagree that new cigar, pipe tobacco, and waterpipe tobacco products introduced in the future will be equally split between grandfathered, SE, and SE exemptions. Only products that were commercially marketed as of February 15, 2007 are grandfathered. We discuss our estimates of the use of the SE and exemptions marketing authorization pathways below.

[Comment]: A commenter estimates, based on the Cigar Cyclopeda, that approximately 80 percent of cigar and pipe tobacco products will be grandfathered products.

[Response]: We assume the commenter's estimate pertains to the cigar and pipe tobacco products that will be on the market when premarket requirements go into effect. As discussed in our analysis of the proposed rule, we used a variety of sources, including the Cigar Cyclopeda, to inform our estimate of the rate of tobacco product churn. We then estimated that between 23 percent and 63 percent would be grandfathered based on that product churn rate. The commenter does not explain how the commenter arrives at an estimate of 80 percent based on the information in the Cigar Cyclopeda.

For the final rule, we have directly estimated the proportion of cigar and pipe tobacco products that are expected to be grandfathered. Based on FDA site visits to cigar manufacturers and other experience, we conclude that 60 percent of cigars and 50 percent of pipe tobacco products will be grandfathered.

[Comment]: Several comments assume or assert that some or all cigars would lack a valid predicate to support an SE determination and, consequently, manufacturers would be required to submit PMTAs. One such comment states that the high cost of premarket tobacco applications, taking 5,000 hours at an estimated cost of \$332,490, will eliminate innovation by small to medium sized firms and concentrate the market in the hands of a few large players.

[Response]: Because a large number of cigars (and other traditional combusted products) were marketed as of the grandfather date, FDA continues to assume in our analysis that new cigars (and other traditional combusted products) will generally enter the market through the substantial equivalence and substantial equivalence exemption pathways, at a fraction of the cost of the PMTA pathway.

[Comment]: Some comments stated that without predicates, small cigar, pipe, and hookah tobacco manufacturers would have to purchase rights to predicate products from competitors, which would be costly.

[Response]: For the SE pathway, a manufacturer may utilize any eligible predicate tobacco product, including one they do not manufacture. If manufacturers do not have predicate products which were on the market as of the grandfathered date, they have the option to select a different premarket review pathway or work with other manufacturers that have eligible predicate products. Options for moving forward include: (1) enter into an agreement with that manufacturer to receive and submit the predicate product information within their SE application, (2) reach an agreement with that manufacturer to allow for a cross-reference to a Master file to maintain the confidentiality of the predicate product information, or (3) submit a PMTA and demonstrate that marketing of the new product is appropriate for the protection of public health.

[Comment]: A comment states that there is insufficient information to forecast the percentage of newly deemed products for which an exemption from substantial equivalence may be obtained, and assumes that manufacturers of non-grandfathered cigars and pipe tobacco products will use the substantial equivalence and substantial equivalence exemption pathways in equal numbers.

[Response]: For the PRIA, FDA estimated that between 5 and 40 percent of new cigar and pipe tobacco products would be marketed using the SE exemption pathway; this estimate was based on early use of the pathway (only available since the August 2011 effective date of the implementing regulation) and an assumption that its use would grow as industry gained experience. In the final RIA, we update our assumptions about the proportion of products using the exemptions and other marketing pathways. See section III.C.3.b.(4).

[Comment]: One comment objected that our cost estimates for the various premarket review pathways come from “unknown ‘experts’ in FDA’s Center for Tobacco Products” and that “no data, studies, reports or other reference materials are cited to justify these figures, nor are any substantiated equations or methodological notes provided.”

[Response]: FDA continues to believe that FDA’s experience with premarket submissions for currently regulated tobacco products provides the closest approximation to premarket submissions for newly deemed tobacco products. Furthermore, reviewers in the Center for Tobacco Products are among the most qualified individuals to estimate these costs. FDA welcomed comments on the topic of the cost of premarket submissions and responds elsewhere to specific points made in those comments.

[Comment]: Comments argued, based on the types of studies that FDA would require, that the cost of a PMTA could be millions of dollars per product.

[Response]: We disagree. As discussed in the PRIA, FDA does not expect most PMTAs to include randomized clinical trials, though other clinical or nonclinical studies may be appropriate. Application costs will vary depending on the types of studies needed to adequately demonstrate that a product is appropriate for the protection of the public health. FDA’s estimate

of the cost reflects the *average* cost per product entering through the PMTA pathway. In the final RIA, we have revised our estimate of the cost per PMTA. See section III.C.3.b for details.

[Comment]: One commenter stated that the cost of premarket reviews will be substantial and will account for as much as 95 percent of the initial cost of the proposed rule. The costs associated with premarket tobacco applications “fall disproportionately on ENDS products” and “will drive the vast majority of product and brand exits for electronic cigarette products.” The commenter estimates that only 633 of existing ENDS products, approximately 5 percent of the current number, would remain viable if the rule is finalized as proposed.

[Response]: We agree that the costs of premarket submissions will be substantial, but we do not estimate that they will account for 95 percent of the initial costs or total costs of the rule. (For example, premarket submissions of all types accounted for between 52 and 71 percent of the estimated present value of total *private sector* costs of the proposed rule and account for between 74 and 85 percent of the present value of total *private sector* costs of the final rule.) Labeling requirements also account for a substantial portion of quantified costs. We agree that premarket tobacco applications are more expensive, on average, than substantial equivalence or SE exemptions. Therefore, we agree that because most ENDS products will face a much higher per-product cost for premarket submissions. We also note that the total cost of premarket submissions depends not only on the unit cost, but on the total number of submissions. Some of the industry segments affected by this final rule consist of very large numbers of products with very low sales volume; substantial amounts of consolidation or exit may occur within those segments. Product consolidation and exit and total cost for premarket submissions are jointly determined.

The commenter’s estimate of the number of electronic cigarette (ENDS) products remaining on the market is difficult to evaluate from the information provided. In our analysis of the proposed rule, we forecasted that all ENDS products would require PMTAs, and that the number of submissions would be far fewer than 633. (Specifically, we forecasted that 20 to 80 premarket tobacco applications would be submitted within the first 24 months and 10 to 20 annually thereafter.) However, we now forecast that some ENDS delivery systems may be able to use the SE pathway and that both e-liquids and delivery systems may be able to use the exemptions pathway after the initial round of marketing authorizations. Given this and the growth we have seen in the ENDS market, we now forecast that a larger number of requests for marketing authorization will be submitted for e-liquids and ENDS delivery systems, as described in Section III.C.3.b.2 of the final RIA.

[Comment]: A large number of comments expressed concern about the cost of complying with premarket requirements. Some stated that premarket requirements are so costly as to be a de facto ban on certain products, such as premium cigars and electronic cigarettes.

Comments stated that premarket review requirements would put the majority of electronic cigarette (or ENDS) manufacturers out of business and delay new products and technological improvements. Only large tobacco companies could survive in the market, and such companies may design their products to push consumers back to cigarettes. Manufacturers of electronic cigarettes (or ENDS), lacking a predicate, will need to submit PMTAs and manufacturers without sufficient resources may have to remove their products from the market. These comments stated that strictly applying the TCA requirements would lead to an effective ban on

e-cigarettes (or ENDS) and that the industry would not survive. Individual manufacturers responded with the cost of submitting PMTAs for their current line of products, arguing that it would be prohibitively expensive.

Comments stated that premarket requirements would also be costly for other tobacco products. For example, with respect to cigars, constant variation in cigar tobacco, special edition, and seasonal cigar blends will impose burdens, and manufacturers may cease introducing new products. Comments stated that because premium cigar manufacturers offer many different products with slight variations, premarket review would be disproportionately expensive for those products. Similar concerns were expressed for premium pipe tobacco blends. Innovation by small and medium-sized businesses will halt, and the industry will become increasingly concentrated. Premarket costs would cause product exit as well as factory closures.

[Response]: We acknowledge that premarket requirements have associated costs, but we disagree that they will be a de facto ban on specific types of products.

The ENDS market has grown into an estimated 3.5 billion dollar market, according to one market source (Herzog et al., 2015). While we expect to see product consolidation and exit in this emerging market, we fully expect the market to be able to support new product applications. Our best forecast in the PRIA was that all manufacturers of ENDS products would seek marketing authorization through the PMTA pathway. However, we now forecast that some ENDS delivery systems may be able to use the SE pathway and that both e-liquids and delivery systems may be able to use the exemptions pathway after the initial round of marketing authorizations.¹¹ Regardless of the pathway through which ENDS products receive premarket authorization, we do not expect ENDS products to disappear from the marketplace; we expect manufacturers to be successful in obtaining premarket authorization for their ENDS products.

We acknowledge that premarket review requirements will be more costly for segments of the cigar or pipe tobacco market characterized by a large number of products with slight variations or frequent changes to products. We agree that product exit is likely to occur, but much of this may occur as a result of consolidation of similar products within product lines instead of through exit by manufacturers, although we expect most vape shops that currently mix e-liquids will convert to a retail model once the initial compliance period for submission of

¹¹ A tobacco product manufacturer must show that a new tobacco product is substantially equivalent to a valid predicate product—i.e., a product that was commercially marketed in the United States as of February 15, 2007, or a tobacco product previously found substantially equivalent. To facilitate identification of a valid predicate, FDA issued guidance that provides information about how companies can establish that a product was on the market as of February 15, 2007. Guidance for Industry: Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (79 FR 58358, Sept. 29, 2014).

Once a manufacturer identifies a predicate it must then demonstrate that the new tobacco product that it seeks to market is substantially equivalent to the predicate. This is done by demonstrating that the new product has the same characteristics as the predicate, or, if the product has different characteristics, the information submitted by the applicant shows that the differences do not cause the new tobacco product to raise different questions of public health. FD&C Act § 910(a)(3)(A). FDA has issued guidance documents on how to demonstrate substantial equivalence, including “Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products” (76 FR 789, January 6, 2011) and “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions, Second Edition” (80 FR 53810 September 8, 2015).

PMTAs ends. It is also possible that we will see less product churn in the future, including a reduction in special edition or seasonal products. However, we do not expect introduction of new products to cease. Finally, consistent with FDA's policy with respect to currently regulated tobacco products, FDA has stated its intention to not take enforcement action against manufacturers that make tobacco blending changes to address the natural variation of tobacco (e.g., blending changes due to variation in growing conditions) in order to maintain a consistent product without first submitting a marketing application for a new tobacco product.

3. LABELING COSTS

[Comment]: A commenter estimates the cost of labeling assuming that no labeling changes can be coordinated with a non-regulatory labeling change, using the commenter's own estimate of the number of products that will remain on the market long enough to undergo the labeling change, using the medium cost estimate from the analysis of the proposed rule, and omitting some of the associated costs such as incremental costs for random display and the cost of point-of-sale warnings for cigars sold individually.

[Response]: Coordination of a regulatory change with a non-regulatory change reduces the incremental burden of the regulatory change. Otherwise, the commenter's estimate is broadly consistent with FDA's approach, though less complete. We continue to estimate labeling costs using our original approach but incorporating the results of an update to the FDA Labeling Cost Model.

[Comment]: Comments asserted that the estimated labeling cost is "extremely conservative" because it doesn't take into account costs such as trademark registrations and copyrights. Furthermore, the addition of warning labels would bring changes to trade dress which would necessitate increased marketing and could potentially lower the value of brands and trademarks.

[Response]: We disagree that the labeling cost estimate is extremely conservative, as we do not expect that new trademark registrations and copyrights would generally be sought as a result of the labeling requirements of this final rule. The cost of changing the visual appearance (the non-warnings portion) of a product package is included in the labeling cost model as part of the label design cost. There could be additional costs to the extent that manufacturers engage in additional marketing or other efforts to compensate for the effects of adding warnings or making other changes. The removal of "light," "mild," "low" and other descriptors is an example of when additional efforts are more likely to occur.

[Comment]: Many other comments addressed the costs of complying with the labeling requirements of the rule. Such comments did not address the accuracy of FDA's estimates so much as state that FDA's proposed policy would be burdensome or costly and have adverse effects on newly regulated products. For example, comments stated that the warning label requirements would disproportionately affect premium cigars, which are often sold in ornate types of packaging. Some stated that the requirements would place a greater burden on cigar manufacturers who are not subject to the FTC Consent Orders. Manufacturers stated that they may need to eliminate well in excess of 50 percent of their current UPCs, possibly more than 60 percent in conjunction with premarket requirements, in order to comply with these requirements.

Comments also stated that labeling requirements would make it more difficult to introduce new products and may force manufacturers to close factories.

[Response]: We acknowledge that labeling requirements are a large contributor to the costs of this rule. Product categories characterized by a large number of (slightly varying) low-volume products will be more affected by costs incurred on a per-product basis than other products. In addition, we agree that the labeling costs for products with unique or ornate packaging may differ from the costs estimated by our Labeling Cost Model, as we acknowledged in the PRIA. While it is true that products not currently carrying the FTC labels would face some additional cost for moving from a single-label to a multi-label system, we disagree that there would be a large difference in burden because *every* product would have to design a new label to incorporate the warnings and create 6 versions of the new format.

While we do not estimate the effects of individual requirements' on product exit, in our analyses of both the proposed and final rule we have included the possibility of product consolidation and exit, as discussed above. However, we do not forecast exit to be as high as these comments suggest. We base our estimate of the rate at which marketing authorizations will be sought for newly deemed new products in the future on the FDA's experience with currently regulated products after premarket requirements went into effect. Finally, while some manufacturer exit is likely, we note that a large amount of product exit is likely to occur through consolidation of the many similar product variants within existing product lines.

4. COMMENTS ABOUT OTHER INDUSTRY COSTS

[Comment]: A commenter estimated the cost of removing non-compliant point-of-sale advertising using a method similar to FDA's. The commenter noted that this estimate does not include the cost to retailers of the loss of Point of Purchase Advertising Incentives from manufacturers, which is considered to be a transfer. Comments stated that to the extent that the advertising has any societal value, the cost calculations are conservative.

[Response]: We agree that we underestimate costs to the extent that point-of-sale advertising is reduced and to the extent that its substitutes are costlier or provide less information to consumers. We note that point-of-sale advertising is not banned by this rule, but the advertising must comply with the warning requirements, which could in principle reduce its use. (We note, however, that, for example, point-of-sale advertisements for smokeless tobacco must have warnings similar to the warnings provided for here and use of these advertisements continues.) If point-of-sale advertising is reduced, manufacturers are likely to increase their use of other retailer-directed incentives, such as those to improve product placement; this could in principle result in a reduction in the amount of information provided to consumers.

[Comment]: Comments stated that eliminating free samples would burden segments of the industry, such as pipe tobacco and premium cigars, for which samples are an important part of the sales process.

Some comments suggested that prohibiting free samples will lead to decreases in sales of such products as premium cigars, pipe tobacco, and electronic cigarettes, and eventual job losses in those industries.

One commenter could find no published evidence showing how cigar or pipe tobacco use or sales would be affected by eliminating free samples, but asserted that brand switching would be reduced. The comments argued that the fact that sampling is currently employed means that it probably has some effect on sales. The commenter further asserts that all effects would occur within the first year.

Another commenter stated that FDA ignored the cost attributable to the fact that, when free samples are banned, marketing will switch to less effective permissible channels, and consequently, marketing costs will increase at all levels of sales or profit. “More concretely, two major events in Pennsylvania, attracting over 10,000 participants, are centered on free samples and free samples are widely used by retail shops.”

[Response]: In 1999, the cigar industry spent \$423,000 on providing free samples (FTC, 1999). Although we do not have more recent data for cigars, or any information for pipe tobacco, the total value of free samples distributed is likely very small. We acknowledge that samples may be concentrated in the premium segments of the industries. Even so, sampling as a marketing strategy may have no effect on total industry profits, but instead may change the distribution of profits among manufacturers as they vie for market share; therefore, the fact that free samples are employed in the pipe tobacco and premium cigar industries does not imply that there must be an effect on total sales. On the other hand, the lack of free samples may discourage consumers from purchasing different products and may affect sales. However, we disagree that the ban on free samples will be a large burden on industry.

As we acknowledged in the economic analysis of the proposed rule, the prohibition of free samples will increase consumer search costs and may reduce brand switching. If there is an effect on the rate at which consumers purchase or switch to new products, we would expect this effect to persist past the first year. However, total economic profits would only be meaningfully affected if total industry sales were reduced.

Manufacturers may switch to other marketing strategies in order to increase or maintain market share; to the extent that alternative marketing strategies are more costly and less effective, we agree that there may be costs, but we expect the effect to be small. We also note that prohibiting samples is unlikely to put an end to major cigar events, as alternative marketing strategies could also be pursued at such events.

5. ADMINISTRATION AND ENFORCEMENT COSTS BORNE BY GOVERNMENT

[Comment]: A commenter estimated the government cost of potential regulatory alternatives by assuming FDA costs are linearly related to the overall industry cost of regulation.

[Response]: While the suggested method is perhaps the simplest approach to take, we do not necessarily find a strong correlation between the share of industry costs and the share of FDA costs accounted for by any particular provision. For example, we expect reasonably strong correlations for some costs, such as preparation by industry and review by FDA of new product submissions. In other areas, such as agency enforcement, however, there is no clear correlation between agency costs and industry costs.

[Comment]: A commenter stated that the agency expects to need 55 new full-time-equivalent employees (FTEs) to implement the proposed rule. The comment stated that this would result in a user fee cost of nearly \$14 million per year, which would continue indefinitely because “the agency would be creating an entirely new bureaucracy.”

[Response]: We reiterate that the total amount of user fees is set by statute, and neither the amount of user fees collected nor overall FDA accounting costs will increase as a result of this rule. We do not believe that it is accurate to state that 55 **new** FDA FTEs will be required to implement this rule. FDA could implement this rule by hiring new employees or by reallocating FTEs assigned to other activities conducted under the Tobacco Control Act; the 55 FTEs have an opportunity cost because other activities will be forgone in order to devote them to implementing this deeming rule.

[Comment]: Many comments argued that FDA will receive thousands of premarket submissions and expressed concern about the backlog and delays this will cause. For example, one comment argued that the proposed rule would generate double the number of SE reports as the agency had received to date (stated to be 4,500 at the time). Comments expressed concern about the diversion of resources from other activities to review of newly deemed products.

[Response]: FDA’s Center for Tobacco Products has estimated 55 full-time-equivalent employees will be needed to implement and enforce this rule. We agree that implementation will require the diversion of resources from their next best alternative use *within FDA’s tobacco program*; this is the concept of opportunity cost. The phrase “within FDA’s tobacco program” is important because the Agency’s regulation of tobacco products is fully funded through tobacco industry user fees; appropriations are not used for tobacco regulation, and tobacco industry user fees are only used for FDA activities related to the regulation of tobacco products under chapter IX of the FD&C Act and the TCA.

We are unable to provide an estimate of how much time it will take to respond to each PMTA or SE application. The average time it takes to review premarket applications is dependent upon the type of application being submitted and other factors, including the application’s content. However, we do not expect the review backlog for newly deemed products to be similar to that for currently regulated products, but rather to be reduced more quickly as FDA’s Center for Tobacco Products and regulated industry gain experience. Therefore, we disagree with predictions of a long-term backlog. We note, however, that if a prolonged backlog were to occur, it would slow the entry of new products compared with the amount of entry we have estimated.

6. OTHER COMMENTS ABOUT COSTS

[Comment]: A comment stated that the cost analysis did not explain why the value of the loss in consumer choice due to product exit and reduction in product variety were not estimated. Comments stated that in order to estimate welfare changes, the analysis must estimate the value of the loss of consumer choice.

[Response]: We note that if this final rule successfully mitigates market failure, there will be a welfare gain for consumers, including consumers who are potentially dissuaded from using tobacco products. For consumers who continue to use tobacco products, we lack a baseline estimate of consumer valuation of tobacco product variety, making it impossible to estimate how consumers would value the potential loss of variety under this rule. We note, however, that today we see very large numbers of products embodying minor variations. In most cases, even if considerable product consolidation were to occur, close substitutes would exist for discontinued products, which would limit the size of the impact on consumers. We discuss consumer search costs associated with this loss in variety in section III.C.4.a.

[Comment]: A commenter asserted that the burden of regulation of newly deemed products would artificially increase the price of newly deemed products, leading to reductions in producer and consumer surplus. The comment stated: “These are real costs that accrue to real people and businesses and need to be taken into account in any RIA.” The comment continued: “Whether or not certain individuals or institutions approve of the morality or the ‘goodness’ of tobacco products, they are subject to, and reflective of, the basic principles of economics.” The commenter attempts to quantify lost producer and consumer surplus and add them to other costs of the rule.

[Response]: The comment does not distinguish between the presence and absence of market failure. In the absence of market failure (considered expansively, as an economic term of art), economic theory predicts that any government intervention will reduce social surplus (the sum of producer and consumer surplus). When market failure exists, social surplus may be increased through government intervention that mitigates or corrects the market failure. Therefore, regulation will reduce (the sum of) producer and consumer surplus unless the regulation efficiently mitigates or corrects market failure. The “need for the rule” section of the RIA identifies incomplete and asymmetric information, intrapersonal market failures (or internalities) such as time inconsistency, and institutional failures as sources of market failure. If the regulation successfully and efficiently mitigates such market failures, it would lead to an increase in social surplus, not a decrease.

FDA notes that the benefit-cost analysis estimates the major impacts of a rule as they may affect social welfare. To find that a regulation increases social surplus is to find that the benefits of a regulation exceed its costs. Estimates of changes in producer and consumer surplus are already conceptual parts of a benefit-cost analysis; they are not calculated and added on separately at the end of the analysis. While we are not able to estimate every potential benefit and cost, we are careful to discuss those which we are able to identify but not estimate.

E. COMMENTS ABOUT THE BREAK-EVEN CALCULATION

[Comment]: FDA received some direct comments on the break-even calculation. One comment argued that FDA overestimated the number of life-years saved necessary to break even with the proposed rule's costs because the Sloan (2004) book entitled The Price of Smoking is outdated. Another argued that use of a break-even calculation is reasonable, because many of the benefits of the proposed rule could not be quantified, but the PRIA's break-even calculation conflated life-years and quality-adjusted life-years.

[Response]: While Sloan's 2004 book was referenced elsewhere in the PRIA, our break-even calculation in the PRIA did not rely on that source; the only inputs to the calculation were the cost of the rule, the value of a statistical life-year, and the welfare gain ratio.

The break-even analysis in the PRIA discussed the break-even in terms of quality-adjusted life-years (QALYs) and life-years. The calculation combined QALYs gained with life-year extensions in an attempt to combine mortality and morbidity. Our intent was not to conflate life-years and quality-adjusted life-years, but to stress that the break-even level of benefits could be obtained through a combination of morbidity and mortality improvements.

Based in part on comments received on the preliminary RIA, we are not basing our breakeven analysis in this final RIA on QALYs. Instead, we are describing changes in societal welfare in terms of a more basic measure: people's implicit willingness-to-pay for the provisions of the rule. Our break-even calculation now shows how much beneficiaries (or more precisely, current consumers) would on average need to be willing to pay for the changes embodied in the rule in order for the rule's benefits to equal its costs.

F. COMMENTS ABOUT DISTRIBUTIONAL AND INTERNATIONAL EFFECTS

[Comment]: Comments stated that the RIA is weak in its discussion of distributional impacts.

[Response]: We disagree that the PRIA was weak in its discussion of distributional impacts. We respond below to concerns about specific potential distributional impacts raised in public comments. Where appropriate, we have also revised the discussion of distributional impacts in the analysis of the final rule.

[Comment]: Several comments addressed the distributional effects of collecting user fees from cigar and pipe manufacturers, arguing that those industries cannot afford to pay user fees, the high cost may lead to the elimination of jobs, and that the imposition of user fees on imported premium cigars would create a trade barrier.

[Response]: We do not discuss the extension of user fees to newly deemed products in the analysis of costs because user fees are not a social cost, but a transfer; cigars and pipe tobacco will begin to pay user fees, and each class of tobacco products currently subject to user fees will pay less. We acknowledge, however, that user fees are a substantial cost from the standpoint of businesses that must pay them; user fees are included in our analysis of the effects of this rule on small entities.

We discuss potential employment effects and trade effects of this rule below.

[Comment]: Many comments discussed the effects of the proposed rule on consumers. Concerns included reduced product variety (including limited edition or seasonal products) due to premarket requirements and increased prices.

Comments specifically questioned the welfare implications of increased prices or reduced product availability or variety among electronic cigarettes, and whether this would cause people who would vape in the absence of this rule to instead smoke combusted tobacco products.

In response to a statement in the PRIA that most of the variable costs would be passed on to consumers in the form of higher prices, a commenter stated, “If variable costs mean marginal costs, this statement is true; in competitive markets profit maximization results in price being set at marginal cost while fixed costs are not passed through to consumers but rather reduce profitability. Since the regulations increase marginal cost, they also increase price.” The commenter further states that the PRIA asserts, without analysis, that the average increase in price would be small. Comments stated that the analysis should estimate the average increase in price relative to current prices for the market as a whole and by product and size of business.

One comment specifically urged FDA to obtain independent estimates of the price impacts on the e-cigarette (or ENDS) market of compliance costs and increased market concentration, the own-price and cross-price elasticities of demand, the impact of all sources of regulatory price increase on demand, and the demand impact of product choice restrictions.

Commenters noted that under option 2 (exempting certain “premium” cigars from this rule), some manufacturers would raise prices to exceed the premium cigar price threshold. Comments also suggested that under option 1, premium cigar manufacturers would switch to mass production techniques, implying the disappearance of premium cigars as we know them today.

[Response]: Most of the costs of this rule do not vary directly with the quantity of output; rather, they are a fixed amount per firm or per product. Some proportion of the costs that do vary with output is expected to be passed on to consumers as an increase in product prices, but the exact proportion depends on the elasticities of supply and demand. Because the increase in variable costs will be small, we do not expect much increase in price due to variable costs being passed on. Fixed costs can also lead to price increases if they reduce profitability enough to affect market participation, but while the rule is expected to reduce the number of manufacturers and products participating, the size of this effect in the market is uncertain. Therefore, while we think the price increase will likely be small for traditional tobacco products, we are unable to estimate the effect of this regulation on prices. Because FDA has chosen option 1 from the proposed rule (all cigars are deemed), there is no longer any concern about cigar manufacturers raising the price of their products in order to meet the definition of premium cigar and thereby avoid regulation.

While we note that although consumers who continue to use traditional tobacco products without changing their consumption levels would be made worse off by an increase in prices, consumers induced to quit or reduce their consumption as a result of increased prices could experience an increase in welfare.

We discussed the welfare effects of electronic cigarettes in the RIA for the proposed rule and include an updated discussion in the final RIA.

While we acknowledge that there likely will be product exit and a reduction in variety, we are unable to estimate the value of this loss in consumer choice. Most product exit is likely to occur in segments of the market characterized by a large number of low-volume variants with slight differences; both the expected low volume of each of the individual products that may exit and the continued availability of close substitutes (we do not expect any product category to disappear) serve to mitigate this cost to consumers.

[Comment]: One comment objected that, although the RIA states that the regulation could reduce tobacco product use, which would reduce the revenues of tobacco manufacturers, distributors, and growers, it does not estimate current revenues or the reduction in revenues. “The paucity of the analysis certainly violates the spirit of the EO.” A better analysis would analyze the impact on profitability, industry structure, and long-term survival.

[Response]: We are unable to estimate the reduction in revenues that would be associated with a possible reduction in consumption. We note, however, that revenues depend on both quantity sold and price. Consistent with Executive Order 12866, we have described the effects we cannot quantify. We now, however, include estimates of the current sales revenues of tobacco products covered by this final rule.

[Comment]: Numerous comments discussed the impact of this rule on particular segments of newly regulated industries. For example, a commenter recommended that the FDA consider the economic impact of the rule on over 44 small-batch manufacturers in the American Boutique Cigar Manufacturers Association. Another comment stated that the costs of this rule would cause the country’s last remaining traditional, vintage machine-made cigar factories to close.

[Response]: While we do not have the data to analyze the specific impacts of this rule on members of the American Boutique Cigar Manufacturers Association or vintage machine-made cigar factories, we acknowledge in our analyses of the proposed and final rules that small entities may be adversely affected, and many may exit. To the extent that data allow, we analyze the effects of this rule on small cigar manufacturers.

[Comment]: Many comments discussed expected adverse effects on employment patterns in newly regulated industries.

For example, comments stated that the proposed regulation would have a large effect on the premium cigar industry. Between 2,400 and 3,000 small brick and mortar retailers would be affected. Those businesses employ an average of 4 to 5 part-time employees. A comment stated that falling revenues and profits would put jobs at risk throughout the supply chain, numbering 10,000 to 20,000 at risk. Comments also stated that although some may argue that employment losses would be offset by employment gains in other industries, jobs will be lost in the tobacco industry. Offsetting job gains will not occur immediately, will be in different locations, and will not be concentrated in a single industry, making it more difficult to identify the people who gain. According to commenters, the 2009 CHIPRA federal excise tax increase caused 2,000 jobs to be lost in Florida alone. Commenters added that the premium cigar industry is less able to survive regulation than mass marketed products.

Comments also asserted that the electronic cigarette (or ENDS) industry provides a large number of jobs, and that this rule would negatively impact manufacturers and retail stores, leading to job losses.

[Response]: As of 2012, Statistics of US Businesses data indicate that tobacco manufacturing employed 14,599 people, tobacco and tobacco product merchant wholesaling employed 48,403, and tobacco stores employed 34,514, for total (nonfarm) employment of 97,516 people. This is 0.07 percent of total May 2012 employment of 130,287,700. These numbers do not account for farm employment or self-employed individuals who do not have hired employees, nor do they account for the growth in the ENDS industry since 2012.¹² Nevertheless, this demonstrates that total tobacco industry employment accounts for only a small proportion of total employment in the US economy. Newly deemed segments of the tobacco industry would only account for a portion of total tobacco industry employment; therefore, the affected segments of the tobacco industry would be extremely small in the context of the US economy. Finally, comments seem to imply that this regulation is banning specific newly deemed products or otherwise reducing employment in specific industries to zero. This rule does not ban any class of tobacco product. While increases in costs and potential reductions in revenue could lead to some reduction in jobs in certain segments of the tobacco industry, employment is not expected to drop to zero in any segment of the tobacco industry. For example, after the initial compliance policy period for submission and FDA receipt of PMTAs, we expect most vape shops to convert to a pure retail model. It is possible that some vape shops may ultimately exit the market if product variety settles at a level at which not all currently-operating vape shops can operate profitably. However, given that we expect premarket applications to be submitted for 1,250-2,500 e-liquids and 360 to 450 ENDS devices, we expect product variety to remain at a level sufficient to enable most vape shops to change over to the retail model.

We also stress that reductions in employment will be offset by employment gains from spending on other products; thus, the effects of reduced employment are primarily distributional. There will, however, be short-term costs associated with these adjustments in the economy.

[Comment]: Numerous comments addressed the effects of the proposed rule on the retail sector, arguing that the rule would lead to financial hardship, reduced sales, job losses, and store closures.

[Response]: Under the final rule, any retailers who meet the definition of manufacturer due to other activities, such as mixing e-liquids or blending pipe tobacco, are likely to cease engaging in manufacturing activities and convert to a pure retail model. We assume that many vape shops will continue to prepare some mixtures that they prepared and offered for sale as of the effective date during the initial compliance policy period for submission and receipt by FDA of PMTAs; we also assume they will comply with other requirements for manufacturers, such as establishment registration, product listing, and ingredient listing requirements. If vape shops chose not to comply with these other requirements for manufacturers, they would not necessarily close; they might simply switch to pure retailing sooner.

¹² However, as demonstrated in Table 29 of Section III.C.6.a, the current size of the ENDS market is small relative to the size of the market for all tobacco products.

Because we are unable to estimate the extent to which this final rule would lead to a reduction in the use of tobacco products, we are unable to estimate the extent to which retailers of newly deemed tobacco products may lose sales. Economy-wide, retailers would not be harmed as consumers would switch to purchasing other goods.

[Comment]: Many comments stated that the rule would lead to a reduction in excise tax revenue, used for such purposes as children's health care, while some other comments stated that decreasing government revenues should not be considered when determining the protection of the public health.

[Response]: We agree that this rule would result in a decrease in government tobacco product excise tax revenues if consumption of taxed tobacco products is reduced. We note that these effects are primarily a transfer: gains to former payers would be offset by losses to former recipients, resulting in no net social cost or benefit.

[Comment]: Comments criticized the PRIA for not addressing local impacts. Florida, with 112 manufacturers of premium cigars, over 45 cigar corporate headquarters, 300 retail establishments and ports through which tobacco is imported, would experience job losses. Comments stated that over half of all premium cigars are distributed through the state of Pennsylvania. The cities of Las Vegas and New Orleans rotate in hosting the national cigar trade show; trade shows and events associated with premium cigars are estimated to bring over 17,000 people and \$20.7 million to Las Vegas. Additionally, there are specific cigar manufacturing and distribution facilities in other locations that would be affected. Comments also stated that tobacco growers and their workers in places such as the Connecticut River Valley or Puerto Rico would also be affected.

[Response]: We agree that there could be some state or local impacts, but given the small size of the premium cigar industry (and other segments of the tobacco industry affected by this final rule) relative to state or local economies, we expect the impact to be small in any but the most extremely local jurisdictions. As described above, the tobacco industry *as a whole* accounts for 97,516 nonfarm employees, which is about 0.07 percent of nonfarm employment in the US. Again, it is important to note that this rule does not ban premium cigars or any other type of tobacco product. While there likely will be some reduction of employment in some affected segments of the tobacco industry, employment in those segments will not be reduced to zero.

We cannot possibly address every potential local effect of this rule. However, we note the following: Current nonagricultural employment in the state of Florida is nearly 8 million.¹³ Current employment in the state of Pennsylvania is approximately 6 million.¹⁴ Any employment frictions in the premium cigar industry would be small relative to those states' total employment. The national cigar trade show and other cigars events are small in the context of tourism in the city of Las Vegas; nearly 40 million people visited Las Vegas in 2013.¹⁵ Moreover, the final rule does not ban cigar trade shows.

¹³ <http://lmsresources.labormarketinfo.com/library/press/release.pdf>

¹⁴ <http://www.portal.state.pa.us/portal/server.pt?open=514&objID=1216762&mode=2>

¹⁵ <http://www.lvcva.com/includes/content/images/media/docs/2013-Vegas-FAQs.pdf>

[Comment]: Several comments addressed government-funded medical services, insurance premiums, and social security costs. Some comments supported the rule on the grounds that medical treatment for tobacco users leads to government (and therefore taxpayer) costs. Some comments stated that the rule would lead current electronic cigarette (or ENDS) users to return to combusted products, thereby increasing government-funded medical costs.

[Response]: We assume that the financial effects of using tobacco products other than cigarettes are qualitatively similar to the financial effects of using cigarettes. That is, for all tobacco products, users bear a portion of their medical costs, but a portion is borne by the general public through private insurance premiums or taxes used to fund government health care programs. Therefore, we agree that a reduction in tobacco product use would transfer value from smokers to the general public. However, we are unable to forecast the impacts of this rule on any potential effects of substitution between different tobacco products.

[Comment:] Comments stated that the rule would have a significant negative impact on Indian reservation economies and lead to the loss of reservation jobs. The difficulty and expense of obtaining marketing authorization through the available premarket pathways and the 2007 grandfather date were cited as the aspects of the rule expected to generate the largest impact.

[Response]: We expect these effects to be similar for tribal and non-tribal businesses. We discuss the effects of the rule on small businesses and the employment effects of this rule elsewhere in this document. Given uncertainties in this area, our analysis assumes no specific or additional costs for tribal entities.

[Comment]: Comments expressed concern that foreign producers of handmade cigars would not be able to comply with the requirements of the proposed rule and about the implications of potential exit from the US market by cigar manufacturers in Honduras, Nicaragua, and the Dominican Republic. Comments state that the premium cigar industry accounts for over 350,000 estimated jobs in Honduras, Nicaragua, and the Dominican Republic. Comments also stated that the tobacco growing nations¹⁶ would be affected. Comments criticized the RIA for not discussing the implications of the proposed rule on import-export relations, foreign debt commitments due to the reliance on premium cigar manufacturing, and related international trade implications. The unintended consequences could contribute to economic instability. Comments argued that the imposition of user fees on premium cigar manufacturers or importers constitutes a trade barrier violating the spirit of the Dominican Republic—Central America Free Trade Agreement. Comments further argued that user fees erect a barrier to the importation of the roughly 260 million premium cigars imported from a specific commenter's Caribbean partners. Foreign impacts, including impacts on employment, could create issues of political and economic instability and lead to domestic security concerns.

Conversely, a comment stated that few US cigar makers use natural tobacco leaf because the process is labor intensive and the cost of labor is relatively high in the US. Therefore, the comment argued providing more favorable treatment to premium cigars would disproportionately harm US cigar manufacturers and favor imported cigars.

¹⁶ Nations such as Ecuador, Brazil, Costa Rica, Panama, Mexico, Indonesia, Cameroon, and the Central African Republic were specifically mentioned.

[Response]: We disagree with comments that this regulation will lead to instability or violate trade agreements.

U.S. parent companies or U.S. importers could assist a foreign manufacturer with meeting regulatory requirements. Employment of 350,000 represents about 1.4 percent of the combined population of Honduras, Nicaragua, and the Dominican Republic.¹⁷ Although the US is the major purchaser of these countries' cigars, it is not the only country receiving these exports. Furthermore, this rule does not ban any type of tobacco product. The amount of product consolidation and exit we expect does not mean that these countries would stop exporting cigars to the U.S.

We note that, with the choice of option 1, this final rule covers all cigars. Establishment registration and product listing requirements are only immediately implemented with respect to domestic manufacturers, and FDA can only apply those requirements to foreign manufacturers by rulemaking. Other provisions, however, such as premarket review requirements, are applied uniformly without regard to foreign or domestic location of manufacture. We do not believe this violates the spirit of any trade agreement.

G. COMMENTS ABOUT THE ANALYSIS OF ALTERNATIVES:

[Comment]: Numerous comments addressed regulatory alternatives analyzed in the PRIA. Most expressed support for or discussed the legality of specific alternatives. For example, many comments expressed support for changing the grandfather date.

[Response]: We respond here to comments about the economic analysis of alternatives. See the preamble for discussions of policy issues associated with the regulatory alternatives analyzed in the PRIA and FRIA or raised by comments. We note that in the preamble FDA concluded that FDA lacks legal authority to adjust the grandfather date, which is set by statute.

[Comment]: Numerous comments recommended a wide variety of policy alternatives not analyzed in the PRIA. Suggested policies included in the comments: deem electronic cigarettes (ENDS) only for the purposes of age restrictions, warning labels, and disclosure requirements, without subjecting them to premarket review; develop a reference product for all companies to use as a predicate in SE applications; exempt electronic cigarettes (ENDS) from premarket review using "investigational use" provisions of the FD&C Act; issue marketing authorizations for non-combusted products without clinical trials; exempt products other than premium cigars; streamline product review and waive user fees for small firms; evaluate PMTAs with respect to individual consumer health rather than population health; stagger testing requirements over a longer period of time; and only deem "cigalike" styles of electronic cigarettes (or ENDS).

[Response]: These comments addressed policy issues in the rule; see the preamble to the final rule for a full discussion of the policy issues associated with the regulatory alternatives

¹⁷ The combined population was 25 million (= 8.1 million + 6.1 million + 10.4 million) in 2013.
<<http://data.worldbank.org/indicator/SP.POP.TOTL>>

suggested in comments. The economic analysis cannot present an analysis of every possible alternative. We have endeavored to assess alternatives that span the potential types of alternatives and vary along dimensions that have meaningful impacts on overall costs and benefits.

[Comment]: One comment put forth several alternatives and provided a preliminary analysis of the costs and benefits of each of them. One alternative considered is FDA taking no regulatory action. Another alternative analyzed is deeming all tobacco products, but then only applying informational provisions to the newly deemed products, thereby exempting all newly deemed products from premarket review, restrictions on youth access and free sampling, and vending machine sales. The information provisions would include establishment registration, product listing, ingredient listing, harmful and potentially harmful constituents reporting, submission of health documents, and labeling changes. A third alternative considered changing the grandfather date for newly deemed tobacco products to the date of publication of the final deeming rule. A fourth alternative would be to deem all tobacco products but only enforce premarket requirements for any products launched or modified after publication of the final deeming rule. Under this scenario, non-grandfathered products that are on the market before publication of the final rule would not require a marketing order to remain on the market, but could not serve as predicate products.

[Response]: For this analysis, “no action” is considered the baseline set of outcomes upon which this rule seeks to improve and is discussed in the need for the rule. As explained elsewhere, the preamble contains discussions of policy issues associated with the regulatory alternatives, and not all of the alternatives analyzed by the commenter are legally permissible. We analyzed an extensive list of alternatives in the proposed RIA. For the final RIA, we have analyzed a more focused set of potentially viable regulatory alternatives.

[Comment]: A commenter’s analysis of several regulatory alternatives points out that cost estimates for some provisions may change under certain alternatives because of differences in the amount of product exit and changes in the rate of introduction of future new products.

[Response]: We agree that the costs of many provisions change when the estimated amount of product exit, or the rate of introduction of future products, changes. Most of the regulatory alternatives we assess in the final RIA are not expected to significantly change product exit or the rate of introduction of future products. However, we incorporate a change in exit among ENDS products in estimating the effects of the alternative in which the premarket review compliance policy is not extended to flavored tobacco products.

H. COMMENTS ABOUT THE SMALL ENTITY ANALYSIS

[Comment]: Comments stated that the Initial Regulatory Flexibility Analysis (IRFA) was deficient. FDA did not provide adequate estimates of the number of entities that would be significantly impacted by size class or adequate estimates of how costs vary between larger and smaller businesses.

[Response]: Our analysis of effects on small entities is as comprehensive and detailed as available data allow. No commenters provided or identified data which would facilitate more

detailed analysis of small entity impacts. The data used in this analysis, however, are sufficient to generate an assessment of the burden of the final rule on small businesses.

[Comment]: Commenters stated that the RIA and IRFA do not show a compelling need for regulating premium cigars and that the economic analysis understates costs and cannot quantify any benefits.

[Response]: We discuss the need for the rule in the FRIA. We disagree that costs are understated. We explain why we do not quantify the benefits of this final rule in the benefits section of the PRIA and again in the analysis of this final rule.

[Comment]: Comments stated that FDA is obligated to minimize any significant economic impact of a rule on small entities.

[Response]: FDA is not obligated to minimize any significant economic impact of the rule on small entities. However, in both the proposed and final rules, we have described significant alternatives to the rule and their impacts on small entities. We also note that in the preamble FDA describes relief it is providing for certain small entities.

[Comment]: One commenter stated that the IRFA was deficient because “Under the RFA, an IRFA must contain: (1) a description of the reasons why the regulatory action is being taken; (2) the objectives and legal basis for the proposed regulation; (3) a description and estimated number of regulated small entities; (4) a description and estimate of compliance requirements, including any differential for different categories of small entities; (5) identification of duplication, overlap, and conflict with other rules and regulations; and (6) a description of significant alternatives to the rule.” Comments asserted that when an alternative is rejected, FDA should provide a policy or economic justification. The comment argued that an alternative discussed elsewhere in the proposed rule should also be discussed in the IRFA portion in the interest of public comment and transparency.

[Response]: The “Small Entity Effects” section of the PRIA, together with other relevant sections of the PRIA and the proposed rule serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act. While the description and estimated number of regulated small entities, estimates of compliance costs, and a description and analysis of alternatives are squarely within the purview of the economic analysis, other requirements pertaining to legal and policy analysis or justification are not part of the economic analysis and are included elsewhere in the rule; the final rule and RIA will cover all of the requirements listed in the comment. Nevertheless, in the small entity section we discussed specifically within the context of small businesses all of the alternatives that would reduce costs, even if we lacked data to fully quantify the per-entity effects. We respond here to comments pertaining to the economic analysis of impacts on small businesses. Comments pertaining to the legal basis and other non-economic requirements of an IRFA are responded to elsewhere in this regulatory package.

[Comment]: Comments stated that FDA “concedes that it has not accurately quantified all of the costs and burdens associated with extending its authority to regulate previously uncovered products.”

[Response]: To the extent that the commenter suggests that FDA did not accurately quantify costs or acknowledge where quantification is not possible, FDA disagrees. With respect to

future rules, FDA is simply stating that we cannot predict the costs or benefits of future rulemaking before the contents of the rules themselves have been established. In other instances, we acknowledge and discuss the existence of specific costs or potential costs that we could not quantify. This practice is standard in the interest of transparency and does not mean that we have not quantified costs and burdens to the fullest extent possible.

[Comment]: Comments stated that, due to inadequacies in the description of the costs of the proposed rule on small entities and the consideration of less burdensome alternatives, the IRFA is deficient and FDA should republish for public comment a Supplemental IRFA.

[Response]: We disagree that the proposed rule's IRFA is deficient or that a Supplemental IRFA should be published. We address specific issues below.

[Comment]: Comments stated that, given the scope and impact of the proposed rule, the IRFA should include more data and analysis about the economic impact. Comments asserted that the IRFA does not adequately describe and estimate the costs the proposed rule would impose on small entities, omits discussion of costs for product categories other than cigars, understates compliance costs, and uses a limited dataset that does not measure new marketplaces such as through the Internet. Comments similarly state that FDA does not recognize the disproportionate burden the proposed rule may have on small entities, that small entities do not have the same "legal resources" as larger entities, and that smaller businesses will have larger per-unit costs because many costs are fixed. Comments express concern that small businesses may not be able to use the substantial equivalence premarket pathway due to the lack of a valid predicate product or because potential, valid predicate products manufactured by other entities rely on proprietary technologies. Comments also state that small businesses, including manufacturers of cigars, premium cigars, and electronic cigarettes (or ENDS), may exit due to the prohibitive cost of premarket submission and other requirements, leading to job losses.

[Response]: The entire PRIA is relevant to the effects of the rule on small businesses. Throughout the analysis, costs for all products (including cigars) are enumerated by product type. The section specifically addressing small entities focused on cigars because cigars were the largest (by both volume and sales revenue) deemed product category and because lack of data about the number of manufacturers or the number of products precluded detailed analysis of per-entity costs for other product types. Based on online research of the burgeoning market for ENDS products, we have added some detailed analysis of the effects of this rule on ENDS manufacturers and importers and discussion of the impacts on vape shops to the final analysis of small entities.

We disagree that we underestimated costs in the PRIA. We attempted to measure new marketplaces, including the Internet. For pipe tobacco, we used a website with a very broad product offering to count the number of products offered for sale. For cigars, we used the Cigar Cyclopedia, which seeks to catalog every cigar brand actively marketed in the U.S., through any channel. We conducted Internet research to learn about ENDS products. Only for cigarette tobacco and roll-your-own tobacco, which are smaller product categories and probably less likely to be sold through specialty channels, did we rely on Nielsen data, which is limited to specific traditional retail channels. We have updated our product counts for the final rule and now use Internet sources to estimate the number of cigar products.

While some costs may indeed have a disproportionate impact on small entities, we disagree that the impact is based on access to “legal resources.” We assume this comment is referring to lack of in-house legal counsel, but the social cost of obtaining legal and regulatory advice is not dependent on whether the activities are outsourced or conducted in house.

We disagree that costs are mostly fixed with respect to business size. The user fees paid by each firm depend on market share. The other largest costs will be incurred to comply with premarket and labeling requirements; these costs depend on the number of products. To the extent that larger firms have more products, they will have higher costs than smaller firms. However, firm size depends not only on the number of products but also on the sales volume of each product. To the extent that smaller firms or firms in particular segments of the industry have relatively low sales volume per product, they will be disproportionately burdened by these fixed costs.

The analysis discusses the potential lack of predicate products for ENDS products and the potential exit of manufacturers or importers from the US market due to premarket or other requirements. FDA anticipates the availability of public dockets on uniquely identified compounds likely to be used in an e-liquid product, allowing stakeholders to submit information, including data, studies, or other files, such as data on individual health effects of inhalation exposure, animal study data examining exposure to varying levels of compounds within e-liquids, or testing the impact of temperature on changes to the aerosol constituents. This information could then be used to support applications for premarket review and to help complete HPHC testing and reporting requirements, thus potentially reducing the time for preparation of a particular application. In addition, FDA anticipates the availability and use of tobacco product master files, as discussed in the preamble and a separate guidance published concurrent with the final rule, which allows manufacturers to rely on the data and analysis submitted to FDA by separate entities. Such a system would allow for reliance on confidential or sensitive non-public information while maintaining its confidentiality, thus saving time and reducing burdens for multiple manufacturers.

[Comment]: One comment stated that “The IRFA does not fully consider significant alternatives which accomplish the stated FDA objectives and which minimize the significant economic impact of the proposal on small entities. All of the alternatives currently considered in the IRFA would only make marginal changes to the overall compliance costs to small entities, such as exempting products from labeling changes.” Agencies should consider alternatives such as: different requirements or timetables for small entities, “clarification, consolidation, or simplification” of requirements for small entities, performance rather than design standards, exemption for certain or all small entities from the rule or parts of the rule. “...[A]ll of these categories would be relevant and useful to consider as part of this rulemaking.”

The comment further asserts that, although FDA considered exempting premium cigars in the proposed rule, it did not analyze this alternative or others yielding similar cost savings in the IRFA, and that FDA did not perform a similar level of analysis for alternatives listed in the IRFA as done elsewhere for premium cigars. FDA should extend the analysis done on exempting premium cigars to other product types, including other “premium” product types.

[Response]: In the alternatives section of the economic analysis of impacts, we discuss expected changes to both costs and benefits for each regulatory alternative.

For the proposed rule, we analyzed seven alternatives that would reduce costs on some or all covered entities, most of which are small. These alternatives are of the types recommended in the Regulatory Flexibility Act. Because most affected entities are small, we analyzed cost-saving alternatives that would apply either to all entities or to sub-groups based on attributes other than size, such as product type. The alternative of extending the labeling compliance period to 36 months applies to all (including small) entities. The alternative of changing the grandfather date to the date of regulation is an example of simplifying requirements for all (including small) entities, because it would greatly reduce the number of products initially requiring premarket submissions – however, the preamble of the final rule makes clear that FDA has determined that it lacks authority to make this change. The following alternatives would exempt all (including small) entities from parts of the rule: deeming only, but exempt proposed deemed products from all labeling changes and premarket submission requirements; deeming only, but exempt proposed deemed products from all labeling changes; and deeming only (no additional provisions). The following alternative would exempt some (including small) entities from parts of the rule: enforce premarket requirements only for machine-made cigars and exempt handmade cigars from labeling changes. Finally, while considered as a co-proposal rather than a regulatory alternative, we analyzed exempting premium cigars from regulation entirely. For the final RIA, we have streamlined our list of alternatives but still include a range of types of alternatives, such as different timetables for compliance and exempting some covered entities.

We disagree that the alternatives analyzed have only a marginal impact on costs. The changes to costs for small entities appear small (for cigars) in comparison to the cost of user fees. While not a cost from the standpoint of society, user fees are a large cost from the perspective of small entities that must pay the fees.

Exempting premium cigars entirely from regulation received more prominent treatment than the other regulatory alternatives because it was the co-proposal. (In the final RIA, it is examined as a regulatory alternative to the final rule.) The number of alternatives that could be generated by combining full exemption from regulation for specific product types with across-the-board elimination of or changes to specific provisions of the rule is nearly limitless. While we could not present the costs and benefits of every possible alternative, we disaggregated costs by product type throughout as much of the cost discussion as possible. We summarized costs by provision in Tables 34a-b and by product category in Table 35. In the final RIA, we continue to summarize costs both by provision and by product category in Table 30 and Table 32. This provides a wealth of information for the interested reader to consider the approximate costs of alternatives not explicitly analyzed.

[Comment]: Numerous comments discussed the number or proportion of affected entities that would be small, including the large number of retailers that manufacture e-liquids. One commenter used more recent data to describe the number of small tobacco product manufacturers than FDA used for the proposed rule. The commenter also presents a more detailed size breakdown from the census and projects that data onto the count of manufacturers affected by the final rule. The commenter states that the vast majority of new ENDS manufacturers would be small businesses.

[Response]: Comments about the number of affected entities are discussed above. In our analyses of both the proposed and final rule we acknowledge that most affected entities are

small. We have updated the analysis to incorporate the most recent data available and have added additional size detail in describing small tobacco product manufacturing firms. We have added some discussion about ENDS manufacturers, including retailers, to our analysis of small entities.

[Comment]: A commenter asserts that the costs of providing information, such as through the ingredient listing or labeling requirements, are sizeable but likely manageable. The costs of premarket requirements could have significant impacts on small entities, in particular manufacturers of ENDS products. Nearly 70 percent of newly regulated products that exist today could exit, including nearly all ENDS products. The rule would virtually halt development of new products. Larger firms might consolidate product offerings, but smaller firms would be disproportionately affected and would exit.

[Response]: We agree that the total costs of the rule, as proposed, could have significant impacts on small entities. As described elsewhere in this document, we agree that product consolidation and exit will occur, though our estimates differ. However, we disagree that the introduction of new products will stop altogether and estimate future product introduction in the final analysis.

[Comment]: A commenter provides three alternatives which it believes meet all of FDA's stated regulatory goals without disproportionately impacting the smaller producers: include information provisions only, change the grandfather date, and enforce premarket review requirements only for products introduced after the date of publication of the final rule. The stated reason for the commenter's conclusion is that each of the commenter's alternatives exempts all products on the market as of the publication date of the final rule, but not on the market as of February 15, 2007, from having to undergo some form of premarket review. This averts what the commenter asserts is the "effective ban" of many existing products within the 24-month compliance policy period described in the proposed rule. The commenter asserts that under the alternatives provided, both large and small companies would remain to compete in the market. The commenter further provides estimates of the number of unique products in the market and the number of firms remaining under the proposed rule and the three alternatives.

[Response]: We agree that the cost of complying with premarket submission requirements for new tobacco products introduced into the market prior to the effective date of the final rule may be a driver of product exit. However, it is likely that some of the manufacturers within any particular industry segment will be able to comply with premarket submission requirements, and it is therefore unlikely that all entities or products within a segment would choose to exit. In the final RIA we update our assumptions about product exit and do not estimate potential exit of manufacturers. We do, however, forecast that most vape shops will cease to engage in mixing or other manufacturing activities, with most converting to pure retailing after the initial compliance period for submission and FDA receipt of PMTAs.

There is also substantial variation among the commenter's proposed alternatives, so the proposed alternatives may lead to more varied outcomes than the commenter suggests. For example, within the ENDS market, changing the grandfather date (an option that FDA has determined it lacks the legal authority to exercise) would allow for each product currently on the market to serve as a valid predicate product in an SE Report for a new product not yet on the

market as of the final rule’s effective date, whereas the compliance policy alternative would not. We respond to the assumptions about product exit (and entry) above.

It is important to note that something would be forfeited with each of the less costly proposed alternatives suggested. Under the information alternative, no newly deemed new tobacco products would undergo premarket review by FDA. Under both the grandfather date and the compliance policy alternatives, no newly deemed new tobacco products that are on the market as of the publication date of the final rule, would undergo premarket review by FDA.

I. OTHER COMMENTS

[Comment]: Some comments discussed the analysis of a previous FDA rule.

[Response]: This is not the appropriate forum to respond to comments about previous FDA benefit-cost analyses, as such comments are out of scope. We only respond in this document to comments that pertain to the PRIA for the proposed “Deeming” rule.

[Comment]: A comment asked FDA to announce a timeline for retrospective review of the costs and benefits of the rule.

[Response]: The timeline for potential retrospective review of the costs and benefits of this rule is beyond the scope of the prospective analysis of impacts.

III. FINAL REGULATORY IMPACT ANALYSIS

A. NEED FOR THE FINAL RULE

Millions of people use tobacco products, such as cigars, pipe tobacco, waterpipe tobacco, and ENDS, all of which would be newly deemed by this final rule. Using the National Adult Tobacco Survey in 2012-2013 and the National Youth Tobacco Survey in 2014, FDA estimates that 34.9 million adults and youth currently use newly deemed tobacco products (including e-cigarettes, cigars, tobacco pipes or waterpipe tobacco) and roll-your-own tobacco.¹⁸ With the recent, rapid growth of ENDS consumption, these products have joined cigars and pipe tobacco as the leading forms of non-cigarette use of tobacco. For example, the 2011–2014 National Youth Tobacco Surveys found that by 2014, “e-cigarettes were the most commonly used tobacco product among middle (3.9%) and high (13.4%) school students” (Arrazola et al., 2015; Agaku, et al., 2014). Data from the National Adult Tobacco Survey (2012-2013) suggest that 4.2% of adults smoke electronic cigarettes. Taken together, we estimate that 12.5 million adults and youths now use ENDS products.

Although the tobacco products newly deemed by this final rule have not been studied as intensively as cigarettes, we have enough information to know that nicotine-containing products

¹⁸ From the National Adult Tobacco Survey (NATS), we include adults who reported using products “every day”, “some day”, or “rarely” users. From the National Youth Tobacco Survey (NYTS), we include youths who used tobacco products in the preceding 30 days. We note that NATS and NYTS use the term hookah, but FDA refers to these products as waterpipe tobacco.

are addictive and can 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 (Shanks and Burns, 1998). Other studies have also found that cigars may cause chronic obstructive pulmonary disease (COPD), (Iribarren, 1999). Similarly, smoking pipe tobacco has been linked to increased risk of death from lung cancer and other smoking-related diseases (Henley et al., 2004; Tverdal and Bjartveit, 2011). A review of 22 studies from 16 different prospective cohorts found that “cigar smoking carries many of the same risks as cigarette smoking” (Chang et al., 2015). A recent review finds waterpipe use to be associated with elevated risks of cardiovascular damage, infection, and cancer (Kadhun et al., 2015). As ENDS products are new and evolving, we have limited information on their health risks. As a 2014 review of findings from 44 studies concludes, “The health impact of e-cigarettes, for users and the public, cannot be determined with currently available data” (Callahan-Lyon, 2014). As we have stated throughout the document, FDA has data regarding health harms generally associated with all of the categories of tobacco products regulated under this rule. FDA is regulating these products in accordance with this knowledge and will continue to regulate as we learn more about the potential for product-specific health harms.

At the same time, consumers’ information about the newly deemed products is imperfect in many dimensions. For more than 45 years, Congress has required textual health warnings for cigarettes on product packages. Warnings in cigarette advertising have been required since the FTC issued its 1972 consent orders and since 1984 by statute. (*See in re Lorillard et al.*, 80 FTC 455 (1972); Comprehensive Smoking Education Act, 98 (1984).) For almost 25 years, Congress has required textual health warnings for smokeless tobacco packages and advertisements. The WHO Framework Convention on Tobacco Control (FCTC) also requires health warnings on tobacco product packages (article 11) and in tobacco product advertising (article 13). The 2000 consent orders between seven cigar manufacturers and the FTC required health warnings for cigar packages and advertisements. People who consume cigars, pipe tobacco and waterpipe tobacco may recognize that consuming them entails some health risks but, such persons have misconceptions about how the risks compare to those of cigarette smoking (O’Connor et al., 2007; Cobb et al., 2010). People tend to believe that ENDS have lower health risks than combusted cigarettes, but with scientific research unsettled at this time, there is notable potential for people’s beliefs to be out of line with what the products’ health risks actually are; furthermore, data regarding the long-term health effects of ENDS products are not yet available given their recent introduction (Tan and Bigman, 2014). Moreover, producers of these tobacco products have not had to report information on ingredients or harmful and potentially harmful constituents, nor have they had to establish that their product formulations are consistent in quality. Consumers’ inability to make well-informed choices is a particular problem because tobacco products containing nicotine are addictive, and much consumption begins when people are young and are more vulnerable to developing nicotine dependence. As a result, suboptimal initial choices can be difficult to reverse over time.

The markets for the products deemed by this final rule are therefore characterized by incomplete and asymmetric information about the quality, risks, and attributes of the affected products. Market failure derived from inadequate information about product characteristics and quality leads to non-optimal levels of consumption and corresponding losses of social surplus. Unlike goods that consumers can learn about prior to purchasing or after purchasing and

experiencing them, tobacco products fall in a category known as post-experience or credence goods (Darby and Karni, 1973). For these goods, consumers are not able to determine all dimensions of quality through pre-purchase searches or through actual consumption. Health risks of consuming tobacco products are distributed within populations of consumers, so that *ex ante* individual consumers face risks they may or may not experience *ex post*. As a result, when people start consuming a product, the initial consumption experiences they have may not be reflective of the consumption experiences they will have over time, and they may only partly learn about consumption costs and risks through direct experience. In these situations, information gaps may persist even long after adverse effects are experienced by consumers. Moreover, even with the information, consumers may not fully recognize and internalize the relationship between consumption of the good and some of its effects (the addictiveness of the good, for example).

There are also public good aspects to providing information on product characteristics. Policies that reduce information asymmetry, including product regulations that require the submission of information to FDA regarding the characteristics of the product, can improve social welfare. In the current markets for newly deemed products prior to this rule, manufacturers may make unsubstantiated claims about their products. Producers may claim that their products have desirable attributes, such as reduced health risks and consistent manufacturing practices, with consumers having little basis for distinguishing what is true and what is false. Moreover, manufacturers who would like to develop products that would likely meet FDA requirements are not able to profit fully from their investments, so the average product on the market is likely to be of lower quality than would be the case in a market where information on product attributes was required to be accurate.

In addition to problems of information failures, tobacco products containing nicotine are addictive goods (HHS, 1988)—so the regulation is consistent with policy recommendations based on psychological and economic models of the consumption of addictive or habit-forming products (examples include Gruber and Köszegi (2001); Bernheim and Rangel (2004); Schelling (1978, 1984); Sloan, Smith, and Taylor (2003); and Gul and Pesendorfer (2007)). These models identify sources of intrapersonal market failures, or internalities. The psychology and economics literature suggests several sources of these intrapersonal market failures, including time inconsistency, impulsive behavior, lack of (or distorted) information salience, and effects of addiction on preferences. These sources are not mutually exclusive: addiction, for example, has been linked to all of the underlying causes of what are referred to in the economics literature as “self-control” problems. In models featuring problems of “self-control”, people’s consumption behaviors are misaligned with their preferences, and although individuals have some degree of recognition of the divergence, problems of expectations, information, time discounting, and addiction may cause their actual consumption to be persistently above its utility-maximizing level. Information requirements, such as those in this final rule, can help address such intrapersonal market failures as well as the information asymmetries we have identified.

In addition to dealing with information and intrapersonal failures, this final rule would address other distortions – including institutional failures -- in the markets for the newly deemed tobacco products. Deeming all tobacco products, except accessories of a newly deemed tobacco product, to be subject to chapter IX of the FD&C Act would 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 cigars, pipe tobacco, ENDS, and other tobacco products. Historically, when products have been taxed or regulated differently, substitutions have occurred.¹⁹

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 (Delnevo and Hrywna, 2007; 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 (Delnevo and Hrywna, 2007).

The Government Accountability Office (GAO) (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 (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, as indicated by their appearance, type, packaging, and labeling. 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.²⁰ Maintaining the status quo provides incentives for manufacturers to market new tobacco products that are not regulated by FDA under chapter IX of the FD&C Act and may induce people to switch to products that FDA does not regulate at all or does not regulate comparably. Recent years have seen the introduction of new nicotine-containing products, such as electronic hookahs, “vape sticks,” and e-liquids with fruit and candy flavorings that are not currently covered under FDA’s regulatory authorities. Consumers may use these products as substitutes for cigarettes, which are currently prohibited from containing characterizing flavors other than menthol and tobacco.

¹⁹ Taxation of tobacco products, as defined by the Internal Revenue Code, falls under the jurisdiction of the U.S. Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Under the Internal Revenue Code, TTB permits and regulates both manufacturers and importers of tobacco products. Although FDA assesses user fees on manufacturers and importers of certain tobacco products pursuant to section 919 of the FD&C Act, neither FDA’s act of “deeming” nor any other FDA regulations directly affect the taxation of any tobacco product, nor do FDA regulations affect which businesses are subject to TTB jurisdiction under the Internal Revenue Code.

²⁰ 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.

Finally, cigars, pipe, and waterpipe tobacco generate second-hand smoke, imposing costs on society external to production and consumption decisions. Although we do not have estimates of the extent to which individuals are exposed to second-hand smoke from these products, the Surgeon General has determined that there is no risk-free level of exposure to second-hand smoke (HHS, 2006). Studies also indicate that both nicotine and other toxicants are found in the exhaled aerosol of some ENDS (e-cigarettes and similar electronic devices) (Etter et al., 2013; Kim and Shin, 2013; Hutzler et al., 2014; Goniewicz et al., 2014; Ohta et al., 2011; Uchiyama et al., 2010), although the exhaled aerosol is potentially less hazardous than secondhand smoke from combusted tobacco products (Goniewicz et al., 2014). These potential negative externalities, therefore, would represent an additional well-established market failure that provides an economic rationale for regulation of these products.

B. BENEFITS

This final rule is deeming products meeting the statutory definition of “tobacco product,” except for accessories of the newly deemed tobacco products, to be subject to chapter IX the FD&C Act, as amended by the Family Smoking Prevention and Tobacco Control Act. Asserting our authority over these tobacco products will also enable FDA to take further regulatory action in the future as appropriate for the protection of public health. These further regulatory actions would be expected to yield benefits in turn. The rule will enable FDA to determine the number of regulated entities, establish effective compliance programs, and monitor the number and types of products that are being marketed to the public. It will also authorize the agency to take enforcement action against adulterated or misbranded products, reducing the potential public health dangers of such products. By asserting authority over all products that meet the statutory definition of tobacco product (except for accessories of the newly deemed tobacco products), FDA will also be correcting any possible misperception that, because certain tobacco products are not regulated, they must be safe. In addition, this rule contains warning statement requirements that also apply to roll-your-own tobacco and cigarette tobacco.²¹ FDA’s detailed review of the non-quantified benefits concludes they would justify the costs.

Reliable evidence on the impacts of warnings labels, premarket review, and marketing restrictions on users of cigars, pipe tobacco, waterpipe tobacco, and ENDS does not, to our knowledge, exist. Estimating the effects of the final rule on users of these products would require extrapolating from the experience of other products and other regulations that provide similar information sets and institutional changes. This extrapolation would also require evidence on the baseline practices, knowledge, and attitudes toward risk of current and potential users of newly deemed products. Nonetheless, the degree of market failure would be reduced with better-informed consumers.

In general, the welfare gains of this rule would be equal to the value that affected individuals attribute to mechanisms that better align consumption and production decisions with socially optimal patterns. In what follows, we describe how specific provisions of the rule could generate benefits in this respect.

²¹ Given the similarities between roll-your-own tobacco and cigarette tobacco, we use roll-your-own tobacco throughout the FRIA to refer to both.

1. YOUTH ACCESS RESTRICTIONS, PROHIBITION ON FREE SAMPLES, AND VENDING MACHINE RESTRICTIONS

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 (ERG, 2011). However, the definition of “tobacco products” varies among states; in most states, until recently, the term has applied to products such as cigars and pipe tobacco and did not explicitly apply to all covered tobacco products (*i.e.*, newly deemed products other than components or parts that are not made or derived from tobacco). In response to the introduction of ENDS products, most states have passed legislation in recent years that prohibits sale of e-cigarettes to minors; data compiled by the U.S. Centers for Disease Control and Prevention indicate that 46 states had passed such legislation as of September 2015 (CDC, 2015). As such, in some states, minors continue to have retail access to some covered tobacco products, such as ENDS, that are not currently the subject of age restrictions. In addition, definitions of tobacco products covered by state laws are not uniform across states (NCSL 2015).

By deeming ENDS and the other tobacco products to be subject to Chapter IX of the FD&C Act and promulgating the additional provisions, the rule extends the restrictions on youth access to these types of tobacco products to all states and the District of Columbia and provides a common definition of the products to be covered by these restrictions. Establishing a consistent national framework for restricting sales to minors is foundational to building and maintaining compliance with sales restrictions by tobacco product retailers. Standard nationwide enforcement across tobacco products will reduce ambiguity about enforcement of youth access restrictions for tobacco products. In addition, the final rule will enable FDA to extend its enforcement activities to cover restrictions on sales of newly deemed products to minors. Without the final rule, FDA’s enforcement activities would remain confined to enforcing restrictions on sales to minors of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products, whether or not state laws restrict sales of other products to youth. The final rule enables FDA to extend its enforcement activities to cover sales of all types of tobacco products, including e-cigarettes, to youth. By establishing a common definition of tobacco products and enabling FDA to extend its enforcement activities to cover deemed products, the final rule will support effective enforcement of restrictions on sales of tobacco products to minors. Improved effectiveness of sales restrictions can be expected to result in health benefits by curbing sales to youth and reducing regular tobacco use by youth. In turn, preventing youth from taking up consumption of tobacco products yields longer lives in better health for youth deterred from starting.

Existing regulations prohibit the distribution of free samples of any tobacco product except for smokeless tobacco samples when distributed in a qualified adult-only facility in accordance with 21 CFR § 1140.16. This provision automatically applies to newly deemed tobacco products. Prohibiting free samples eliminates a pathway to tobacco products for youth. As the Institute of Medicine (IOM) has concluded (1994), free samples of cigarettes “encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity.” A review of evidence by FDA also found that free samples of tobacco products “offer young people easy and inexpensive access.” (61 FR 44396). Although available research on free samples pertains to cigarettes, as discussed in the deeming proposed rule (79 FR 23149) and final rule (81 FR 28973), FDA believes that the same rationale applies to the newly deemed products.

With the growth in the use of ENDS, particularly by youth and young adults, a free sample prohibition is expected to remove this potential stimulus to uptake of consumption of tobacco products, with resulting health benefits.

In accordance with the final rule, covered tobacco products may only be sold in vending machines if the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time. Studies show that youth are able to access tobacco vending machines, and, therefore, vending machine restrictions are important in preventing youth from gaining access to these products. This provision closes a regulatory loophole and could prevent future substitution effects (i.e., increased purchase of newly deemed tobacco products from vending machines when other retail access is prohibited). Given that vending machine sales have been dwindling in recent years, the scope for this provision to reduce youth access is small. However, if in the absence of the final rule future years were to see an expansion in vending machine sales of newly deemed products, this prohibition would have a larger public health benefit than the one described here.

2. ADDITION OF HEALTH WARNING STATEMENTS TO NEWLY-DEEMED AND CERTAIN OTHER TOBACCO PRODUCTS AND RESTRICTIONS AGAINST MAKING FALSE OR MISLEADING PRODUCT CLAIMS

The rule requires certain warning statements, containing factual and accurate information, be added to product packaging and advertising for covered tobacco products, as well as for cigarette tobacco and roll-your-own tobacco. For all covered products, the required warnings state that: “This product contains nicotine. Nicotine is an addictive chemical.” Cigar warning statements will additionally provide specific information on health risks known to be associated with cigar smoking (including certain cancers, cardiovascular disease, and effects on those exposed to secondhand smoke).²² The addition of warning statements for products that have not been required to carry them to date may reduce misconceptions about their health risks and addictiveness.

Including this information on product packaging and advertising increases the amount of information about products’ health risks and addictiveness that is available to consumers and helps consumers understand and appreciate the risks of using tobacco products. This could improve their ability to make well-informed choices. Improved information is of value to consumers whether or not it changes their behavior, as having an accurate informational basis for gauging the consequences of one’s consumption choices is itself welfare-improving. In addition, improved information on health risks and addictiveness is expected to help reduce consumption.

The rule also authorizes FDA to take enforcement against those who sell or distribute newly deemed tobacco products with false or misleading claims on their labeling or advertising or unsubstantiated modified risk tobacco product (MRTP) claims, thus allowing for better-informed consumers and helping to prevent the use of misleading campaigns targeted to youth populations. Prohibiting such claims helps ensure that the informational basis on which people make decisions about consuming these products is consistently accurate. Prohibiting

²² See sections 903(a)(2), 920(a) and 911 of the FD&C Act for additional labeling requirements.

unsubstantiated modified risk tobacco product (MRTP) claims will prevent consumers from being misled about the relative risks of the products.

3. PREMARKET AUTHORIZATIONS

Manufacturers of newly deemed products that are “new tobacco products” will be required to obtain premarket authorization of their products through one of three pathways—substantial equivalence, exemption from substantial equivalence, or premarket tobacco product applications. The requirement of premarket review leads to fewer harmful or addictive products reaching the market and acts as a mechanism to inform consumers about these attributes of products entering the market. Thus, with the final rule, health risks of products within deemed categories can be expected to be lower than would have been the case without the final rule.

FDA's premarket review of the newly deemed products will increase product consistency. For example, FDA's oversight of the constituents of e-cigarettes cartridges would help to ensure quality control relative to the chemicals and their quantities being aerosolized and inhaled. At present, there is significant variability in the concentration of chemicals amongst products--including variability between labeled content and concentration and actual content and concentration. The health consequences of these products are still largely unknown and the popularity of these products is growing exponentially (Arrazola et al. 2015). Without deeming these products subject to FDA's tobacco authorities, users who expect consistency in these products may instead be subject to significant variability in nicotine content among products, raising potential public health and safety issues.

Through premarket review, FDA will also monitor product development and changes and prevent more harmful or addictive products from reaching the market. Monitoring product development and changes will be beneficial because FDA will be able to keep products with attributes newly identified as harmful off the market, reducing user exposure to such attributes in a timely way.

4. CHANGES IN DEMAND ACROSS AND WITHIN CATEGORIES OF TOBACCO PRODUCTS

A potentially important issue in describing potential benefits of the deeming rule concerns shifts in demand across and within categories of tobacco products. In the categories of combusted tobacco products – cigars, pipe tobacco, waterpipe tobacco, roll-your-own and cigarette tobacco – the possible changes in behavior that could generate benefits include reductions in use, switching to less risky products, and compensating health behaviors.

Estimating benefits associated with ENDS and other novel non-combusted products, however, is more complicated and uncertain.²³ Their use has been rising rapidly in recent years, with numbers of delivery systems and varieties of e-liquids proliferating at extraordinary rates.

²³ Our discussion of health and welfare effects of ENDS would also apply to other novel non-combusted tobacco products, such as certain nicotine gels. We focus on ENDS because they are the most widely used novel non-combusted product.

The effects of the deeming rule have to be measured relative to what would be expected to happen to consumption in the absence of the rule. Yet the novelty of product offerings and the fact that preferences for them are only just emerging make it difficult to project how demand for them will evolve in the years ahead. Potentially, the extraordinary growth in use of ENDS products could level off in years ahead, with their prevalence of use remaining in a range similar to other non-cigarette tobacco products. Yet some analysts predict prevalence will continue to grow, so that ENDS will eventually come to rival traditional cigarettes in popularity.

In a broad sense, because producers of ENDS products would need to incur sizable costs to be able to continue selling their products, we can expect the deeming rule to reduce the number of distinct ENDS products available on the market, relative to what would have been observed in the absence of the rule. However, chances are good that numbers of distinct ENDS products would fall anyway in years ahead, as competition causes consolidation of sales in the most popular product lines; as a result, the change caused by the rule has to be measured against an inherently dynamic counterfactual. For present purposes, an important point is that, although numbers of distinct ENDS products are expected to decline as the final rule takes effect, FDA expects that a range of delivery systems and e-liquids will remain available to consumers.

The direction of the deeming rule's effects on ENDS consumption in terms of health and welfare depends on several questions for which answers are currently highly uncertain:

- Relative health effects. If consumption of ENDS products entails individual health risks that are more moderate than those of other tobacco products, it is possible that, if provisions of the rule tend to discourage their use disproportionately, any ongoing improvements in population-level health risks associated with changing patterns of use of tobacco products could potentially be reduced.
- How the deeming rule's provisions would affect demand for ENDS products. If the rule's restrictions on youth access to ENDS dampen growth in their prevalence of use among young people, the rule will have health benefits for those dissuaded from starting to use them. The decline in the variety of ENDS products could have the same effect. In addition, it is possible that ENDS products may face relatively high costs of meeting premarket review requirements. If cost increases are passed along to consumers, and this tends to increase the relative price of ENDS products, it may reduce consumption of ENDS products, with potential health consequences.
- Whether the deeming rule's provisions induce shifts in demand across tobacco products. If the rule increases prices of ENDS products relative to those of other tobacco products, the rule could shift demand to other tobacco products that may act as substitutes for ENDS. There is currently limited research available to predict whether higher prices or other effects of the deeming rule may induce substitution into other tobacco products. Research estimating a system of demand equations for tobacco products does not suggest higher prices of ENDS products would cause demand for combusted products to rise (Zheng et al., 2014). A study by Friedman (2015) found that states that enacted early bans on sales of ENDS products to minors may have seen downtrends in youth smoking of combusted cigarettes slow after bans were enacted. Although some have interpreted this finding as providing evidence that e-cigarettes and combusted cigarettes are substitutes for each other, and that

policies that regulate e-cigarettes could increase consumption of combusted tobacco products, such conclusions are not supported by the study. The study examines adolescent smoking only, giving no insight into substitution issues in the adult population; experimentation and incidental use are common in the adolescent population but rare among adults. The study included a number of caveats clarifying that its evidence is suggestive only. Because the state-level data used in the study tracks cigarette smoking only, it cannot establish whether state-level bans caused youth to switch out of ENDS products and into combusted products, only that smoking of combusted products rose relative to what would have been expected when bans were imposed. The study used any cigarette consumption in the past 30 days as a measure of smoking, which captures experimentation and intermittent use as well as regular smoking and may not capture increased regular smoking. The study examines a period very early on in the development of the market for ENDS products, which may limit the inferences that can be drawn for substitution patterns that will emerge as the market matures. Finally, states that enacted early bans tended to have much lower adolescent youth smoking rates to begin with as compared to states that didn't enact bans early; therefore, the leveling off in smoking rates may be a result of other reasons. Given these issues, FDA acknowledges this paper as providing some early insights into possible substitution patterns among adolescents, but does not rely on it as evidence of product switching.

5. WILLINGNESS TO PAY FOR BENEFITS OF RULE

We have described the effects of this final rule as potentially coming from:

- premarket review, which will result in fewer harmful or addictive products from reaching the market than would be the case in the absence of the rule;
- youth access restrictions and prohibitions on free samples, which can be expected to constrain youth access to tobacco products and curb rising uptake;
- health warning statements, which will help consumers understand and appreciate the risks of using tobacco products;
- prohibitions against false or misleading claims and unsubstantiated MRTP claims lead to better-informed consumers and help prevent the use of misleading campaigns targeted to youth populations;
- other institutional changes, such as FDA monitoring of product developments and changes and required ingredient listings, which will enable FDA to propose more informed regulations appropriate for the protection of the public health.

As discussed above, we cannot quantify the benefits of the final rule due to lack of information and substantial uncertainties associated with estimating its effects. Nonetheless, the welfare gains to affected individuals could be estimated from data on the willingness to pay for the policy instruments embedded in the rule. The fundamental measure of an increase in societal welfare is people's willingness to pay for the change. As discussed in the Office of Management

and Budget’s Circular A-4, “[t]he principle of “willingness-to-pay” (WTP) captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit.” The value of the rule to the affected individuals, as measured by their willingness to pay, reflects the effects of any behavioral and health changes that result from the rule’s provisions.²⁴ In principle, consumers’ willingness-to-pay reflects the value of health benefits they experience from the rule, net of any costs they bear which could potentially include utility offsets to health gains.²⁵ The market failures associated with addictive goods and problems of asymmetric and imperfect information make it difficult to directly infer willingness to pay for the benefits of this rule from market behavior. The willingness-to-pay for this rule would therefore have to be inferred from indirect or adjusted measures of the implicit value of health benefits net of any consumer costs. This willingness-to-pay approach avoids specifying specific responses to changes in information and product characteristics due to the rule, and is equally applicable to effects associated with combusted tobacco products and ENDS products.

C. COSTS

The final rule deems products meeting the statutory definition of “tobacco product,” except for accessories of the newly deemed tobacco products, to be subject to chapter IX of the FD&C Act, as amended by the Family Smoking Prevention and Tobacco Control Act. It will create new burdens for some domestic manufacturers of tobacco products, as well as for some foreign manufacturers or importers.²⁶ Several reports or submissions of information to FDA will occur 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 final rule also establishes three restrictions for covered tobacco products—requirements for minimum age of purchase, requirements for health warnings for product packages and advertisements (which FDA is also applying to cigarette tobacco and roll-your-own tobacco), and the prohibition of vending machine sales, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time. These three provisions will affect retailers in addition to manufacturers and importers.

1. NUMBER OF AFFECTED ENTITIES

a) Manufacturers and Importers

²⁴ See (Rousu and Thrasher, 2014) for an example of a willingness-to-pay for information approach to estimating the welfare gain from tobacco regulation.

²⁵ We use the term “consumers” in the economic sense to capture all members of society affected by the rule, not limited to users of any tobacco products.

²⁶ Certain provisions of chapter IX of the FD&C Act and its implementing regulations would automatically apply to the newly deemed products, as described in the preamble to the final rule.

Based on aggregate information obtained from the Alcohol and Tobacco Tax and Trade Bureau (TTB), in 2013 there were 113 domestic manufacturers of cigars, 216 importers of cigars, 74 manufacturers of pipe (including waterpipe) tobacco, and 43 importers of pipe (including waterpipe) tobacco. The baseline number of manufacturers and importers of ENDS products is uncertain.²⁷ Some public comments referenced the Smoke-Free Alternatives Trade Association in stating that there are over 1,200 ENDS manufacturers. Many of these manufacturers, however, are believed to be smaller, informal participants in this market; in describing the current landscape in the ENDS industry, an industry survey respondent wrote, “Too many companies are making e-liquid in their kitchens/bathrooms,” (Herzog et al., 2014a). We do not have reliable counts on these informal producers but we expect that few if any of them will continue to manufacture after this final rule takes effect.²⁸ We therefore restrict our analysis to those we call the formal manufacturers in this market. Based on logo counts from trade association websites and information from FDA listening sessions, we estimate that there are 168 to 204 formal manufacturers of ENDS products; we use this range for the quantitative analysis. We acknowledge that the total, including informal manufacturers, may be far greater. Using the same logo counts from trade association websites and information from FDA listening sessions, we also estimate that there are 14 importers of ENDS products. Due to lack of data, we are unable to estimate the number of manufacturers and importers of smaller product categories, such as nicotine gels, affected by the deeming action.

Based on aggregate information from TTB, 21 manufacturers and 18 importers of roll-your-own tobacco will be affected by the health warning provisions of this final rule. We do not have data to estimate the number of cigarette tobacco manufacturers or importers that will also be affected by the health warning provisions of this rule.

Therefore, we estimate 376 to 412 manufacturers and 291 importers will be affected by this final rule. However, summing the manufacturer and importer counts obtained from TTB overcounts establishments that produce multiple types of affected tobacco products or engage in both manufacturing and importing of affected products because an establishment is counted for each type of tobacco product it manufactures or imports. (For example, TTB estimates that there are 135 manufacturers and 200 importers in total, including both currently regulated products and newly deemed products except for ENDS.) Not taking the overlap into account overestimates the costs for some activities.

In addition to establishments specifically engaged in manufacturing, retailers may meet the definition of tobacco product manufacturers if they manufacture, fabricate, assemble, process, or label a tobacco product. Vape shops that engage in e-liquid manufacturing and mixing are perhaps the most prominent example. Based on public comments, news articles, and industry reports, we estimate that there are approximately 5,000 to 10,000 vape shops; we assume that 70

²⁷ ENDS products that do not contain tobacco do not satisfy the definition of “tobacco products” in the Internal Revenue Code, and, therefore, are not subject to tax under the Internal Revenue Code. Accordingly, TTB does not collect information about the number of ENDS manufacturers and importers. The term “tobacco product” is defined differently in the IRC and the FD&C Act.

²⁸ The costs of exit by informal manufacturers are expected to be small due to low levels of investment in specialized capital and skills.

percent of them, or 3,500 (=70%*5,000) to 7,000 (=70%*10,000), currently engage in manufacturing activities (Burke, 2015).

Some manufacturers or importers may cease to sell products in the U.S. rather than bear the cost of complying with this final rule. In particular, some low-volume cigar or ENDS manufacturers and importers may cease to offer their products in the U.S. We note foreign producers may not necessarily cease to operate; rather, they may reduce the number of products they sell in the U.S. or cease to sell their products in the U.S. We do not estimate the amount of potential exit among manufacturers and importers.

As a result of this final rule, retailers who currently meet the definition of manufacturer may cease to engage in manufacturing activities. Although we have not estimated entity exit, we assume the proportion of vape shops that continue to prepare some mixtures that they prepared and offered for sale as of the effective date may fall (from the baseline proportion of 70% who currently mix as some part of their business) during the initial compliance policy period for submission and FDA receipt of PMTAs. To reflect uncertainty about the extent of the decline, we assume that the share of vape shops that continue to mix during the initial compliance policy period could drop to as low as 30% or could remain as high as 70%; thus, the number of businesses that we estimate will continue to mix during this period could be as low as 1,500 (=30%*5,000) or as high as 7,000 (=70%*10,000) shops. After this initial compliance policy period, we further assume many vape shops will continue to operate, with those that have not already switched to pure retailing doing so at this time.

Table 4 summarizes information about the types of manufacturers and importers affected by this final rule.

Table 4—Number of Tobacco Product Manufacturers and Importers Affected

Domestic Manufacturing Establishments:	
Cigars	113
Pipe (including waterpipe) tobacco	74
ENDS ¹	168 to 204
Roll-your-own tobacco	21
Total	376 to 412
Retailers that engage in manufacturing:	
Vape Shops	3,500 to 7,000
Importers:	
Cigars	216
Pipe (including waterpipe) tobacco	43
ENDS	14
Roll-your-own tobacco	18
Total	291

¹ We acknowledge that the total number of ENDS manufacturers including informal manufacturers may be significantly greater at baseline.

b) **Retailers**

Compliance with the applicable warning statement provisions requires the removal of non-compliant point-of-sale advertising 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. It is also possible that decreased

consumer demand of products due to diminished product variety or preferred product types may result in reductions in retailers' total revenues.

We use data from the 2012 Economic Census report on preliminary product line sales of establishments that sell tobacco products (2012 Economic Census Retail Trade, 2012 Economic Census Accommodation and Food Services).²⁹ 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 as for establishments with payroll (2012 Nonemployer Statistics). We add an additional category for specialized ENDS retailers because their recent proliferation would not be captured by the 2012 Economic Census. As shown in Table 5, an estimated total of 357,273 to 362,273 retail establishments currently sell tobacco products.

Table 5—Baseline Establishments that Sell Tobacco Products

Type of Business	NAICS	Establishments With Employees ^a			Nonemployer Establishments ^b		Total Number of Establishments
		Number	Number Selling Tobacco Products	Percentage Selling Tobacco Products	Number	Estimated Number Selling Tobacco Products	
General merchandise stores	452	49,248	18,494	38%	36,297	13,631	32,125
Food & beverage stores	445 excluding 44512	121,033	59,752	49%	107,875	53,256	113,008
Convenience stores	44512	26,531	22,880	86%	E		22,880
Gasoline stations with convenience stores	44711	97,181	89,647	92%	E		89,647
Gasoline stations	44719	17,042	4,715	28%	8,732	2,416	7,131
Health & personal care stores ^c	446	92,505	15,504	25%	145,847	36,584	52,088
Other retail stores	d	538,222	2,017	0.37%	759,645	2,847	4,864
Accommodation	72	620,765	4,351	1%	310,841	2,179	6,530

²⁹ For NAICS 446: Health and Personal Care stores, we exclude 7,700 CVS retail pharmacies from the count of employer establishments that sell tobacco products (2012 Economic Census Retail Trade). CVS stopped selling tobacco products that would be covered by this proposed rule in September 2014 (<http://www.cvshealth.com/research-insights/health-topics/were-tobacco-free>). However, we do not know of a broader shift outside of CVS in this NAICS category ending sales of tobacco products. Therefore, we include CVS retail pharmacies to calculate the percentage of employer establishments that sell tobacco products and apply this percentage to nonemployer establishments.

and food services	excluding 7224						
Drinking places	7224	41,722	5,441	13%	29,929	3,903	9,344
Tobacco stores	453991	8,937	8,937	100%	E		8,937
Non-store retailers	454 excluding 4542	59,536	359	1%	796,097	4,800	5,159
Vending machine operators	4542	4,155	87	2%	22,572	473	560
Specialized ENDS Retailers (vape shops) ^f							5,000 to 10,000
Total		1,676,877	232,184	14%	2,217,835	120,089	357,273 to 362,273

^a Sources: 2012 Economic Census: United States: Retail Trade: Industry Series: Preliminary Product Lines Statistics by Industry for the U.S.; 2012 Economic Census: United States: Accommodation and Food Services: Industry Series: Preliminary Product Lines Statistics by Industry for the U.S.

^b Source: 2012 Nonemployer Statistics.

^c Estimated number of employer establishments selling tobacco excludes 7,700 CVS retail pharmacies; percentage selling tobacco is calculated including CVS retail pharmacies.

^d Includes NAICS 441, 442, 444, 448, 451, 453 excluding 453991

^e Data on nonemployer establishments unavailable for this NAICS category

^f We add an additional category for specialized brick and mortar ENDS retailers (vape shops), because the 2012 census would not have captured their recent proliferation.

2. NUMBER OF AFFECTED PRODUCTS

a) Baseline Number of Products

Many costs of this final rule depend on the total number of affected products, estimated as the number of unique product formulations or product-package combinations, recognizing that these numbers may be an under- or overestimate of the number of products with respect to certain regulatory requirements that result from this rule. (The number of product-package combinations exceeds the number of product formulations because the same product can be packaged in multiple ways.)

Among the types of products affected by the final rule, estimating the baseline number of cigar products is especially difficult. There are no generally accepted statistics on cigar counts, and a widely used comprehensive private source of data has not been published since 2010. The data source for the cigar product counts in the preliminary regulatory impact analysis was Perelman's Pocket Cyclopedia of Cigars (Perelman, 2010). Published between 1995 and 2010, this was a compendium of cigar brands and products that was a widely-consulted reference for cigar manufacturers, retailers and smokers. The PRIA used the 2010 version of the Cyclopedia as the source of the estimates for cigar products. That source showed the number of cigar brands to be 1,473, and numbers of product formulations and product-package combinations to be 11,169 and 11,449 respectively. That number is outdated, however, and the year-to-year fluctuations in the number of cigar products shown in past editions of the Pocket Cyclopedia demonstrate that the 2010 count may not be accurate now. Over the 15 years that the Cyclopedia was published, the number of brands fluctuated, falling from 1,448 in 1999 to 1,002 in 2004, then rising again to

1,473 in 2010. We therefore need to rely on current information for a cigar count, using resources that are publicly available.

We have looked at several prominent sources of data, including Nielsen scanner data, internet retailers with large product selection (cigarsinternational.com and pipesandcigars.com), and a cigar-community website that compiles information on available cigars (cigarageeks.com). The counts available from these sources range from roughly 3,465 cigar universal product codes (UPCs) sold in outlets tracked by Nielsen scanner data (2012-13), to tens of thousands of cigars listed on cigarageeks.com. For reasons discussed below, those numbers are respectively under-inclusive and over-inclusive for purposes of producing an overall count to enable an accurate assessment of likely costs of the deeming rule. As we will explain, for this purpose, we think the most relevant point in the range of potential cigar counts is around 7,500 products.

A data source that is often used for product counts is retail scanner data compiled by Nielsen. The Nielsen data tracks sales of products sold through food, drug, mass merchandise, and convenience stores across the U.S., using detailed product codes. The Nielsen data are not well-suited to estimating numbers of cigar products, however. The data cover a subset of outlet types and in particular do not cover specialty retailers like tobacco stores. The mix of products carried in stores in the Nielsen data provides good coverage of machine-made cigars and high-volume hand-rolled brands, but will not cover lower-volume hand-rolled and premium cigar products. As a result, the 3,465 UPCs found in the Nielsen data clearly undercount the possible number of products.

Another potential method is to compile data from well-known internet retailers that carry a large selection of cigars. Such retailers carry both the high volume products found in Nielsen outlets, as well wide selections of hand-rolled products. The information they provide to consumers systematically identifies cigar brands, sizes available per brand, and package combinations per brand/size combination, providing the detailed information that is needed to estimate the baseline number of products that would be subject to premarket review as a result of the deeming rule.

In fall of 2014, FDA staff counted the numbers of cigar product formulations and product-package combinations available for sale via two well-known websites, cigarsinternational.com and pipesandcigars.com.³⁰ The product offerings of the two websites were very similar, though not identical. It was not straightforward to match products across sites, due to difficulties determining whether a given product sold on one site was identical to one sold on the other, or just very similar, from the product descriptions given on retailer websites (for example, a product may be listed as “Brand X Holiday Blend” on one site and “Brand X Holiday Blend 2014” on the other). As a result, rather than trying to build a single roster of unique products and product-package combinations, FDA staff counted products on each site and treated the totals as independent estimates of the number of widely available cigar products actively marketed in the U.S. -- expecting this to provide good representation of the parts of the market for cigar products likely to be grandfathered or submitted for premarket review.

³⁰ These sites were identified by first compiling a list of about 10 sites that were either mentioned in lists of top online cigar retailers published on cigar websites, or came up in internet searches of online cigar retailers. About half of these sites carried numbers of brands clearly well below the ranges found in annual editions of the Cigar Cyclopedia. For the remaining sites, we counted the number of brands carried. The two sites used for our product count, cigarsinternational.com and pipesandcigars.com, had hundreds more cigar brands than the other sites.

On both sites the number of cigar brands offered was just below 1,100 (1,070 and 1,095 respectively); we took 1,100 as the central estimate of the number of brands from this method. On the site that had a larger number of products per brand, the number of products per brand was 4.4; we multiplied this number by the number of brands and rounded up to estimate the total number of products as 5,000. In turn the average number of product/package combinations per product on this site was 1.5, implying a total number of product/package combinations of 7,500. The estimate of 1,100 brands falls with the 1,000-1,500 range from the annual brand counts from the Pocket Cyclopedia. A disadvantage of the use of the Internet sites carrying a large variety of products is that it omits cigar products sold only through traditional retail outlets or through other venues. Nonetheless, for reasons given below, we use these numbers as the basis for our estimates of baseline numbers of cigar products for projecting effects of the deeming rule.

Alternatively, one could make use of data from a cigar-community website such as cigargeeks.com. This website compiles information on cigar products from cigar smokers and producers, in the interest of making information on cigar products widely available and providing cigar smokers with chances to exchange information on their product perceptions. On the site, cigar users and producers can enter basic information on cigar products by brand and size; people who run the website check entries before adding them to the data base; then users can rate cigars and leave comments on them. It is not clear when this particular website was created. Comments on products go back to 2007.

As of December 2015, the cigargeeks.com database contained entries for 42,000 products. However, this number will overstate the total number of cigars available to consumers in the U.S. at any given time for two reasons. First, cigargeeks.com does not remove products that have gone off the market from its database. The cigar market sees relatively high product turnover as seasonal and special products enter and exit the market, and cigar makers adjust their product lines. Without removing products that have gone off the market from the data, the number of entries will exceed the number of products currently sold by an amount that increases over time. Second, the website does not restrict entries to products available to consumers in the U.S., so its counts could include cigars produced in other countries or the U.S. but not sold in the U.S. market.

Nonetheless, the cigargeek.com data can provide some insight into the potential extent of understatement of product counts that might result from using information from large internet sites, because it can be used to find brands that are currently sold in the U.S. not carried on those sites. To do this, we examined a specific portion of the alphabetized list of brands carried on cigarsinternational.com in December 2015 and compared the brands shown on that site to those shown on cigargeeks.com at that time. Cigargeeks.com had many (but not all) of the brands available on cigarsinternational.com, as well as others not available on that site. Many of the brands found on cigargeeks.com that were not found on cigarsinternational.com did not appear to be available for sale on the internet, although it is not possible to rule out that they are available for sale in tobacco shops. This exercise suggested that the number of brands available for sale in the U.S. may be 25-30% higher than the 1,100 identified from the count of internet retailers. This would imply a total brand count of 1,375-1,430, a figure that is somewhat below the Cigar Cyclopedia count of 1,473 for 2010. However, these estimates come from undertaking an exploratory comparison of the two data sources, based on a limited sample. A more

comprehensive data-collection exercise would be required to be able to quantify the potential undercounting of the baseline number of cigar products currently for sale in the U.S. associated with estimating the total from the large internet retailers.

Given the difficulties with reliably estimating the magnitude of possible understatement from using the counts from the large internet retailers, we opt to use the estimate of 7,500 products, acknowledging its potential for undercount but expecting that it provides good representation of the parts of the market for cigar products likely to be grandfathered or submitted for premarket review. As discussed below, the costs of undergoing premarket review are expected to be relatively low for cigar products that seek marketing authorization through the substantial equivalence or exemption from substantial equivalence pathways.

At the same time, we note that staying on the market entails costs. These will be higher for some existing products than for others. We expect that cigar makers will evaluate the sales levels of their various brands, products and product-package combinations and consider submitting applications for premarket review for those products with relatively high sales levels. This, in turn, will likely lead to an overlap between products more likely to be omitted from the 7,500 product count and products for which applications for premarket review will not be submitted. These include products with low sales values, products with small-batch production runs, and low-volume products sold only in specialty retail outlets or other channels. We expect such products will exit the market as a result of this rule.

To develop a lower bound estimate of the number of pipe tobacco formulations and product-package combinations, we count the products on a web site with a broad product offering, <http://www.pipesandcigars.com/>³¹. We estimate formulations with the number of the distinct product names and product-packages with the number of distinct product-package combinations, which yields an estimated 900 pipe tobacco formulations and 1,100 pipe tobacco product-package combinations.³² Similarly, we estimate based on this website that there are at least 4,610 different types of pipes. This count excludes handcrafted pipes.

Based on a study that identified products for sale on many web sites, we estimate that there are 779 unique hookah (shisha) products (Morris, 2013). Assuming there are 1.25 times as many product-packages, we estimate there are 974 product-packages. Based on one of the websites included in the study by Morris, www.hookah-shisha.com, we estimate that there at least 520 different types of waterpipes.

This final rule would also extend the FD&C Act tobacco authorities to tobacco products that do not fit into traditional product categories, such as ENDS and nicotine gels. We are unable to quantify the costs for novel tobacco products other than ENDS due to lack of data.

³¹ Nielsen also provides estimates for the number of pipe tobacco UPCs sold through Nielsen channels. Using this data, we estimate that there are 337 pipe tobacco UPCs. Currently, 22 percent of smoking tobacco sales volume (pipe and roll-your-own) takes place through specialty tobacco retailers (Euromonitor, 2014b). Therefore, we use other sources of data to estimate the baseline number of pipe tobacco products.

³² 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 include only products listed as in-stock as of October 2014.

Zhu et al. (2014) estimate that there were 466 unique brands and 7,764 unique flavors (“in the sense of unique linguistic labels for flavor”) of ENDS products on the market in January 2014. The authors’ research method described is aimed at determining the number of linguistically unique flavors without regard to brand or product name, but the number of distinct ENDS products is expected to exceed the number of unique flavor names. To the extent that brands (or sub-brands) differentiate their flavor names (i.e., wild blueberry vs. harvest blueberry), the reported flavor count would accurately represent brand-flavor combinations. To the extent that brands do not differentiate basic flavor names, the reported flavor count would underrepresent brand-flavor combinations. For example, if both Brand X and Brand Y market a flavor called “blueberry,” the products would share a single flavor name but would be considered different products because the different brand names render them distinct.³³ We are unable to identify the extent to which the number of flavors understates the number of brand-flavor combinations. In addition, many brand-flavor combinations come in varying nicotine strengths. Considering brand-flavor-strength combinations, if Brand X sells “blueberry” in 3 nicotine strengths, while Brand Y sells “blueberry” in 4 nicotine strengths, there would be 7 distinct products. Zhu et al. report the average number of strengths per brand website, but the average number of strengths per flavor (or brand-flavor combination) is not reported. We are also unable to determine how many of the flavors identified by Zhu et al. are in the form of e-liquids, delivery systems sold with a liquid component, or refill cartridges.

Because the market may have changed since January 2014 and the flavor count reported by Zhu et al. (2014) is difficult to map to counts of e-liquid products and delivery systems, staff at FDA’s Center for Tobacco Products cataloged the ENDS products currently available on 5 websites and in scanner data from Nielsen.³⁴ On the websites examined, 5,521 e-liquids were counted, without adjusting for potential duplicate products, while 2,630 other products were counted, including accessories, batteries, hardware components, and delivery systems kits. In the Nielsen scanner data, 820 liquid-containing products were identified, while 187 products not containing liquid were counted. However, because vape shops selling open systems and other specialized products are not captured by Nielsen, the liquid-containing products in the Nielsen scanner data were more likely to be in the form of a delivery system as opposed to bottles of e-liquid or refill cartridges. The extent of overlap in product offerings between the Nielsen scanner data and websites is unknown. Based on this information, FDA estimates that these products correspond to baseline estimates of 5,000 to 10,000 e-liquid product-package combinations and 800 to 1000 delivery systems product-package combinations. Assuming a ratio of product-packages to product formulations of 1.25, the corresponding number of product formulations is 4,000 to 8,000 for e-liquids and 640 to 800 for delivery systems.

In addition to product-package combinations that can be identified online, many vape shops mix their own e-liquids on site. During the initial 24-month compliance policy period for

³³ Under the recently issued guidance dated September 8, 2015 entitled, “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2),” FDA explained that “if a product’s label is modified in any way that renders the product distinct from the predicate, even if its characteristics remain the same, it is a new product[.]” A change to a tobacco product’s name is a modification that makes the product distinct. See FDA, 2015a.

³⁴ The websites cataloged are: eliquid.com, vaporworld.com, thevaporisland.com, myvaporstore.com, and vaporworld.com.

submission and FDA receipt of PMTAs, we expect that many vape shops will continue to prepare some mixtures that they prepared and offered for sale as of the effective date. Nevertheless, as described in the preamble to the final rule, FDA intends to enforce other requirements for manufacturers—such as establishment registration, product listing, and ingredient listing—prior to the expiration of that initial compliance policy period for premarket review. We therefore assume that during the initial 24-month compliance policy period for premarket review, vape shops will narrow down their set of potential mixed products from those that the vape shop prepared and offered for sale as of the effective date of the final rule based on whether the expected sales justify the costs. We estimate the potential number of mixed products by assuming that 5 percent of e-liquid product formulations are mixed with each other in all possible combinations of 2 products at a time. This yields 19,900 to 79,800 ENDS mixtures.³⁵ Assuming the lower bound estimate of the number of ENDS mixtures corresponds to the lower bound estimate of the number of vape shops mixing, and vice versa, this would be 11 to 13 products per vape shop.

The final rule also deems components and parts (but not accessories) of newly deemed tobacco products to be subject to chapter IX of the FD&C Act, although the three additional provisions of this final rule apply only to components or parts that are made or derived from tobacco. We have not quantified the cost of deeming components and parts, aside from pipes, waterpipes, and components and parts that are included in the ENDS product counts.³⁶

To estimate the number of roll-your-own tobacco products, we have drawn information from internal and external sources. Domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product or products are required to register with FDA and list the products with which they are involved. FDA estimates that those firms have listed about 352 roll-your-own products through September 2014. These data have some limitations, however. For example, some products included in the total have likely been discontinued, indicating that the data over-estimate the number of products. Therefore, we will make some adjustments based on other, more recent, submissions to FDA. As a lower-bound estimate for the number of currently regulated roll-your-own tobacco products, we use the number of products for which there have been submissions of constituent testing data. FDA estimates there

³⁵ The number of possible combinations of k objects from a set of n objects is given by $C(n,k) = (n!)/[k!(n-k)!]$. Using 5 percent of existing product formulations, the number of combinations at the lower bound is $C(200,2) = (200!)/[2!(200-2)!] = (200*199)/2 = 19,900$. The number of combinations at the upper bound is $C(400,2) = (400!)/[2!(400-2)!] = (400*399)/2 = 79,800$.

³⁶ For the proposed rule, we did not quantify the cost of deeming tobacco product components and parts (such as e-cigarette tanks, e-liquids, waterpipe heating sources such as flavored charcoals) but requested comment on the issue. We did not receive data specifically regarding tobacco product components and parts in response to our request for comments. However, for this final rule, we have added baseline counts for pipes and waterpipes. We have also quantified the baseline number of ENDS products in terms of e-liquids and delivery systems. These counts contain some components and parts that are not made or derived from tobacco, including e-liquids not containing nicotine (if they are intended or reasonably expected to be used with or for the human consumption of a tobacco product and do not constitute a tobacco product accessory) and delivery systems not containing a tobacco-derived component. The costs for other components and parts are not quantified due to lack of data. Note that at this time, FDA does not intend to enforce certain requirements for components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products. See the preamble of this final rule for details.

are approximately 272 roll-your-own products based on these submissions. We also examined scanner data from Nielsen, but the estimated number of UPCs for roll-your-own products in Nielsen is lower than our internal estimates for the number of roll-your-own products. Therefore, we use the upper-bound product estimate as our estimate for the number of roll-your-own product-package combinations.

Table 6 summarizes the number of products affected by this final rule.

Table 6-- Products Affected by this Final Rule

	Product Formulations ⁵	Product-Package Combinations ⁵
Cigars ¹	5,000	7,500
Pipe Tobacco	900	1,100
Pipes ²	4,610	4,610
Waterpipe tobacco ²	779	974
Waterpipes	520	520
E-Liquids	4,000 to 8,000	5,000 to 10,000
ENDS Delivery Systems	640 to 800	800 to 1,000
Roll-Your-Own Tobacco ³	272 to 352	352
Total, Excluding E-Liquid Mixtures	16,721 to 20,961	20,856 to 26,056
E-Liquid Mixtures ⁴	19,900 to 79,800	NA

1 We estimate that cigar products belong to 1,100 distinct product families.

2 We set our estimate of the number of product-packages for pipes and waterpipes equal to the number of product formulations because pipes and waterpipes are not typically sold to consumers with product-specific packages.

3 Roll-your-own tobacco products are currently regulated; they are, however, affected by the health warning statement provisions of this final rule.

4 For the sake of simplicity, we do not estimate the number of ENDS mixtures product-package combinations.

5 Product formulations and product-package combinations are used as baseline estimates for simplicity and may under- or overestimate the number of products with respect to certain regulatory requirements that result from this final rule.

b) Potential Product Consolidation

It may not be profitable for firms to bear the per-product costs of this final rule for all products currently marketed. Given the potential compliance costs, we assume that 5 percent of baseline newly deemed combusted products, such as cigars, pipes and pipe tobacco, and waterpipes and waterpipe tobacco, will exit from the market rather than submit a marketing application.³⁷ For these types of products, FDA expects product exit to be relatively low because many products will be grandfathered and most new products will be able to use generally lower-cost pathways to marketing authorization.

At most, a handful of ENDS products may have been on the market as of February 15, 2007. Therefore, nearly all ENDS products will be subject to premarket review. A majority of all ENDS submissions will be PMTAs, especially during the initial wave of submissions for existing products, given the limited number of valid predicate products that could be found to support an SE determination. Additionally, in order to utilize the SE exemption pathway, a minor

³⁷ Some comments asserted that exit rates would be higher, but without providing sufficient basis to evaluate those assertions.

modification must be made with respect to a legally marketed product. The PMTA pathway is generally more costly than the other pathways for marketing new tobacco products. Therefore, we expect that considerable product consolidation and exit would occur, augmenting the consolidation and exit that would anyway be expected to occur in an emerging market under baseline conditions. (For example, consolidation and exit would be expected to occur under the baseline as successful firms represent an increasing share of market sales, market leaders perhaps absorb smaller firms and products, and smaller firms merge into larger entities or exit from the market). We expect a much larger share of ENDS products to exit rather than submit a premarket application. Based on estimates from FDA staff of expected numbers of product submissions, which take into account experiences with currently regulated tobacco products as well as current understanding of the science, manufacture, distribution, and consumer use of ENDS products, we expect that one percent of ENDS devices may be grandfathered. We also assume 54 percent of delivery systems and somewhere between 50 and 87.5 percent of e-liquids will not submit a marketing application and will exit the market after the initial compliance period for the submission and FDA receipt of PMTAs ends. The e-liquid share is particularly difficult to predict in view of uncertainties about the number of distinct products currently available on the market.

We make simplifying assumptions about product exit and consolidation and premarket authorization throughout this analysis: For newly deemed new tobacco products that do not seek marketing authorization, we assume that exit occurs 2 years after the publication date of this final rule. (This coincides with the effective date for the health warning statement requirements and the expiration of the compliance policy period for § 903(a)(2) and § 920(a) of the FD&C Act, and roughly with the expiration of the initial compliance policy period for the submission and FDA receipt of PMTAs for newly deemed new tobacco products.) We also assume that 90 percent of products seeking marketing authorization will obtain marketing authorization.³⁸

Table 7 forecasts the number of newly deemed products after the initial round of marketing authorizations, under these assumptions.

Table 7—Forecasted Future Number of Newly Deemed Products After the Initial Round of Marketing Authorizations

	Product Formulations	Product-Package Combinations
Cigars	4,575	6,863
Pipe Tobacco	815	996
Pipes	4,356	4,356
Waterpipe tobacco	705	881
Waterpipes	491	491

³⁸ We incorporate this assumption as a placeholder to acknowledge that it would not be realistic to expect 100 percent of products seeking marketing authorization to obtain marketing authorization. This 90% placeholder is comparable to the high end of observed medical product approval rates. The marketing authorization rate for tobacco products, however, may differ, and this placeholder is not a forecast of actual marketing authorization rates or an estimate based on currently regulated tobacco products. Furthermore, this assumption does not imply that marketing authorizations are in any way prejudged. The actual proportion of products that will be successful in obtaining marketing authorization will depend on many factors that are difficult to forecast in advance, such as the characteristics of the products seeking marketing authorization and the quality of the SE exemption requests, SE reports, and PMTAs submitted.

E-Liquids	900 to 1,800	1,125 to 2,250
ENDS Delivery Systems	266 to 332	332 to 415

Note: Roll-your-own tobacco products are currently regulated under the FD&C Act and therefore are not included in the costs of marketing authorizations for this rule. We set our estimate of the number of product-packages for pipes and waterpipes equal to the number of product formulations because pipes and waterpipes are not typically sold to consumers with product-specific packages.

Our analysis reflects a significant degree of product exit and consolidation. We note that this will be accompanied by changes in the composition of products available on the market, given the requirements of premarket review. For example, products that have proliferated in the absence of FDA regulation currently lack quality control and consistency, so that consumers have highly imperfect information for choosing among products and acutely toxic products may be offered for sale. To the extent that this is the case, we expect that product exit would raise the overall quality level of the products in the market compared to the quality level that would otherwise prevail.

c) **Changes in Products over time**

After the initial round of premarket submissions and decisions for existing products, there will be ongoing submissions for new products seeking marketing authorization. For the proposed rule, FDA estimated that cigar and pipe products were changed at a rate of 5 to 15 percent per year. This estimate was based on data for tobacco products not regulated under the FD&C Act and data that predate regulation for currently regulated products. Data compiled by FDA’s Center for Tobacco Products indicate that since premarket requirements went into effect, manufacturers of currently regulated products have sought to introduce new products at a slightly lower rate. Therefore, we forecast that annual submissions for new products seeking marketing authorization will be between 5 and 10 percent of the number of products that will remain on the market after the initial round of premarket submissions and decisions. We assume this to be true both for combusted products and ENDS products. However, the distribution of types of new products that are the subject of ENDS applications might differ from those that would be introduced in the absence of regulation. In particular, the mix of new products may be more heavily weighted towards types of products that are suitable for being marketed through exemptions or SE rather than the PMTA pathway.

We assume for simplicity that product changes do not occur during the first two years after publication while manufacturers are preparing submissions for products marketed as of the date of publication of this final rule.³⁹

3. COMPLIANCE COSTS FOR MANUFACTURING, IMPORTING OR SELLING NEWLY DEEMED PRODUCTS

a) **Regulation Review and Administrative Setup**

³⁹While submissions for new products not marketed as of the effective date of the final rule are not likely to be zero during the first two years, they are likely to come more slowly as manufacturers work on preparing large numbers of submissions for products marketed as of the date of publication of this final rule.

All manufacturers and importers of newly deemed tobacco products will need to devote time to reading and understanding this final deeming rule. This is true both for entities that will remain in the market and entities that may respond by exiting the market. Entities that expect to remain in the market will incur some general administrative setup costs for activities such as becoming familiar with the electronic submission procedures and obtaining a DUNS number if they do not already have one. We estimate that manufacturers and importers will spend on average 10 hours on regulation review and potential administrative setup.

In valuing the time spent on regulation review and administrative setup, 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.^{40,41} We use a mix of 50 percent management occupations (occupation code 11-0000) and 50 percent legal occupations (occupation code 23-0000). This mix yields a composite wage of \$66.66. We double this to account for benefits and overhead, yielding an hourly labor cost of \$133.31.

We assume these costs are incurred by retailers who currently meet the definition of manufacturer. Such retailers at a minimum will need to read and understand the regulation in order to make a decision about whether to continue or cease engaging in manufacturing activities and will incur administrative setup costs if they continue to engage in manufacturing activities during the initial compliance period for the submission and FDA receipt of PMTAs. Although we do not estimate the effect of manufacturer and importer turnover after this final rule is fully effective, any new entrants would also bear regulation review and administrative setup costs.

Table 8 shows the cost of regulation review.

Table 8-- Cost of Regulation Review and Administrative Setup

	Year 1 (Lower Bound)	Year 1 (Upper Bound)
Cigar Manufacturers	113	113
Pipe (including waterpipe) tobacco manufacturers	74	74
ENDS manufacturers	168	204
Vape shops	3,500	7,000
Cigar Importers	216	216
Pipe (including waterpipe) tobacco importers	43	43
ENDS importers	14	14
Total (entities)	4,128	7,664
Time (hours)	10	10
Total cost (\$)	5,503,037	10,216,878

b) Marketing Authorizations for Newly Deemed Tobacco Products

⁴⁰ May 2014 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200—Tobacco Manufacturing. <<http://www.bls.gov/oes/>>

⁴¹ The BLS did not publish wage estimates for legal occupations within the tobacco manufacturing industry in 2014. We use instead, the legal occupation wage reported for the beverage and tobacco manufacturing industry (NAICS 312000).

Tobacco products that were on the market as of February 15, 2007, are grandfathered and are not subject to premarket authorization requirements. However, as described throughout the preamble, these products are subject to the other requirements of the FD&C Act.

No new, newly deemed tobacco product may be legally marketed without first receiving premarketing authorization from FDA.⁴² As described in the preamble to this final rule, the FD&C Act contains three pathways for obtaining premarket authorization: SE exemptions, SE reports, and PMTAs. The costs for seeking marketing authorizations will depend on the number of products seeking marketing authorization, the cost of preparing an application for each marketing pathway, and the proportions of products that seek marketing authorization through each marketing pathway.

(1) Compliance Policy for Premarket Review Requirements

For those newly deemed products that were on the market on the effective date of this final rule, but that were not on the market on February 15, 2007, FDA is providing two compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization. Although such products are subject to the premarket review requirements of the FD&C Act, FDA does not intend to initiate enforcement action for failure to have premarket authorization during the respective compliance periods.

The compliance period for submission and FDA receipt of applications for newly deemed tobacco products under the three premarket pathways is as follows:

SE Exemption Requests--12 months from the effective date of this final rule

SE Reports--18 months from the effective date of this final rule

PMTAs--24 months from the effective date of this final rule

FDA is adopting the staggered timelines in this policy to account for the possibility that applicants may need additional time to gather information for certain premarket submissions that may require additional data. For example, if a manufacturer plans to submit an SE Exemption Request, the firm may only need to identify the product, provide certification statements, and gather scientific information on the additive change itself and any supporting information demonstrating that the change to the product is minor and an SE Report is not necessary. This is less information than that likely required for a PMTA. We expect this policy will also create a more manageable flow of premarket applications for newly deemed products. FDA expects that this staggering of deadlines also will benefit regulated industry, since it will allow for greater efficiency of FDA review and incentivize higher quality applications, which will reduce review times for all products. New products for which no application has been submitted by 24 months from the effective date of this rule will no longer be subject to this compliance policy and will be subject to enforcement.

⁴² The term new tobacco product means any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. See Section 910(a)(1) of the FD&C Act.

Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period, which is as follows:

SE Exemption Requests--24 months from the effective date of this final rule (12 months after the compliance period for submission of such requests)

SE Reports--30 months from the effective date of this final rule (12 months after the compliance period for submission of such reports)

PMTAs--36 months from the effective date of this final rule (12 months after the compliance period for submission of such requests).⁴³

Once the continued compliance period ends, new tobacco products on the market without authorization will be subject to enforcement. FDA will act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met. Further, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.

(2) Number of Newly Deemed Tobacco Products Seeking Marketing Authorization

Newly deemed new tobacco products are subject to premarket review. Table 9 shows the number of products expected to apply for some form of marketing authorization during the first two years after the publication date of this final rule, after subtracting the number of products expected to be grandfathered and the number expected to not submit a marketing application. Projections of submission rates for e-liquids are particularly uncertain due to uncertainty about numbers of products currently on the market.

We have updated our assessment of the proportion of combusted products that will be grandfathered. During the early part of 2015 FDA conducted a series of tobacco manufacturing site visit tours, which provided an opportunity for FDA scientists to visit, learn, and view how tobacco products are manufactured. Several cigar manufacturers entered the program and agreed to host a FDA site visit. As a part of these site visits to cigar manufacturers, FDA was able to view how cigar wrapper leaves are fermented, how tobacco fillers are blended, how cigars are rolled and manufactured, and how cigars are packaged. FDA found that many cigars are manufactured similarly with few, if any, modifications and many of the ingredients and suppliers are the same as those utilized in previous years. Based on these findings, FDA has revised the estimated number of grandfathered cigars that were commercially marketed in the United States

⁴³ In addition, we note that any new tobacco product that was not on the market on the effective date of the rule (i.e., 90 days after the publication date) is not covered by this compliance policy and will be subject to enforcement if marketed without authorization after the effective date.

as of February 15, 2007. While FDA has not participated in site visits with pipe tobacco manufacturers, we believe they are also manufactured similarly with few, if any, modifications and many of the ingredients and suppliers are the same as those utilized in previous years.

Given FDA’s understanding of the industry, we believe many pipes and waterpipes are similar in design and that most have been in the marketplace for a long time with few changes. Accordingly, we estimate that the majority of pipe and waterpipes will be grandfathered products.

Table 9 – Outcomes for Baseline Products

	Number of product-packages at baseline ¹	Number Grandfathered	Proportion Grandfathered	Number Applying for Marketing Authorization	Proportion Grandfathered or Submitted for Premarket Review	Number of new currently –marketed products not submitted for review
Cigars	7500	4,500	60%	2,625	95%	375
Pipe Tobacco	1100	550	50%	495	95%	55
Pipes	4,610	4,149	90%	230	95%	231
Waterpipe tobacco	974	487	50%	438	95%	49
Waterpipes	520	468	90%	26	95%	26
E-liquids	5,000 to 10,000	0	0%	1,250 to 2,500	12.5 to 50%	2,500 to 8,750
ENDS Delivery Systems	800 to 1,000	8 to 10	1%	360 to 450	46%	432 to 540
Total	20,504 to 25,704	10,162 to 10,164		5,424 to 6,764		3,668 to 10,026

Note: For pipes and waterpipes we use the number of products as the number of product-packages, because they are not typically sold to consumers with product-specific packages.

After the initial period of processing marketing applications and authorizations for existing products, we assume the number of new products seeking authorization annually is equal to 5 to 10 percent of the number of products estimated to remain on the market. (Similar to existing guidance for currently regulated tobacco products, FDA does not intend to enforce premarket review requirements for manufacturers that make tobacco blending changes to address the natural variation of tobacco (e.g., tobacco blending changes due to variation in growing conditions) in order to maintain a consistent product.) Table 10 shows the number of tobacco products seeking authorization annually after the initial compliance period.

Table 10--Number of Products Seeking Marketing Authorization Annually After the Initial Compliance Period

	Low	Medium	High
Cigars	343	514	687
Pipe Tobacco	50	75	100
Pipes	218	327	436

Waterpipe tobacco	44	66	88
Waterpipes	25	37	49
E-liquids	56	127	225
ENDS Delivery Systems	17	28	42
Total	753	1,174	1,627

(3) Description and Cost of Each Marketing Pathway

(a) PREMARKET TOBACCO APPLICATION (PMTA)

FDA has made available draft guidance for public comment, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. A PMTA must contain sufficient information to show that the marketing of the new tobacco product is appropriate for the protection of the public health. As explained in section 910(b)(1) of the FD&C Act, the information required includes, among other things, information on the ingredients, additives, and properties of the product; investigations of the health risks of the products; and the methods of manufacturing. This may or may not require significant outlays on original research and testing, depending on the extent to which firms can compile the expected elements of the PMTA from existing information.

Firms can make intensive use of existing research on toxicological properties of the ingredients in their products, including from public sources such as the Environmental Protection Agency or Occupational Safety and Health Administration. Manufacturers can rely on any internal data they may have based on their own quality control processes or research and development. Firms may cite scientific and scholarly research on usage patterns or characteristics of products similar to their own. FDA also expects the availability of public dockets that will allow manufacturers to access and rely on already available data and studies, to reduce the time it takes to prepare an application in many cases. FDA is developing a public docket of such research and is also funding more than 70 studies on ENDS products. Information for these public dockets may be provided by researchers, businesses, stakeholders, FDA, or other parties and is likely to include previous work conducted or submitted as part of a publication or application, or other information that can be publicly referenced. In addition, FDA expects the availability and use of tobacco product master files (discussed in a separate final guidance) to increase efficiency and reduce burdens on manufacturers, by allowing manufacturers to rely on the data and analysis submitted to FDA by separate entities. The system will enable manufacturers to rely on confidential non-public information from suppliers, while maintaining its confidentiality, when compiling their submissions. For example, a tobacco product master file could be created by the company that sells liquid nicotine to downstream e-liquid manufacturers; then a variety of manufacturers that use that same supplier can be granted a right of reference to the supplier's master file for use in their applications. FDA's review of supplier websites indicates that multiple producers of liquid nicotine advertise that they have already created master files to support nicotine replacement therapy products, pointing to the potential utility of this system.

As ability to rely on information in the master files and other sources of evidence can play an important role in moderating PMTA costs, firms are likely to favor submitting products for

which the PMTA would not require high outlays on original research and testing. At the same time, firms may have products or product lines that contain ingredients for which health risks are not well-established or that raise questions about usage patterns that cannot be answered using existing data. This will not necessarily deter them from undertaking PMTAs, as long as they expect the sales to result from marketing an authorized product to be sufficiently high to warrant the costs.

Estimating expected costs of submitting PMTAs is made complicated not only by the flexibility firms have to decide on how best to provide the information expected in the PMTA, but also by the diversity of products in the ENDS category. These include both e-liquids and devices; the device category in turn includes both closed-system products like disposable or cartridge-based cig-a-likes and open-system vapor tanks and mods. In both product categories, there are both relatively simple and relatively complex products. As the contents of PMTAs will likely differ substantially across types of products, we estimate average PMTA costs by building up estimates for specific types of products, based on information provided by FDA scientists who have experience with review of premarket applications as well as their knowledge of research and testing costs from coordinating or conducting research in areas such as toxicology and human health studies.

For each of the two product categories, the analysis uses three representative types of PMTAs that have low, medium and high average costs, where the main source of cost variation is the need to conduct original research and testing. It is important to stress that research burdens of PMTAs are quite different from premarket applications for new drugs. For example, FDA does not expect that PMTAs will include randomized clinical trials like those conducted to support drug approvals. Instead, the emphasis is on understanding actual use of ENDS products of different types, establishing the toxicological profile of ingredients, and acquiring sufficient clinical, non-clinical, and behavioral data to evaluate the products' health impacts.

Tables 11(a) and 11(b) provide information on expected costs of compiling PMTAs for e-liquids having low, medium, or high average costs. In Table 11(a), the first three columns show estimated costs of initially applying for premarket authorization. The next three show estimated costs of PMTAs submitted subsequently; for some large share of subsequent PMTAs, costs are expected to be substantially below initial costs, as firms will be able to reference material compiled for initial reviews. The four main categories of costs include: composition, design, and manufacturing studies; toxicological studies; human studies; and administrative staff hours. Details of expected activities or tests entailed in the first three categories are explained in Appendix 2. In brief, composition, design and manufacturing information entails establishing the quality control of production, possibly including microbiological and chemical analysis. Toxicological studies entail the evaluation of toxicological and pharmacological characteristics of each of the product's ingredients, the specific mixture of ingredients, and the aerosols produced by the product. Human studies entail characterizing how people view and use the product and the health impacts it may have. This could include information on how people perceive the product, its potential for misuse, comprehension of product labelling, and clinical findings on the product's health impacts. Human studies are a relatively expensive part of the information required for PMTAs, because some amount of research on the specific products to

be submitted for premarket review will typically be required. Administrative staff hours entail hours spent by the firm’s staff compiling the PMTA, evaluated at the rate of \$40.30 per hour.⁴⁴

Table 11. Estimated Average PMTA Costs for E-liquids with Different Average Cost Profiles: Initial and Subsequent Costs

Table 11(a): Application process costs for E-liquids (may cover multiple products)

	Initial PMTAs: Products with low average costs	Initial PMTAs: Products with medium average costs	Initial PMTAs: Products with high average costs	Subsequent PMTAs: Products with low average costs	Subsequent PMTAs: Products with medium average costs	Subsequent PMTAs: Products with high average costs
Composition, design, and manufacturing	\$27,000	\$54,000	\$45,000	\$0	\$27,000	\$22,500
Toxicological Studies	\$7,596 ¹	\$68,400	\$153,000	\$0	\$68,400	\$153,000
Human Studies	\$135,000	\$967,500	\$1,800,000	\$0	\$967,500	\$1,800,000
Administrative Staff Hours ²	\$12,090	\$20,150	\$16,120	\$12,090	\$20,150	\$16,120
Total costs of application process (may cover multiple products)³	\$181,686	\$1,110,050	\$2,014,120	\$12,090	\$1,083,050	\$1,991,620

¹ Assumes no original toxicological research will be needed, but it will take scientific staff 100 hours to compile existing findings, valued at \$75.96 per hour.

² For the low, medium and high cost PMTAs, the estimated numbers of administrative staff hours are 20, 50, and 80 per product respectively. The hourly wage is the Bureau of Labor Statistics’ estimate of the average wage for office and administrative support in the tobacco industry of \$20.15, doubled to account for benefits and overhead.

³ Sum of composition, design and manufacturing; toxicological studies; human studies; and administrative staff hours for the application process. We note that, in the rows for composition, design and manufacturing and administrative staff hours, the cost estimates are higher for the low- and medium- average cost application processes than they are for the high average cost process, because those types of costs are more dependent on the number of products covered by the application process than are the research costs associated with toxicological and human studies, where the costs are more directly related to the expected complexity of underlying research.

Table 11(b): Average Costs per PMTA: E-liquids

	Initial PMTAs : Products with low average costs	Initial PMTAs : Products with medium average costs	Initial PMTAs : Products with high average costs	Subsequent PMTAs: Products with low average costs	Subsequent PMTAs: Products with medium average costs	Subsequent PMTAs: Products with high average costs
--	-------------------------------------------------	----------------------------------------------------	--------------------------------------------------	---------------------------------------------------	------------------------------------------------------	----------------------------------------------------

⁴⁴ The hourly wage comes from the Bureau of Labor Statistics’ estimate of the average wage for office and administrative support in the tobacco industry of \$20.15, doubled to account for benefits and overhead.

Expected number of products covered by the application process	15	10	5	15	10	5
Expected average cost per product submitted via PMTA⁴	\$12,112	\$111,005	\$402,824	\$806	\$108,305	\$398,324
Expected average cost per product, assuming alternative number of products per application ⁵	\$10,094 (18)	\$92,504 (12)	\$335,687 (6)	\$672 (18)	\$90,254 (12)	\$331,937 (6)
	\$15,141 (12)	\$138,756 (8)	\$503,530 (4)	\$1,008 (12)	\$135,381 (8)	\$497,905 (4)
Estimated proportion of E-liquids	25%	65%	10%	20%	75%	5%
Weighted Average Cost per PMTA ⁶	\$115,464			\$101,306		
Overall average cost per PMTA including Environmental Assessment ⁷	\$131,643			\$117,486		

⁴ Total costs of the application process (from Table 11(a)), divided by the number of products covered by the application process.

⁵ Total costs of the application process (from Table 11(a)), divided by alternative number of products covered by the application process.

⁶ Computed as the sum of the averages for the three cost categories multiplied by their proportions of PMTAs in each category.

⁷ Environmental assessment is assumed to take calculated as requiring 213 hours at \$75.96 per hour, totaling \$16,179.

The cost estimates assume firms will almost always compile premarket applications for e-liquids as a set. Currently e-liquids are almost always marketed as part of a product line. The requirement of premarket review is expected to reduce the number of flavor variants and levels of nicotine in firms' product lines, as firms opt to submit PMTAs for products with relatively high sales and discontinue those with relatively low sales. Nonetheless, we expect e-liquids to continue to be marketed as part of branded sets. Although PMTAs are submitted for individual products, in compiling information required for them firms may often conduct studies and gather existing research for the product line, as products within the line will typically share common attributes, and it will usually be less expensive to conduct studies that collect information on multiple products rather than conducting highly similar studies for each product.

The estimates in Table 11(a) cover the costs of the e-liquid PMTA application process under three scenarios having different average PMTA costs. In the first, low-cost case, the firm intends to submit PMTAs for a set of products in a product line for which the ingredients of the products are well-understood. In this case information on composition, design and manufacturing and toxicology can largely be acquired from existing resources. FDA scientists estimate 100 scientific staff hours would be needed to review research literature for existing toxicological

studies, valued at a rate of \$75.96 per hour. The relatively costly part of compiling information for premarket review in this case is the human studies, as some original information on perceptions and usage of the product will be needed for each of the individual products. The total cost of compiling the information for these types of PMTAs is approximately \$181,686.

The products in the medium average cost scenario are not able to rely as heavily on existing research, requiring additional expenditure on toxicological and human studies and higher spending in the other two categories as well. Here the cost of human studies is expected to be substantial, for example, if the products in the product line include novel flavor variants requiring greater investigation of types of users they would appeal to and implications for usage patterns. The estimated total cost of the PMTA work in this case is approximately \$1.1 million. Note that this is not a cost per product but rather is the total cost of the application process which will cover several products; estimated costs per product are discussed below.

Finally, the high cost scenario is based on an application process involving a small number of e-liquids and significant original research required to establish their potential health risks (for example, tobacco and menthol variants, at two or three nicotine levels). For example, the specific products may have unusual ingredients with poorly understood risk properties, or they may differ significantly from other products and may require original research studies. In this case, the total cost of compiling information for the PMTAs in this category is estimated to be \$2.0 million, where again this is the total cost of the application process, not the cost per product.

How costly the application process will be on a per product basis depends on the number of products studied for which a submission is compiled. Thus, Table 11(b) shows average costs per product covered in the application process. In the low average cost case, a typical number of e-liquids that may be covered by this type of application process is assumed to be 15 products; dividing the total cost of \$181,686 (from Table 11(a)) by 15 yields an average PMTA cost per product of \$12,112. As most e-liquid PMTAs will entail more complexity than this, we assume that the proportion of PMTAs having low average costs is around 25%. To capture uncertainty about the number of products covered, we compute averages under alternative assumptions about the number of products in the application process. If the number of products is 18, the average cost per product is \$10,094; if it is 12, the average cost per product is \$15,141. In the medium-cost scenario, a typical number of products in this type of application process is assumed to be 10, resulting in an average cost per product of \$111,005. We expect that approximately 65% of ENDS products will have average costs per product in this category. A plausible range of average costs for products in this scenario is \$92,504 if 12 products are included or \$138,756 if 8 products are included. The high-cost scenario assumes a typical number of products of 5, resulting in an average cost of \$402,824 per product. We expect the proportion of e-liquid PMTAs having average costs in this range to be around 10%. A plausible range around the average is \$335,687 for 6 products to \$503,530 for 4 products.

To compute the overall expected average cost per PMTA, we take the weighted average of the primary estimates of average costs in the three average-cost categories, where the weights are the category's expected proportion of the number of e-liquid PMTAs. The overall average cost of compiling the submission is \$115,464 per PMTA. PMTAs are also expected to include environmental assessments (EA); for each product, we estimate the average EA burden to require 213 staff hours at a cost of \$75.96 per hour, for a total of \$16,179. Adding the EA cost to the cost of compiling the submission results in an average PMTA cost of \$131,643 per e-liquid.

Estimated costs for subsequent PMTAs are determined similarly. Here it is assumed that in the low average cost case, subsequent PMTAs will entail very modest costs due to small or moderate changes in the product, as well as the ability to refer back to information compiled for the original PMTA. Subsequent PMTAs could also be for entirely novel products, and these costs are reflected in the medium and high average cost categories; as before the medium average cost case reflects an ability to rely on some existing data, and the high average cost case would entail more original research and testing. Overall, the average total cost per subsequent PMTA is somewhat lower at \$117,486.

Tables 12(a) and 12(b) present similar estimates for ENDS delivery systems. As shown in Table 12(a), at the low end of the average cost spectrum would be product lines of cartridge- or disposable e-cigarettes which have an identical underlying delivery system, flavor variants likely to share basic ingredients, and similar ingredients and constituents for which existing information can be used to support a PMTA. This case is assumed to have total costs of \$285,656. The medium-cost case also involves a closed-system product line involving a smaller number of products and greater burden to conduct original research on their health effects and risk attributes. The total cost is somewhat higher at \$440,725. Finally, at the high average cost end is a single open-system device requiring considerable original research and testing amounting to \$2.6 million.

Table 12(b) shows average costs per ENDS product covered in the application process. In the low average cost case, a typical number of products covered by the application process is assumed to be 10 products, resulting in an average cost per product of \$28,566. The medium cost case assumes the application process will cover 5 products, with an average cost of \$86,145. The high cost case is assumed to involve only one product so the average and total costs are the same. Taking the weighted average across the three categories, the overall average cost per initial PMTA for ENDS delivery systems, including the EA cost, is estimated to be \$466,563. For subsequent PMTAs, the overall average is much lower at \$192,654, as it is estimated that about 30% of subsequent PMTAs for devices would require only modest additional spending because they could reference information in their original PMTAs.

Table 12. Estimated Average PMTA costs for ENDS Delivery Systems with Different Average Cost Profiles: Initial and Subsequent Costs

Table 12a: Application Process Costs for ENDS Delivery Systems (may cover multiple products)

	Initial PMTAs : Products with low average costs	Initial PMTAs : Products with medium average costs	Initial PMTAs : Products with high average costs	Subsequent PMTAs: Products with low average costs	Subsequent PMTAs: Products with medium average costs	Subsequent PMTAs: Products with high average costs
Composition, design, and manufacturing	\$135,000	\$168,750	\$54,000	\$0	\$85,500	\$27,000
Toxicological Studies	\$7,596 ¹	\$68,400	\$765,000	\$0	\$68,400	\$765,000
Human Studies	\$135,000	\$193,500	\$1,800,000	\$0	\$193,500	\$1,800,000
Administrative	\$8,060	\$10,075	\$3,224	\$8,060	\$10,075	\$3,224

Staff Hours ²						
Total costs of application process (may cover multiple products)³	\$285,656	\$440,725	\$2,622,224	\$8,060	\$357,475	\$2,595,224

¹ Assumes no original toxicological research will be needed, but it will take scientific staff 100 hours to compile existing findings, valued at \$75.96 per hour.

² For the low, medium and high cost PMTAs, the estimated numbers of administrative staff hours are 20, 50, and 80 per product respectively. The hourly wage is the Bureau of Labor Statistics' estimate of the average wage for office and administrative support in the tobacco industry of \$20.15, doubled to account for benefits and overhead.

³ Sum of composition, design and manufacturing; toxicological studies; human studies; and administrative staff hours for the product line. We note that, in the rows for composition, design and manufacturing and administrative staff hours, the cost estimates are higher for the low- and medium- average cost application processes than they are for the high average cost process, because those types of costs are more dependent on the number of products covered by the application process than are the research costs associated with toxicological and human studies, where the costs are more directly related to the expected complexity of underlying research.

Table 12b: Average Costs per PMTA: ENDS Delivery Systems

	Initial PMTAs : Products with low average costs	Initial PMTAs : Products with medium average costs	Initial PMTAs : Products with high average costs	Subsequent PMTAs: Products with low average costs	Subsequent PMTAs: Products with medium average costs	Subsequent PMTAs: Products with high average costs
Expected number of products covered by the application process	10	5	1	10	5	1
Expected average cost per product submitted via PMTA⁴	\$28,566	\$88,145	\$2,622,224	\$806	\$71,495	\$2,595,224
Expected average cost per product, assuming alternative number of products per application ⁵	\$23,804 (12)	\$73,454 (6)	N/A	\$672 (12)	\$59,579 (6)	N/A
	\$35,707 (8)	\$110,181 (4)		\$1,008 (8)	\$89,369 (4)	
Estimated proportion of delivery systems	30%	55%	15%	30%	65%	5%

Weighted Average Cost per PMTA ⁶	\$450,383	\$176,475
Overall average cost per PMTA including Environmental Assessment ⁷	\$466,563	\$192,654

⁴ Total costs of the application process (from Table 12(a), divided by the number of products covered by the application process.

⁵ Total costs of the application process (from Table 12(a), divided by alternative number of products covered by the application process.

⁶ Computed as the sum of the averages for the three cost categories multiplied by their proportions of PMTAs in each category.

⁷ Environmental assessment is calculated as requiring 213 hours at \$75.96 per hour, totaling \$16,179.

(b) SUBSTANTIAL EQUIVALENCE (SE)

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.^{45,46} For every identified design feature, ingredient, material, heating source, composition, and other features, including the presence of harmful or potentially harmful constituents (when providing HPHCs in an SE Report, they should be appropriate for the type of tobacco product and predicate product used for comparison), the report should provide a comparison of the new tobacco product with its predicate tobacco product. The report must also provide an adequate summary of any 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 220 hours to prepare and submit a full substantial equivalence report.⁴⁷

Under the recently issued guidance dated September 8, 2015 entitled, “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2),” FDA is recommending that certain modifications might be addressed in either a “Same Characteristics SE Report” or “Product Quantity Change SE Report.” In some circumstances manufacturers may be able to submit a shorter substantial equivalence report. In particular, if a tobacco product is distinct (e.g., it has a different name), but has the same characteristics as a valid predicate product, manufacturers may submit a Same Characteristics SE Report. If the only change is a change to product quantity, and the per-weight composition inside the package remains identical, the manufacturer may submit a Product Quantity Change SE Report. FDA’s Center for Tobacco products estimates that it will take less time to prepare those shorter substantial equivalence reports, as shown in Table 13 below. In addition, when

⁴⁵ Substantially equivalent is defined in Section 910(a)(3) of the FD&C Act.

⁴⁶ See FDA guidance entitled “Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products” (FDA, 2011).

⁴⁷ The burdens for the SE pathways are estimated on average and cover the diversity of submitted SE applications. This estimate is based on FDA’s experience with SE applications to date.

groups of substantial equivalence reports are submitted by the same manufacturer for the same product category and sub-category, they may be bundled; when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report. This further reduces costs, as shown in Table 13 below.

An environmental assessment is required with a substantial equivalence report. Based on FDA’s experience with environmental assessments (EA) for currently regulated tobacco products, we expect industry to spend 80 hours to prepare an environmental assessment for a full SE Report, but less time to prepare an environmental assessment for shorter substantial equivalence reports, as shown in Table 13 below.

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.

Table 13--Time Cost Per Substantial Equivalence Report

	Time (Hours)
Initial Full SE report	220
Initial Full SE EA	80
Total, Initial Full SE	300
Bundled Full SE report	10
Bundled Full SE EA	80
Total, Bundled Full SE	90
Initial Quantity Change SE report	35
Initial Quantity Change EA	52
Total, Initial Quantity Change SE	87
Bundled Quantity Change SE report	10
Bundled Quantity Change EA	52
Total, Bundled Quantity Change SE	62
Same characteristics SE report	20
Same characteristics EA	27
Total, same characteristics SE	47

(c) SUBSTANTIAL EQUIVALENCE EXEMPTIONS (EXEMPTIONS)

Manufacturers may also request exemptions from the SE requirements for new tobacco products if the new tobacco product has been modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, and FDA determines that (1) such modification would be a minor modification of a tobacco product that can be sold under the FD&C Act, (2) a report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health, and (3) an exemption is otherwise appropriate. Before a product can be legally marketed through the exemption pathway, 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). The requirements of an exemption request are also described in the preamble for this

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.

An environmental assessment is also required to accompany an exemption request and is estimated to take 12 hours to prepare. If the exemption request is granted, the manufacturer must then submit a 905(j)(1) report (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B). Based on our estimate for currently regulated tobacco products, the submission of a 905(j) report citing one or more exemptions is expected to take 3 hours to prepare (76 FR 38971 and 76 FR 38973).⁴⁸

Because manufacturers may submit one exemption request for multiple tobacco products, 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.⁴⁹ Taking this into account, FDA estimates that the average time cost of introducing a new tobacco product through the exemption pathway is 19 hours [=12*(2/3) + 12*(2/3) + 3].

(d) SUMMARY OF APPLICATION TYPES

Table 14 summarizes the estimated average cost for each premarket review pathway. In valuing the time for preparing premarket submissions, FDA uses a composite wage calculated using the Bureau of Labor Statistics’ national industry-specific occupational employment and wage estimates for the tobacco manufacturing industry.^{50,51} We use a mix of 30 percent life, physical, and social science occupations (occupation code 19-0000); 20 percent architecture and engineering occupations (occupation code 17-0000); 30 percent office and administrative support occupations (occupation code 43-0000); and 20 percent legal occupations (occupation code 23-0000). This mix yields a composite wage of \$37.98.⁵² We double this to account for benefits and overhead, yielding an hourly labor cost of \$75.96.

Table 14—Summary of Premarket Pathways

Premarket Pathway	Average Cost per Application (\$)
PMTA, E-liquid, Initial Submission (Year 2)	131,643
PMTA, E-liquid, Years 3-20	117,486
PMTA, Delivery Systems, Initial Submission (Year 2)	466,563
PMTA, Delivery Systems, Years 3-20	192,654
Initial Full Substantial Equivalence	22,787

⁴⁸ 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.

⁴⁹ Please note that even if a manufacturer submits one exemption request for multiple products, if an exemption request is granted for each uniquely identified product, the manufacturer will need to submit an Abbreviated Report covering the information required in 905(j)(1)(A)(ii) and 905(j)(1)(B) for each exempted product.

⁵⁰ May 2014 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200—Tobacco Manufacturing. <<http://www.bls.gov/oes/>>

⁵¹ The BLS did not publish wage estimates for legal occupations within the tobacco manufacturing industry in 2014. We use instead, the legal occupation wage reported for the beverage and tobacco manufacturing industry (NAICS 312000).

⁵² The calculation is 0.3*(\$33.04) + 0.2*(\$42.74) + 0.3*(\$19.65) + 0.2*(\$68.12) = \$37.98.

Bundled full substantial equivalence	6,836
Initial product quantity change substantial equivalence	6,608
Bundled product quantity change substantial equivalence	4,709
Same characteristics substantial equivalence	3,570
Substantial Equivalence Exemptions	1,443

(4) Newly Deemed Tobacco Products Use of the Marketing Pathways

The number or proportion of new products entering the market through each pathway may differ by type of product and by timing of market entry. For example, there are fewer potentially valid predicate products that can be found to support a substantial equivalence determination for non-combusted products as compared to traditional (combusted) products, leading to wider use of the substantial equivalence pathway for traditional (combusted) products. Additionally, the relative lack of grandfathered non-combusted products is expected to largely preclude the use of exemptions for ENDS products until after such products receive marketing authorization through one of the marketing pathways.⁵³

Table 15 summarizes our estimates of the proportions of products that will seek marketing authorization through each of the marketing pathways. These estimates are based on discussions with experts in FDA’s Center for Tobacco Products who have experience developing policies and reviewing applications for currently regulated tobacco products, as well as researching newly deemed tobacco products in anticipation of this final rule. Table 15 also shows the weighted average cost for each product type based on the proportions contained therein and the cost estimates in Table 14 above.

Table 15--Newly Deemed Combusted Products’ Use of the Marketing Pathways and Weighted Average Cost Per Product

	Cigars (Initial Compliance Period) ¹	Cigars (After Initial Compliance Period)	Pipe and Waterpipe Tobacco (Initial Compliance Period) ²	Pipe and Waterpipe Tobacco (After Initial Compliance Period)	Pipes and Waterpipes (Initial Compliance Period)	Pipes and Waterpipes (After Initial Compliance Period)
PMTA	0%	0%	0%	0%	0%	0%
Full SE, Initial	14%	25%	22%	25%	40%	30%
Full SE, Bundled	14%	15%	11%	15%	20%	20%
Product Q Change, Initial	11%	5%	9%	5%	0%	0%
Product Q change, bundled	3%	10%	2%	10%	0%	0%
Same Characteristics SE, Initial	29%	20%	22%	20%	20%	30%

⁵³ Pursuant to section 905(j)(3), the Secretary may exempt certain new tobacco products from the substantial equivalent requirements if the Secretary determines, among other things, that the modification would be a minor modification of a tobacco product that can be sold under this chapter.

SE Exemptions	29%	25%	33%	25%	20%	20%
Weighted Average Cost Per Product (\$)	6,560	8,598	7,783	8,598	11,485	9,563

1 These proportions are based on estimates from within FDA’s Center for Tobacco Products that 60 percent of cigars would be grandfathered, 5 percent would withdraw, 5 percent would submit full SE reports, 5 percent would submit bundled full SE reports, 4 percent would submit product quantity change SE reports, 1 percent would submit bundled product quantity change SE reports, 10 percent would submit same characteristics SE reports, and 10 percent would request SE exemptions.

2 These proportions are based on estimates from within FDA’s Center for Tobacco Products that 50 percent of pipe tobacco products would be grandfathered, 5 percent would withdraw, 10 percent would submit full SE reports, 5 percent would submit bundled full SE reports, 4 percent would submit product quantity change SE reports, 1 percent would submit bundled product quantity change SE reports, 10 percent would submit same characteristics SE reports, and 15 percent would request SE exemptions.

3 These proportions are based on FDA estimates that 90 percent of pipe and waterpipe products would be grandfathered, 5 percent would withdraw, 2 percent would submit full SE reports, 1 percent would submit bundled full SE reports, 1 percent would submit same characteristics SE reports, and 1 percent would request SE exemptions.

The proportions of new e-liquids and ENDS delivery systems that will utilize each marketing pathway are uncertain. The FD&C Act does not place limitations on which pathway manufacturers can use to seek market authorization for a new product. Thus, manufacturers may choose to file applications under any of the three legal pathways. For products seeking authorization through the PMTA pathway, manufacturers must demonstrate that permitting the new products to be marketed, as they are likely to be actually used—alone or together with other legally marketed tobacco products—will be appropriate for the protection of the public health. This showing may require analysis of potential variations on use and public health impact, based on the likely range of variation in other products with which the new product may be used.

For example, where a manufacturer seeks authorization of a new e-liquid to be used in ENDS, the manufacturer may need to provide evidence and analysis of the product’s likely impact when used in the range of delivery systems available. Similarly, a manufacturer seeking authorization of a stand-alone device component—such as a heating coil or cartridge—may need to provide evidence and analysis of the product’s likely impact when used together with the range of other components and liquids available.

In the case of e-liquids, FDA expects that it may be possible for manufacturers to satisfy the statute by demonstrating that marketing of the liquid is appropriate for the protection of public health as it may be used in *any* of the legally available delivery systems. While FDA recognizes that there may remain some degree of uncertainty in any such analysis, FDA expects that the range of delivery system specifications authorized by FDA will provide a sufficiently specific spectrum of possibilities, such that a meaningful public health impact analysis can be done.

In the case of hardware or device components, FDA expects that it may be difficult for manufacturers to make the showing necessary to meet the statutory standard, given the great extent of possible variations in combinations of hardware components, if all considered and sold separately. Thus, with respect to devices, FDA expects that manufacturers will be most successful where authorization is sought for entire delivery systems, rather than individual

components.⁵⁴ In the case of these complete delivery systems—systems for which the application covers all potential parts, including customizable options as applicable, and where labeling, instructions for use or other measures are used to help ensure use as intended—FDA expects that the range of possible outcomes may be narrow enough for the manufacturer to demonstrate, and for FDA to assess, public health impact.

Table 16 summarizes our estimates of the proportion of ENDSs products that will seek marketing authorization through each of the marketing pathways. Table 16 also shows the weighted average cost for each product type based on the proportions contained therein and the costs in Table 14 above.

Table 16--Newly Deemed ENDS Products' Use of Marketing Pathways and Weighted Average Burden Per New Product

	ENDS—E-Liquids (Initial Compliance Period) ²	E-Liquids (After Initial Compliance Period)	ENDS Delivery Systems (Initial Compliance Period) ³	ENDS Delivery Systems (After Initial Compliance Period)
PMTA ¹	100%	40%	78%	35%
Full SE, Initial	0%	0%	11%	15%
Full SE, Bundled	0%	0%	11%	10%
Product Q Change, Initial	0%	0%	0%	10%
Product Q change, bundled	0%	0%	0%	5%
Same Characteristics SE, Initial	0%	0%	0%	15%
Exemptions	0%	60%	0%	10%
Weighted Average Cost Per Product (\$)	131,643	47,860	366,274	73,107

1 These proportions correspond to 1,250 to 2,500 PMTAs for e-liquids in the initial compliance period and 22 to 90 per year thereafter and 280 to 350 PMTAs for ENDS delivery systems in the first year and 6 to 15 per year thereafter.

2 These proportions are based on estimates from within FDA's Center for Tobacco Products that all e-liquids submitting marketing applications in the first round would use the PMTA pathway.

3 These proportions are based on estimates from within FDA's Center for Tobacco Products that 1 percent of delivery systems would be grandfathered, 54 percent would withdraw, 5 percent would submit full SE reports, 5 percent would submit bundled SE reports, and 35 percent would submit PMTAs.

(5) Costs for Complying with Premarket Requirements for Marketing Tobacco Products

Table 17 summarizes the cost of obtaining marketing authorizations using the counts from Table 9 and Table 10 and the weighted average burdens from Table 15 and Table 16. The total cost for complying with the premarket requirements for newly deemed new tobacco products is

⁵⁴ A marketing application must demonstrate that the subject product meets the applicable public health standard (e.g., appropriate for protection of public health) for issuance of a marketing order. PMTAs should contain information on whether the product is likely to be used alone or together with other legally marketed tobacco products (such as available delivery systems), as well as the type and range of other products with which it is likely to be used.

estimated to be \$324 to \$521 million during the initial compliance period and \$10 to \$26 million annually thereafter. For simplicity, we assume that costs incurred in the initial compliance period are spread over the first two years after this final rule publishes.

Table 17--Cost of Complying With Premarket Requirements (\$)

	Initial Submission ¹ Lower Bound	Initial Submission ¹ Medium	Initial Submission ¹ Upper Bound	Annually Thereafter Lower Bound	Annually Thereafter Medium	Annually Thereafter Upper Bound
Cigars	17,219,698	17,219,698	17,219,698	2,949,267	4,419,601	5,907,132
Pipe tobacco	3,852,340	3,852,340	3,852,340	429,922	644,883	859,845
Pipes	2,641,515	2,641,515	2,641,515	2,084,758	3,127,138	4,169,517
Waterpipe tobacco	3,408,737	3,408,737	3,408,737	378,332	567,497	756,663
Waterpipes	298,606	298,606	298,606	239,078	353,835	468,592
E-Liquid	164,554,038	246,831,056	329,108,075	2,680,170	6,078,242	10,768,539
ENDS Delivery System	131,858,588	148,340,911	164,823,235	1,242,816	2,046,992	3,070,487
Total	323,833,521	422,592,863	521,352,206	10,004,343	17,238,188	26,000,776

¹ The initial submission period is 15 months after publication of the final rule for SE exemptions, 21 months after for SE reports, and 27 months for PMTAs. (The first 90 days is the time between the publication date and the effective date.) We assume, for simplicity, that premarket costs for the initial compliance period are spread over the first 2 years after publication of this final rule.

c) Annual Registration and Product Listing

The FD&C Act requires annual registration by owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products and immediate registration of new owners-operators and new establishments.⁵⁵ Product listing is also required for registered establishments.⁵⁶ Changes in the product list are to be reported twice a year.

The number of establishments is the main determinant of this cost. Previous burden estimates for registration and product listing did not fully incorporate the availability of an electronic system known as FURLs for submitting registration and product listing information to FDA. With the FURLs system, companies can enter information quickly and easily. For example, product label pictures can be uploaded directly and we anticipate that most, if not all companies, already have electronic versions of their labels for printing, sales, or marketing purposes. We anticipate that initial establishment registration will take two hours and initial product listing will take an additional two hours per establishment, for a total of four hours. Once the initial registration and listing takes place, the yearly registration confirmation and twice yearly updates to product lists are simplified as all information previously entered is maintained in the system. Therefore, we expect that ongoing maintenance of the establishment registration and product listing information will take 30 minutes twice a year for a total of one hour annually.

⁵⁵ See Section 905(b), (c).

⁵⁶ See Section 905(i). The product listing includes additional information, such as a copy of all consumer information and other labeling as well as a representative sample of advertising for a listed tobacco product.

Those persons who own or operate domestic establishments engaged in the manufacture, preparation, compounding, or processing of newly deemed tobacco products will be required to register with FDA and submit product listing under section 905. Foreign establishments are not required to register their establishments or list their tobacco products sold in the United States until FDA issues regulations establishing such requirements in accordance with section 905(h) of the FD&C Act. However, importers who engage in the manufacture, preparation, compounding, or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user would also be required to register and list.⁵⁷ To account for the foregoing, we include both domestic manufacturing establishments and importers in our upper bound estimates, using the total count of TTB permitted manufacturers and importers as a likely overestimate of the number of entities that need to comply with registration and product listing. We assume that many vape shops who currently mix e-liquids will continue to do so during the initial 24-month compliance policy period for the submission and receipt by FDA of PMTAs. As described in the preamble to the final rule, FDA intends to enforce the establishment registration and product listing requirements prior to the expiration of that initial 24-month compliance policy period. Therefore, we include vape shops that continue to mix e-liquids in the costs for establishment registration and product listing during the first two years.

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, \$20.15 per hour.⁵⁸ We double this to account for benefits and overhead, yielding an hourly cost of \$40.30.

Table 18 shows establishment registration and product listing costs for the first year, while Table 19 shows establishment registration and product listing costs for years two through 20. Throughout this document, when only upper and lower bounds are presented, we use the midpoint as our primary estimate.

Table 18-- Establishment Registration and Product Listing Costs in Year 1

	Year 1 Lower Bound	Year 1 Upper bound
Cigar Establishments	113	329
Pipe (including waterpipe) tobacco Establishments	74	117
ENDS Manufacturing Establishments	168	218
Vape Shops (ENDS Mixing Establishments)	1,500	7,000

⁵⁷ Under the Internal Revenue Code, the manufacture, preparation, compounding, or processing of a tobacco product may require a permit as a manufacturer of tobacco products. As we understand TTB's permitting requirements, entities lacking a manufacturer permit, including importers, may not engage in any of the listed activities, including repackaging tobacco products after such products are released from customs custody. It is unclear whether TTB would require a manufacturer permit for all activities for which FDA would determine the entity must register and list; using the total count of TTB permitted manufacturers and importers is a likely overestimate of the number of entities that need to comply with registration and product listing.

⁵⁸ May 2013 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200—Tobacco Manufacturing. <<http://www.bls.gov/oes/>>

Total	1,855	7,664
Time (Hours)	4	4
Cost--Cigars (\$)	17,764	51,719
Cost—Pipe (including waterpipe) tobacco (\$)	11,633	18,392
Cost—ENDS Manufacturing (\$)	26,410	34,270
Cost—ENDS Mixing	235,800	1,100,400
Total Cost (\$)	291,606	1,204,781

Source: Table 4. We estimate that 30 to 70 percent of the baseline number of vape shops will mix during the initial compliance policy period for the submission and receipt by FDA of PMTAs.

Table 19--Establishment Registration and Product Listing Costs in Years 2 through 20

	Year 2 Lower Bound	Year 2 Upper bound	Years 3-20 Lower bound	Years 3-20 Upper bound
Cigar Establishments	113	329	113	329
Pipe (including waterpipe) tobacco Establishments	74	117	74	117
ENDS Manufacturing Establishments	168	218	168	218
Vape Shops (ENDS Mixing Establishments)	1,500	7,000	0	0
Total	1,855	7,664	355	664
Time (Hours)	1	1	1	1
Cost--Cigars (\$)	4,441	12,930	4,441	12,930
Cost—Pipe (including waterpipe) tobacco (\$)	2,908	4,598	2,908	4,598
Cost—ENDS Manufacturing (\$)	6,602	8,567	6,602	8,567
Cost—ENDS Mixing	58,950	275,100	0	0
Total Cost (\$)	72,902	301,195	13,952	26,095

Source: Table 4. We estimate that 30 to 70 percent of the baseline number of vape shops will mix during the initial compliance policy period for the submission and receipt by FDA of PMTAs.

d) Ingredient Listing

The FD&C Act requires tobacco product manufacturers or importers, and agents thereof, to submit a listing of all product ingredients by brand and by quantity for each brand and sub-brand.⁵⁹ As described in the preamble, FDA is providing a six month (or nine months after publication) compliance period for the ingredient listing provisions. (FDA presently does not intend to initiate enforcement action against those small scale tobacco manufacturers who submit the required ingredient listing information within 12 months of the effective date. We discuss this in greater detail in Section IV of this analysis.) Ingredient lists must also generally be submitted prior to changing additives in an existing product or 90 days prior to introducing a new product into interstate commerce.⁶⁰

We assume that manufacturers of all products that are not mixed in a retail shop will comply with the initial ingredient listing. For ENDS products mixed in a vape shop, we assume that vape shops will narrow down the number of products for which to submit ingredient lists from the mixtures the vape shops prepared and offered for sale as of the effective date of the final rule; moreover, we assume that the vape shop will select only those products expected to have

⁵⁹ See Section 904(a)(1).

⁶⁰ See Sections 904(c)(1)-(c)(3).

sufficient sales to justify the cost. We estimate that there will be no new ENDS mixtures manufactured in vape shops in subsequent years, and therefore we do not expect vape shops to submit ingredient lists in such years.

FDA expects manufacturers and importers to submit ingredients lists for tobacco products that differ in any way other than packaging differences that do not affect characteristics of the product (FDA, 2009). To the extent product-package combinations are separately listed, we assume the additional burden of listing such variations would be negligible. Therefore, to simplify the analysis, we estimate the number of products using the number of unique product formulations. The number of products would be the main determinant of the ingredient listing cost.

Based on FDA experience with currently regulated tobacco products, we estimate that it requires three hours per product to submit an ingredient list (FDA, 2009). We use the composite labor cost described above in the section on premarket submissions, \$75.96 per hour, to value the time spent on ingredient listing. Table 20 shows the cost of ingredient listing.

Table 20--Ingredient Listing Costs

	Initial Ingredient Listing ¹ (Lower Bound)	Initial Ingredient Listing ¹ (Upper Bound)	Annual Ingredient Listings ² (Lower Bound)	Annual Ingredient Listings ² (Upper Bound)
Cigars	5,000	5,000	206	412
Pipes and Pipe Tobacco	5,510	5,510	233	465
Waterpipes and Waterpipe tobacco	1,299	1,299	54	107
ENDS (E-liquids and delivery systems)	4,640	8,800	52	192
ENDS Mixtures ³	19,900	79,800	0	0
Total Number of Ingredient Lists	36,349	100,409	545	1,176
Time (Hours)	3	3	3	3
Cost--Cigars (\$)	1,139,370	1,139,370	46,942	93,884
Cost—Pipes and Pipe Tobacco (\$)	1,255,586	1,255,586	53,095	105,961
Cost—Waterpipes and Waterpipe Tobacco (\$)	296,008	296,008	12,305	24,383
Cost—ENDS (E-liquids and delivery systems) (\$)	1,057,335	2,005,291	11,849	43,752
Cost--ENDS Mixtures (\$)	4,534,693	18,184,345	NA	NA
Total Ingredient Listing Cost (\$)⁴	8,282,992	22,880,600	124,191	267,980

1 See Table 6

2 See Table 6 and Table 7. We assume the number of new products introduced each year is 4.5 to 9 percent of the total number of products.

3 We assume that vape shops that manufacture ENDS mixtures will submit initial ingredient lists. We estimate that there will be no new ENDS mixtures manufactured in vape shops in subsequent years, and, therefore, we do not expect vape shops to submit ingredient lists in such years.

4 Time is valued at \$75.96 per hour.

e) Harmful or Potentially Harmful Constituents

The FD&C Act requires manufacturers or importers, or agents thereof, to submit a listing of all constituents, including smoke constituents as applicable, identified by FDA as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each

tobacco product, by brand and by quantity in each brand and subbrand, beginning three years after enactment of the statute.⁶¹ The newly deemed products will be required to comply with the HPHC testing and reporting requirements of sections 904(a)(3) and 915 of the FD&C Act. FDA, however, does not intend to enforce the HPHC testing and reporting requirements for such products for three years after the effective date of the final rule. FDA intends to issue a guidance document regarding HPHC reporting under section 904(a)(3), and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. FDA, however, does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance and the section 915 regulation are issued well in advance of that time.

Although section 904(a)(3) creates an obligation that imposes costs, pursuant to section 915, the Secretary “shall promulgate regulations” to “require testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents.” Since we expect the regulations to be in effect before reports are due, and since the content of those regulations will in large part determine the costs of testing, we will include the cost of compliance with testing and reporting for newly deemed products when those regulations are promulgated.

FDA has, however, calculated burdens for HPHC reporting in the context of premarket submissions for new products and included that information in the burden hour estimates for each pathway. While applicants should submit certain information about HPHCs as part of their applications, the requirement to submit HPHC listings under section 904 is separate and distinct from the premarket review requirements under section 910. For example, in the SE FAQ guidance FDA noted that for combusted products changing paper to fire safe compliant paper, reporting of TNCO (tar, nicotine, and carbon monoxide) may be helpful to demonstrate substantial equivalence.

f) Tobacco Health Documents

Tobacco product manufacturers or importers are required 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, 2009.⁶² Documents are “developed” when they are created or modified in any way (FDA, 2010).

Because most manufacturers of newly deemed products will be small, FDA assumes that very few routinely develop health documents.

Although section 904(a)(4) sets out an ongoing requirement to submit tobacco health documents developed after June 22, 2009 (the date of enactment of the TCA), FDA generally does not intend to enforce the requirement with respect to all such documents at this time, so long as a specified set of documents are submitted by [the effective date + 6 months]. FDA will

⁶¹ See Section 904(a)(3) of the FD&C Act.

⁶² See Section 904(a)(4) of the FD&C Act.

publish additional guidance that specifies the scope of such documents with sufficient advance time for manufacturers and importer to prepare their submissions.

FDA does intend to collect other tobacco health documents developed after June 22, 2009, but before doing so the agency will publish additional guidance specifying the timing of subsequent submissions. Note that, despite this compliance policy with respect to timeliness of submissions, manufacturers and importers are still to preserve all tobacco health documents developed after June 22, 2009 for future submissions to FDA. Failure to submit tobacco health documents developed after June 22, 2009 because of a failure to preserve them after publication of this rule will constitute a violation of section 904(a)(4).

For these reasons, we expect the cost of this provision to be small (and negligible for small entities) and do not quantify it.

g) Prohibition of Free Samples

Current regulations that ban the distribution of free samples would automatically apply to newly-regulated tobacco products. In 1999, the cigar industry only spent \$423,000 on providing free samples (FTC, 1999). Although we do not have more recent data for cigars, or any information for other newly deemed tobacco products, the total value of free samples distributed is likely very small. We acknowledge, however, that distribution of free samples may be concentrated in the certain segments of newly regulated industries.

Prohibiting free samples eliminates a category of potential industry expenditures. Prohibiting free samples will not reduce total economic profits if the primary effect is to induce brand switching and change the distribution of profits rather than total profits. On the other hand, the lack of free samples may discourage consumers from purchasing different products and may affect sales. Manufacturers may switch to other marketing strategies in order to increase or maintain market share; there may be some small social costs if manufacturers engage in more costly or less effective marketing strategies.

4. OTHER COSTS ASSOCIATED WITH NEWLY DEEMED PRODUCTS

a) Consumer Costs

We lack a baseline estimate of consumer valuation of tobacco product variety, making it impossible to estimate how consumers who continue to use tobacco products would value the potential loss of variety due to product exit under this final rule. Today we see very large numbers of products embodying minor variations. Even if considerable product consolidation were to occur, close substitutes would exist for discontinued products, which would limit the size of any ongoing impact on consumers who switch to a substitute product. However, there will be some one-time costs for searching for a suitable substitute when products exit the market. We do not quantify these search costs here.

Free samples encourage current and non-tobacco product consumers to try different and new tobacco products, enabling them to learn about their own preferences and possibly change their purchasing behavior as a result. Losing this low-cost opportunity to sample different products

would raise consumer search costs. However, we expect this cost to be small and do not quantify it here.

b) Costs of Market Adjustment

As noted above, some manufacturers or importers of newly deemed tobacco products may cease to sell their products in the U.S. rather than bear the cost of complying with this final rule. Foreign manufacturers, for example, would not necessarily cease to operate; rather, they may reduce the number of products they sell in the U.S. or cease to sell their products in the U.S. Retailers who currently meet the definition of manufacturer may continue to operate but cease to engage in manufacturing activities and convert to a pure retail model. We do not estimate the amount of potential exit among manufacturers and importers, but we assume that vape shops will change their business model and switch to pure retailing. We do, however, expect there to be a substantial amount of product exit for certain product categories, such as ENDS. Whether this product exit results in loss of producer surplus depends on whether the rule primarily causes market consolidation, with a smaller number of firms selling a smaller number of products yet with similar levels of production and sales, versus a contraction in total levels of production and sales.

Products will be withdrawn from the market or firms will opt to shut down if the cost of complying with the final rule exceeds the cost of exiting (including forgone profits). Because some of the industry segments affected by this rule consist of very large numbers of products with very low value of sales volume, and the per product compliance cost of premarket review can be significant, substantial amounts of product consolidation or product or firm exit may occur within those segments. The extent of producer surplus loss from exit depends on the difference between the value of any resources that will be redirected from their current use and the value of their next best use under this final rule. By contrast, product consolidation would lead to transfers between products and firms rather than social costs, that is, production and sales may become more concentrated in a smaller number of firms or products, but they would not necessarily drop off. In addition, any product or firm exit will entail one-time friction costs. Friction costs from firm exit include labor search costs, as displaced workers look for other jobs, and capital reallocation costs, as firm owners sell off productive assets. As some businesses, such as vape shops, change their business model to pure retailing in response to the rule, friction costs are incurred as they reposition themselves in the marketplace. However, lack of baseline data on distributions of sales within and across market segments and the considerable uncertainties associated with predicting effects of the rule on business decisions imply we lack a basis for estimating these costs of market adjustment here.

We also note that the burgeoning market for ENDS is still in a state of flux. Considerable product consolidation might be expected to occur under the baseline due to industry life-cycle consolidation in coming years, as successful products gain rising market shares and less successful ones are driven out, and as larger firms or manufacturers of traditional tobacco products enter this market and perhaps absorb smaller manufacturers and products. Because the entry, exit, and consolidation that would occur in the absence of the rule is likely to be considerable yet is difficult to forecast, identifying the extra amount of product exit attributable to the final rule is especially difficult to predict. However, costs of market entry under the final rule are likely to be higher than they would be under the baseline, so we can expect the industry

to become more concentrated more quickly than would be the case without the rule, as the substantial expense of seeking premarket authorization will represent an important new barrier to entry.

5. LABELING COSTS

Compliance with the final rule requires certain label changes, including changes to satisfy the requirements of chapter IX of the FD&C Act and the warning statement provisions.⁶³ Under chapter IX of the FD&C Act, a newly deemed tobacco product in package form would be misbranded unless it contained the following information on 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). Section 911 of the FD&C Act prohibits the introduction into interstate commerce of modified risk products, including products, the label, labeling, or advertising of which, use "light," "mild," or "low," or other modified risk claim without the appropriate FDA order in effect. Pursuant to the warning statement provisions, cigarette tobacco, roll-your-own tobacco, and covered products other than cigars will be required to carry a single addiction warning. Cigars will be required to display 6 rotating warnings, 5 of which are the same as or similar to warnings currently displayed by a sizable segment of the cigar market as a result of FTC consent decrees. For cigars sold individually without a product label, the required warning statements will be displayed on a sign at the point of sale.

The compliance period for the § 903(a)(2) and § 920(a) labeling requirements is two years after publication of the final rule, and the effective date for the warning statement provisions is two years after publication of the final rule. The compliance period is one year from the effective date (15 months after the publication of the final rule) for compliance by manufacturers with section 911(b)(2)(A)(ii), which prohibits the use of "light," "low," "mild," and other similar descriptors in label and labeling, unless the manufacturer has a modified risk tobacco product order in effect.⁶⁴ Newly deemed products bearing modified risk descriptors will face higher costs from either complying with all labeling requirements early (15 months after publication of this final rule instead of 2 years after publication) or conducting two separate labeling changes. However, because only a small number of products bear these descriptors, we do not estimate this additional cost.

⁶³ With the possible exception of ENDS products, 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 for other products, but we have not observed this in other jurisdictions that have implemented large warning labels.

⁶⁴ Manufacturers must not introduce a modified risk tobacco product (as defined in the remaining sections of 911(b) (e.g., tobacco products the label, labeling, or advertising of which explicitly or implicitly represents that the product is lower risk, contains a reduced level/presents a reduced exposure to a substance, or does not contain/is free of a substance, or action taken by a manufacturer directed to consumers that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk, contains a reduced level/exposure to a substance, or does not contain/is free of a substance without an FDA order authorizing such marketing)) into interstate commerce as of the effective date of the final rule (i.e., 90 days after the publication date).

We assume the number of products that will comply with the labeling changes is equal to the number of products marketed as of the effective date of this final rule and that are either grandfathered or submit an application for premarket review during of the relevant initial compliance period (12 months from the effective date for an SE exemption request, 18 months from the effective date for an SE report, and 24 months after the effective date for a PMTA). See Table 9, above.

In order to estimate the cost of tobacco product labeling changes, FDA relies primarily on the FDA labeling cost model developed by RTI International (RTI, 2015). The model uses universal product code (UPC) and product formulation counts based on scanner data from 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 as likely to be accurate for other tobacco products. Therefore, we use our own estimates of the number of product-packages affected by this final rule in place of the model's estimates of the number of UPCs within each affected product category.

The FDA labeling cost model incorporates three potential cost components of a labeling change: label design costs, inventory costs, and testing costs. However, for tobacco product labeling changes conducted within 24 months, the model estimates that there will be no discarded inventory costs.⁶⁵ Additionally, we do not include market testing costs because we assume few manufacturers of affected tobacco products would conduct market testing for the required labeling changes.

(1) Pipe Tobacco, Waterpipe Tobacco and RYO Tobacco

The changes required for cigarette tobacco, roll-your-own tobacco and combusted newly 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 newly deemed-product labels, not just minor

⁶⁵ We assume all products are branded because the sources we use to develop expanded estimates of the number of product-package combinations do not allow us to identify private label products. This does not affect the estimated cost of changing tobacco product labels within 24 months because neither private label nor branded products would be expected to have label inventory on hand 24-months after publication of the rule (*i.e.*, at the effective date of the warning statement provisions and the close of the compliance period for § 903(a)(2) and § 920(a)). For shorter time periods, this assumption eliminates costs that would be associated with discarded inventory for private label products. However, such costs would be small if we could measure them.

alterations of existing text.⁶⁶ Satisfying one or both of these sets of requirements requires the layout of a label to be changed to accommodate additional text.

Given the effective date for the required warning statements (24 months after publication) and the 24-month compliance period for § 903(a)(2) and § 920(a) of the FD&C Act, the labeling cost model assumes that labeling changes for 22 percent of branded UPCs can 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.

Table 21 summarizes the estimated labeling 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 21--Per UPC Label Design Costs for a Major Labeling Change

	Low	Medium	High
Per-UPC Cost For Uncoordinated Changes (\$)	3,847	7,739	13,963
Per-UPC Cost For Coordinated Changes (\$)	387	1,304	2,930

Table 22 summarizes the label change costs for pipe, waterpipe, and roll-your-own tobacco. We do not estimate labeling costs for pipes and waterpipes. Pipes and waterpipes sold alone (not as part of a kit containing tobacco) are not “covered tobacco products” because, although they are components or parts, they are not made or derived from tobacco, and, therefore, are not subject to the warning statement provisions. Given that pipes and waterpipes appear to frequently be offered for sale to consumers without product-specific packages, any costs to comply with § 903(a)(2) and § 920(a) would be expected to be much lower than costs for products offered for sale in product-specific packages.

Table 22--Label Change Costs for Pipe, Waterpipe and RYO Tobacco

	Low	Medium	High
Number of uncoordinated pipe tobacco changes	815	815	815
Number of coordinated pipe tobacco changes	230	230	230
Cost for pipe tobacco (\$)	3,224,706	6,606,928	12,053,664
Number of uncoordinated waterpipe tobacco changes	722	722	722
Number of coordinated waterpipe tobacco changes	203	203	203
Cost for waterpipe tobacco (\$)	2,856,442	5,852,025	10,676,004
Number of uncoordinated RYO Tobacco changes	275	275	275
Number of coordinated RYO Tobacco changes	77	77	77
Cost for cigarette tobacco and RYO tobacco (\$)	1,087,856	2,228,540	4,065,408
Total Cost (\$)	7,169,004	14,687,492	26,795,075

(2) Cigars

⁶⁶ 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 already included on tobacco product labels.

Compliance with the final rule requires certain labeling changes, including changes to satisfy requirements under chapter IX of the FD&C Act and the warning statement provisions, the latter of which requires the use of 6 rotating warning statements. Cigars covered by the FTC consent orders already have 5 rotating warning statements. 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 6 versions of its new label, regardless of whether the product 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 will be larger for a label with 6 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 required under the FD&C Act) minor changes will be needed to alter the black or white text for the 5 additional versions of the label. Therefore, we estimate the cost of materials needed for producing the extra versions of the label to be 5 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 6 warnings.⁶⁷

Table 23 summarizes the total label design costs per UPC, accounting for the need to have 6 versions of each new label. Table 24 shows the cost of changing cigar labels when 6 versions of every new label are needed.

Table 23--Total Per UPC Label Design Costs (6 Versions of Each New Label)

	Low	Medium	High
Per-UPC Cost For Uncoordinated Changes (\$)	5,000	9,601	16,659
Per-UPC Cost For Coordinated Changes (\$)	1,540	3,166	5,626

Table 24--Cigar Labeling Changes (6 Versions of Each New Label)

	Low Cost	Medium Cost	High Cost
Number of uncoordinated cigar changes	5,557	5,557	5,557
Number of coordinated cigar changes	1,568	1,568	1,568
Cost for cigars (\$)	30,201,675	58,318,006	101,395,075

The provisions covering equal random display and special rules for cigars sold singly generate additional costs. Equal and random display of the 6 cigar warning statements will 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 will be part of the upfront label change, continued operation of such a system in subsequent years will have incremental ongoing administrative and recordkeeping costs. FDA assumes that the ongoing yearly administrative labor cost per UPC will be equal to 10 percent of the (non-rush) administrative labor cost of an uncoordinated labeling change, and the yearly recordkeeping cost will be equal to 50 percent of the (non-rush) recordkeeping cost of an uncoordinated labeling

⁶⁷ Some of the subcomponents of other cost categories might increase due to the 6-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 six warning statements.

change. FDA estimates that 20 percent of cigar UPCs currently carry FTC warnings, leaving 80 percent that do not.⁶⁸

Table 25 shows the incremental annual costs of equal random display.

Table 25--Incremental Annual Costs for Equal Random Display of Cigar Warnings

	Low	Medium	High
Ongoing Administrative Costs per UPC (\$)	75	255	576
Ongoing Recordkeeping Costs per UPC (\$)	17	32	55
Administrative and Recordkeeping Costs per UPC (\$)	91	287	631
Number of Cigar UPCs Affected	5,700	5,700	5,700
Total Cost (\$)	519,270	1,635,330	3,595,560

All six of the required warning statements will have to be displayed on a sign at the point-of-sale in every retail establishment that sells cigars individually without a package. The upfront costs include the administrative set-up costs and material costs (sign and holder). The time of retail clerks is valued at the median wage in the retail sector as reported by the Bureau of Labor Statistics, or \$11.19.⁶⁹ We double this to account for benefits and overhead, yielding an hourly cost of \$22.38. Each retail establishment selling cigars singly without packaging will need at least one sign, although some establishments are likely to use multiple signs. 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 26.

Table 26--Costs for Point-of-Sale Warnings

	Low	Medium	High
Number of retail establishments displaying warning sign	123,003	212,448	301,893
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	13
Time required for each retailers' administrative set-up (min)	60	60	60
Retail wage	22.38	22.38	22.38
Upfront costs for signs, display stands, and set-up	3,867,224	7,316,718	11,302,881
Annual refresh cost (15% of Upfront Cost)	580,084	1,097,508	1,695,432

(3) ENDS

⁶⁸ This was estimated using raw data indicating the presence or absence of a warning label, by product, for all 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 master settlement agreement 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 lower than the proportion of cigar units sold that have warnings.

⁶⁹ May 2014 National Industry-Specific Occupational Employment and Wage Estimates for Sectors 44 and 45 -- Retail Trade. <<http://www.bls.gov/oes/>>. We use the median rather than mean wage so that value of retail time will not be as severely affected by the wages of more highly paid occupations, such as management occupations, which are less likely than retail clerks to be involved in performing the work described above.

The labeling change for ENDS products will be a major change, except in some cases in which the current packaging is too small to accommodate the required warning statement. In such cases, ENDS manufacturers may increase the size of the product package to accommodate the warning, place the required warning on a carton or other outer container or wrapper, or place the required warning on a hang tag firmly and permanently affixed to the product package. Increasing the package size or adding an outer carton or container would constitute an extensive change in the labeling cost model, which is more expensive than making a major labeling change; there would also be a slight increase in the unit cost of production going forward. If a hang tag is used to accommodate the warning, the product label would still have to be changed to comply with requirements of the FD&C Act (a major labeling change), and there would be a slight increase in the unit cost of production going forward. We do not estimate these potential greater costs because we lack information about the proportion of products remaining on the market that may be unable to accommodate the required warning statement due to the current packaging size.

We estimate labeling costs for all ENDS e-liquids and delivery systems that are expected to be grandfathered or expected to submit an application for premarket review during the initial premarket review compliance policy period. We note that this likely overestimates costs to the extent that some products may not be “covered tobacco products” (as they are components or parts that are not made or derived from tobacco and, therefore, are not subject to the rule’s warning statement requirements) and may have lower costs to comply with § 903(a)(2) and § 920(a) if they lack product-specific packaging.

FDA judges that low-volume ENDS products may be more likely to use digital printing than the labeling cost model estimates for non-cigarette combusted tobacco products. Therefore, we adjust the per-UPC labeling cost for ENDS products assuming that 90 percent of ENDS labels use digital printing. Table 27 summarizes the estimated labeling cost per UPC under this assumption.

Table 27: Per UPC Label Design Costs for a Major ENDS Labeling Change

	Low	Medium	High
Per-UPC Cost For Uncoordinated Changes (\$)	3,239	6,752	12,533
Per-UPC Cost For Coordinated Changes (\$)	387	1,304	2,930

Table 28 shows the costs of changing ENDS product labels assuming that ENDS products remaining on the market only require a major labeling change.

Table 28--Label Change Costs for ENDS Products (E-liquids and Delivery Systems)

	Low	Medium	High
Number of uncoordinated ENDS changes	1,262	1,786	2,309
Number of coordinated ENDS changes	356	503	651
Label Change Cost for ENDS (\$)	4,225,769	12,714,984	30,845,434

6. ADDITIONAL PRIVATE SECTOR COSTS

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

Compliance with the warning statement provisions requires removal of any existing point-of-sale advertising that fails to conform to the new requirements. In the analysis of FDA’s 1996 final tobacco rule⁷⁰, 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, but we adjust the level of effort downward to reflect the size of the market for products covered by the warnings provisions relative to the total size of the tobacco market.⁷¹ We also adjust the cost of removal to current dollars using the GDP deflator. We acknowledge, however, that this approach may overstate or understate the costs for a particular action or type of business.

Based on the information shown in Table 29 below, FDA estimates that sales of tobacco products covered by the warning statement provisions were approximately 11 percent of expenditures for all tobacco products in 2013. Appendix Table 2 shows that 351,554 to 356,554 establishments selling tobacco products will be covered by the point-of-sale advertising requirements of the final 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.) Adjusting the level of effort required in 1996 downward to reflect the size of the market for products covered by the warning statement provisions, we find that costs will range from an average of about \$1 for “other establishments” to \$23 for convenience stores, with a weighted average of about \$14.88 to \$14.93, as shown in Appendix Table 2. The total one-time cost of complying with restrictions on point-of-sale advertising is then estimated to be \$5.2 to \$5.3 million. Lacking information about the amount of point-of-sale advertising used for each type of tobacco product affected by this provision, we attribute total estimated cost from Appendix Table 2 to specific product classes based on current relative dollar sales volume, as shown in Table 29, below.

Table 29 –Relative Sales Volume and Costs for Removal of Noncompliant Point-of-Sale Advertising

	Sales (\$ Million)	Proportion of total sales for products covered by warnings provisions	Cost (Low) (\$)	Cost (High) (\$)
Cigars ¹	7,980	63.33%	3,312,796	3,372,413
Pipe Tobacco ²	1,763	13.99%	731,998	745,171
Roll-Your-Own Tobacco ²	657	5.21%	272,714	277,622
ENDS ³	2,200	17.46%	913,337	929,773
Total for products covered by warnings provisions	12,600	100.00%	5,230,845	5,324,978
Total for all tobacco⁴	114,469			

1 Euromonitor, 2014a.

2 Euromonitor, 2014b.

⁷⁰ The majority of the 1996 final tobacco rule was reissued in 2010, as directed by the Tobacco Control Act.

⁷¹ That is, we are implicitly assuming that cigarettes made up the entirety of point-of-sale tobacco advertising in 1996, and the total amount of such advertising in each type of retail outlet has not changed, but the product mixture has shifted away from cigarettes as product sales have shifted away from cigarettes.

3 Herzog et al., 2014b.

4 Euromonitor, 2014c; Herzog, et al., 2014b.

b) Minimum Age and I.D. Restrictions

We expect that the minimum age and identification provision will impose a negligible incremental cost because nearly all retailers should already be conducting identification checks for purchases of newly-deemed tobacco products. We reach this conclusion because, under state laws currently in place, all states prohibit the sale of most types of tobacco products to minors (ERG, 2011). (However, as described previously, the definition of “tobacco products” varies among the states and generally does not include all newly deemed covered tobacco products.) Moreover, under current federal regulations (21 CFR § 1140.14), no retailer in any state may sell cigarettes, roll-your-own tobacco, cigarette tobacco, or smokeless tobacco to any person under 18 years of age, and retailers must verify the age of cigarette, roll-your-own tobacco, cigarette tobacco, 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.

We acknowledge, however, that “vape shops,” which have recently been entering the market, could present a minor exception. To the extent that these shops are located in states or localities that do not ban the sale of vapor products to minors, and to the extent that these shops do not also sell traditional tobacco products, there may be incremental per-transaction time costs or costs for training employees. The baseline of state laws regulating ENDS is changing rapidly, but as of January 2015, at least 41 states banned sales of electronic cigarettes or ENDS products to minors.⁷² Therefore, we expect any incremental costs of the minimum age and identification restrictions in this final rule to be very small.

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 (Vending Times, 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 \$17.0 million in 2012 (U.S. Census, 1995; 2012 U.S. Census Retail Trade Product Lines). Tobacco products accounted for 7.1 percent of vending machine establishment sales in 1992 but only 0.3 percent of sales in 2012.

Most current vending machine sales of tobacco products already take place in adult-only establishments because of state restrictions in place or because of federal restrictions on cigarette, roll-your-own tobacco, cigarette tobacco, and smokeless tobacco vending machine sales that went into effect in 2010. (We expect that, to some extent, vending machine sales of other tobacco products may have moved into adult-only facilities when these federal regulations

⁷² <http://www.ncsl.org/research/health/alternative-nicotine-products-e-cigarettes.aspx>

went into effect.) Therefore, only a small proportion the \$17.0 million in annual tobacco vending machine revenue is likely to be affected by this rule; any associated reduction in profits is expected to be very small.

7. ADMINISTRATION AND ENFORCEMENT COSTS BORNE BY GOVERNMENT (COSTS TO FDA)

FDA tentatively projects that 55 full-time-equivalent employees (FTEs) will be needed to implement and enforce this final rule. FDA’s regulation of tobacco products is fully funded by industry user fees, which are fixed by statute. Therefore, these FTEs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the federal budget, or the total amount of tobacco industry user fees. Fully loaded employee costs vary with the type of employee (e.g., field inspectors versus administrative), but an average of \$250,000 per FTE places the dollar cost at approximately \$13.75 million per year.

In order to disaggregate total FDA costs by product type, we assume that FDA costs are proportional to annualized private sector premarket submission costs because a considerable portion of FDA costs will be attributable to the review of premarket submissions (substantial equivalence exemption requests, substantial equivalence reports, premarket tobacco applications).⁷³

8. SUMMARY OF COSTS

Table 30 summarizes the present value of costs of the final rule. The total present value of costs is estimated to range from \$722 million to \$1.31 billion, with a primary estimate of \$988 million, at a 3 percent discount rate. The total present value of costs is estimated to range from \$596 million to \$1.09 billion, with a primary estimate of \$ 817 million, at a 7 percent discount rate.

Unquantified costs which may be attributable to this final rule include: some consumer costs for users of the newly deemed products due to loss of product variety or higher prices; recordkeeping costs for exporters of deemed tobacco products; compliance costs for components and parts other than complete pipes, waterpipes, and ENDS delivery systems; the cost of testing and reporting for harmful and potentially harmful constituents; the cost of any clinical testing that may potentially be conducted to support substantial equivalence reports; market adjustment (friction) costs and lost producer surplus associated with product consolidation, exit of manufacturers (including some vape shops currently engaged in manufacturing activities), and the switch to pure retailing among retailers such as vape shops who currently engage in manufacturing activities.

Table 30—Present Value of Quantified Costs (\$mill)

	Lower	Primary	Upper	Lower	Primary	Upper

⁷³ \$13.75 million is 33 percent of the best estimate of annualized premarket submission costs of the final rule, calculated with a 3 percent discount rate. We therefore assume that the FDA cost attributable to each product class is 33 percent of the product class’s best estimate at 3% of annualized premarket submission costs.

	Bound (3%)	(3%)	Bound (3%)	Bound (7%)	(7%)	Bound (7%)
Private Sector Costs:						
Regulation Review ¹	5.3	7.6	9.9	5.1	7.3	9.5
New product submission requirements	439.5	627.8	835.9	380.6	533.5	699.7
Registration and Product Listing ¹	0.5	1.2	1.8	0.5	1.0	1.6
Ingredient Listing ¹	9.7	17.7	25.7	8.8	16.3	23.7
Label Changes	57.7	124.4	231.6	50.8	108.1	200.5
Point-of-sale advertising ¹	4.9	5.0	5.0	4.6	4.6	4.7
Private Sector Subtotal	517.7	783.7	1,109.8	450.4	670.9	939.8
Government Costs ³	204.6	204.6	204.6	145.7	145.7	145.7
Total Cost	722.3	988.2	1,314.4	596.1	816.5	1,085.4

¹ We use the midpoint of the estimated lower and upper bounds as our primary estimate.

³ Government costs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the federal budget, or the total amount of tobacco industry user fees.

Table 31 shows the total annualized value of costs. The primary estimate of total annualized costs is \$35 million at a 3 percent discount rate and \$77 million at a 7 percent discount rate. Note that, although annualized values computed using a higher discount rate are often below those found when computed using a 3 percent discount rate, whether this is true in a given analysis depends on the timing of the costs. See Appendix Table 3 for the undiscounted stream of total costs.

Table 31 Annualized Value of Quantified Costs (\$mill)

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Private Sector Costs	34.8	52.7	74.6	42.5	63.3	88.7
Government Costs ¹	13.8	13.8	13.8	13.8	13.8	13.8
Total Costs	48.5	66.4	88.3	56.3	77.1	102

¹ Government costs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the federal budget, or the total amount of tobacco industry user fees.

9. SUMMARY OF COSTS BY PRODUCT CATEGORY

We quantify costs for five categories of tobacco products: 1) cigars, 2) pipes and pipe tobacco 3) waterpipes and waterpipe tobacco, 4) ENDS, and 5) 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.

Table 32 shows the present value of costs by product category.

Table 32--Present Value of Quantified (Private Sector and Government) Costs by Product Category (\$mill)

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Cigars						
New product submission requirements	54.7	73.8	93.1	41.5	54.4	67.5
Labeling	46.8	98.2	176.4	40.5	83.3	148.4

Total, including not otherwise listed ¹	130.9	201.8	299.7	103.9	160.0	238.4
Pipe Tobacco						
New product submission requirements	38.8	55.1	71.4	28.0	39.0	50.1
Label Changes	3.1	6.3	11.5	2.9	6.0	10.9
Total, including not otherwise listed ¹	62.6	82.5	104.4	46.1	60.5	76.7
Waterpipe tobacco						
New product submission requirements	11.6	15.5	19.4	8.8	11.4	14.1
Label Changes	2.7	5.6	10.2	2.6	5.3	9.7
Total, including not otherwise listed ¹	19.8	26.7	35.3	15.4	20.8	27.9
ENDS						
New product submission requirements	334.4	483.4	652.0	302.4	428.6	568.1
Label Changes	4.0	12.2	29.5	3.8	11.5	27.9
Total, including not otherwise listed ¹	507.6	674.8	870.9	429.5	573.0	738.6
Roll-your-own tobacco and cigarette tobacco						
New product submission requirements ²	NA	NA	NA	NA	NA	NA
Label Changes	1.0	2.1	3.9	1.0	2.0	3.7
Total, including not otherwise listed ¹	1.3	2.4	4.2	1.2	2.3	3.9
All quantified						
New product submission requirements	439.5	627.8	835.9	380.6	533.5	699.7
Label Changes	57.7	124.4	231.6	50.8	108.1	200.5
Total, including not otherwise listed ¹	722.3	988.2	1,314.4	596.1	816.5	1,085.4

1 The totals include the FDA costs attributed to each product class. FDA costs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the federal budget, or the total amount of tobacco industry user fees.

2 The only costs for cigarette tobacco and roll-your-own tobacco stem from the warning statement provisions in the final rule, as these products are already subject to FDA's tobacco authorities.

D. BREAK-EVEN CALCULATION FOR THE FINAL RULE

The benefits of the final rule flow from policies that mitigate or correct market failures that exist in the market for tobacco products, as discussed in the “need for the final rule” section. These market failures include asymmetric or imperfect information, internalities, externalities, and institutional failures. The policies contained in this final rule may lead to behavioral changes that could improve health or other welfare-enhancing changes. As discussed above, the effects of this final rule potentially come from: premarket review; youth access restrictions and prohibitions on free samples; health warning statements; prohibitions against false or misleading claims and unsubstantiated MRTP claims; and other institutional changes, such as FDA monitoring of product developments and changes and required ingredient listing.

As described in the benefits section above, the welfare gains of this rule come from mechanisms that better align actual consumption and production decisions with socially optimal patterns. In principle this value could be measured by consumers' willingness to pay for the policy instruments embedded in the rule. Without being able to quantify the rule's benefits, a measure with which a rule's potential value can be compared is obtained by dividing its total

costs by the number of people expected to benefit from it. This measures what the rule's expected beneficiaries would need to be willing to pay on average for the rule in order for the benefits to equal the costs.

The primary estimate of the value of costs of this final rule, annualized over 20 years, is \$66.4 million with a 3 percent discount rate and \$77.1 million with a 7 percent discount rate. As discussed in a previous section, FDA estimates from the National Adult Tobacco Survey (2012-2013) and the National Youth Tobacco Survey (2014) that approximately 34.9 million adults and youth currently use newly deemed tobacco products and roll-your-own tobacco.⁷⁴ The break-even annual willingness-to-pay for this rule, based on the current number of users, is therefore approximately \$2 per current user at both discount rates. FDA notes that the pool of beneficiaries is broader than the estimated number of current users of newly deemed products. Specifically, FDA expects that many individuals who are not current users, and thus not included in this calculation, will benefit from the rule. For example, future potential users of these products who will be deterred from use as a result of the provisions embodied in the rule will benefit from that deterrence. Additionally, non-users may benefit from reduced second-hand exposure to these products. Further, FDA expects that premarket review of ENDS products will benefit individuals by making it more likely that firms will implement protections against accidental poisoning. Similarly, parents of youth will benefit from the protections created and enabled by this rule, to the extent that their children are deterred from initiation and use. Lack of information on usage patterns and health risks of newly deemed products means it is not possible to estimate numbers of people in these additional groups of potential beneficiaries with any degree of confidence. However, FDA notes that if quantitative estimates of these additional beneficiaries could be included in the analysis, the break-even annual willingness-to-pay would be even lower than the estimated \$2 per current user.

E. DISTRIBUTIONAL EFFECTS

This final rule will have effects that are experienced as losses by some segments of U.S. society and as gains by other segments of society; as such, some portion of these effects do not constitute net social costs or benefits. In general, sectors affiliated with tobacco and tobacco products may lose sales revenues as a result of this final rule. In contrast, non-tobacco-related industries may gain sales, because dollars not spent for tobacco products may be spent on other goods. Additionally, the net social costs and benefits of this rule will not be borne equally by all segments of society.

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-

⁷⁴ From the National Adult Tobacco Survey (NATS), we include adults who reported using products "every day", "some day", or "rarely" users. From the National Youth Tobacco Survey (NYTS), we include youths who used tobacco products in the preceding 30 days.

your-own tobacco.⁷⁵ In the event that any of these product classes are not subject to the FD&C Act—as was the case for cigars and pipe tobacco prior to this final rule—the amount that would be paid by their manufacturers and importers is reallocated to manufacturers of classes that are subject to the FD&C Act (cigarettes, snuff, chewing tobacco and roll-your-own tobacco). Therefore, upon deeming cigars and pipe tobacco to be subject to the FD&C Act, cigar and pipe tobacco classes will start to pay user fees and the percentage of the total user fee assessment paid by other tobacco product classes will decrease accordingly. The total amount of tobacco industry user fees is fixed by statute and will not change as a result of this final rule.

Table 33 estimates how much cigar and pipe tobacco manufacturers will be charged in user fees from fiscal year 2016 through 2019, and how much other product manufacturers’ fees will decrease, assuming that the allocation to each tobacco product class follows the same percentages currently in effect for fiscal year 2016 (FDA, 2016). The actual percentages will change each year according to changes in market share. After 2019, the total amount of user fees will remain constant.

Table 33--Reallocation of User Fees to Cigars and Pipe Tobacco from Other Tobacco Product Manufacturers

Year	Total Tobacco Product User Fees (\$1,000)	Fees Allocated to Cigars, Assuming Class Allocation of 10.8979% (\$1,000) ¹	Fees Allocated to Pipe Tobacco, Assuming Class Allocation of 0.7659% (\$1,000) ¹	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)
2016	599,000	65,278	4,588	68,861	899	58	48
2017	635,000	69,202	4,863	73,000	953	61	51
2018	672,000	73,234	5,147	77,254	1,009	65	54
2019	712,000	77,593	5,453	81,852	1,069	68	57

¹ This assumes that the allocation to each tobacco product class follows the same percentages currently in effect for fiscal year 2016 (FDA, 2016). The actual percentages will change each year according to changes in market share.

2. CONSUMERS OF TOBACCO PRODUCTS

This final rule deems products meeting the statutory definition of “tobacco product,” except for accessories of newly deemed tobacco products, to be subject to chapter IX of the FD&C Act. The final rule also includes three additional provisions for covered tobacco products, including a requirement for warning statements for product packages and advertisements (which also apply to cigarette tobacco and roll-your-own tobacco). These actions entail social costs, as estimated and discussed above in Section III.C, such as loss of choice due to a reduction in product variety through product exit or consolidation and increased search costs attributable to the ban on free samples. Much of the cigar market is characterized by a large number of low-volume products. Many distinct products are minor variants within a brand or sub-brand. Therefore, due to the availability of these close substitutes, the number of variants could be reduced without greatly reducing the variety available to consumers. In addition, FDA has clarified in the preamble to

⁷⁵ See Section 919.

the final rule that allowing prospective adult customers to handle and smell a cigar is not considered the distribution of a free sample.

Similarly, the market for e-liquids is characterized by a large number of brands and an even larger number of uniquely described flavors, recently estimated to be 7,764 (Zhu et al., 2014). The number of distinct brand-flavor variants of e-liquid could be reduced without substantially altering the variety available to consumers. For example, blueberry e-liquid might continue to be available, but the number of brands offering blueberry or the number of subtle variations of blueberry could be reduced.

The majority of the compliance costs of this final rule are fixed, but a portion of the costs are variable. Most of the variable costs would be passed on to consumers in the form of higher prices. Any increase in prices faced by consumers as a result of this final rule could dissuade some people from using newly deemed tobacco products.

3. TOBACCO MANUFACTURERS, DISTRIBUTORS, AND GROWERS

As shown in Table 29, we estimate that annual sales of tobacco products, including ENDS, total \$114.5 billion per year. Based on the same sources (Euromonitor, 2014a; 2014b; and 2014c; Herzog et al., 2014b), we estimate that newly deemed tobacco products, and cigarette tobacco and roll-your-own tobacco products affected by the additional provisions of this final rule, account for \$12.6 billion in annual sales. This final rule may reduce tobacco product use, which would reduce revenues of tobacco product manufacturers.

According to USDA's 2012 Census of Agriculture (USDA, 2014), there were 10,014 tobacco farms covering 342,932 acres and producing around 766.6 million pounds of tobacco. Upon implementation of the rule, these farms may shift some of their acreage from growing tobacco to producing other agricultural products.

Domestic production of all types of cigar tobacco accounted for around 1 percent of total domestic tobacco production in both 2012 and 2014 (USDA, 2015). Production of flue-cured and burley tobaccos, the main cigarette tobaccos, accounted for around 89 percent of domestic tobacco production in both 2012 and 2014.

Some retailers, such as vape shops that mix e-liquid, currently engage in activities that fall within the definition of manufacturer under the FD&C Act. We expect that rather than comply with the FD&C Act requirements for manufacturers, which would impose significant costs, most of these establishments will cease to engage in manufacturing activities, but most will convert to a pure retail model after the initial compliance period for the submission and FDA receipt of PMTAs expires.

4. NATIONAL EMPLOYMENT PATTERNS

Several studies estimate the contribution of tobacco products 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 (Chaloupka and Warner, 2000). Any income and employment effects associated with a potential reduction in consumption of tobacco products covered by this final rule would be small.

As of 2012, Statistics of U.S. Businesses data indicate that tobacco manufacturing employed 14,599 people, tobacco and tobacco product merchant wholesaling employed 48,403, and tobacco stores employed 34,514, for total (nonfarm) employment of 97,516 people. This is 0.07 percent of total May 2012 employment of 130,287,700.⁷⁶ These numbers do not account for farm employment or self-employed individuals who do not have hired employees. Nevertheless, this demonstrates that tobacco industry employment accounts for only a small proportion of total employment in the U.S. economy. Newly deemed products account for only a portion of total tobacco industry employment. Therefore, the affected segments of the tobacco industry will be extremely small in the context of the U.S. economy.

5. REGIONAL AND LOCAL IMPACTS

As discussed above, the tobacco industry *as a whole* accounts for about 0.07 percent of nonfarm employment in the US. However, we note that certain parts of the US have a higher proportion of employment in the tobacco industry. For example, cigar filler tobacco is grown in Pennsylvania, and tobacco for cigar binders and cigar wrappers is grown in Connecticut and Massachusetts (USDA, 2015). In addition, Florida has cigar manufacturers that will be affected. We respond to some regional and local concerns in the responses to comments, and we expect these effects to be small.

The total acres of cigar filler harvested was around 0.05 percent of the total acres harvested in Pennsylvania in 2014 ($= (2000/3719000) * 100$). Total acres of cigar binder and cigar wrapper tobacco harvested accounted for a little over 1.5 percent of the total acres harvested in Connecticut and Massachusetts combined in 2014 ($= (2780/167000) * 100$).

6. RETAIL SECTOR

Apart from expected effects on vape shops discussed previously, any reduction in tobacco product sales that may result from this rule is expected to have minimal impacts on other retailers. Retailers would be able to shift shelf space and other activities to non-tobacco products. If some retailers who rely heavily on tobacco sales are not 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. We note, however, that these effects would be small. The Bureau of Economic Analysis reports that personal consumption expenditures on all tobacco products were \$108.0 billion in 2013.⁷⁷ Total

⁷⁶ <http://www.bls.gov/oes/2012/may/oes_nat.htm>

⁷⁷ Table 2.4.5, Personal Consumption Expenditures by Type of Product, available at <<http://www.bea.gov/iTable/iTable.cfm?reqid=9&step=1&acrdn=2#reqid=9&step=1&isuri=1>>. This differs slightly from our estimate above, but is most comparable to the estimate of total personal consumption expenditures.

personal consumption expenditures were \$11,484.3 billion. Expenditures on all tobacco products represented less than 1 percent of total personal consumption expenditures; because cigarettes account for the largest share of tobacco spending, expenditures on the tobacco products affected by this rule account for a fraction of 1 percent of total personal consumption expenditures.

We discuss the effects of this final rule on retailers who meet the definition of manufacturer above.

7. EXCISE TAX REVENUES

If this final rule leads to a decrease in consumption of taxed tobacco products, government tobacco product excise tax revenues would fall. Sales tax revenues generated through tobacco product sales would also fall, but those changes would be much smaller than the changes in excise tax collections and are likely to be offset as consumers use their money to purchase other taxable products.

The Tax Burden on Tobacco estimates that excise tax collections from non-cigarette tobacco products were about \$907 million at the federal level and \$1.6 billion at the state level for the fiscal year ending June 30, 2014 (Orzechowski and Walker, 2014). Excise tax revenues from non-cigarette tobacco products make up 6.3% of federal and 7.8% of state total tobacco excise tax revenues. These estimates overstate the excise tax collections from deemed products because they include tobacco tax revenues from chewing tobacco, snuff, and roll-your-own tobacco. ENDS products that do not contain tobacco are not currently subject to federal tobacco excise taxes and are subject to excise taxes in only a few states.⁷⁸

Any decrease in tobacco tax revenues resulting from any decreases in consumption of taxed tobacco products would be partially offset by increases in consumption of other taxable goods and services. The Joint Committee on Taxation estimates between 25 and 30 percent of any excise tax revenue reduction would be offset (Joint Committee on Taxation, 2005; 2011).

Leaving aside potential changes in 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 any reduction in excise tax collections that may occur as a result of this final rule.

8. 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 lifetime net costs are estimated to be \$5,822 per female 24-year-old smoker and \$4,056 per male 24-year-old smoker

⁷⁸ As of November 2015, Minnesota, North Carolina, Louisiana, and the District of Columbia tax ENDS or e-cigarette products. See <<http://publichealthlawcenter.org/sites/default/files/The-Legal-Landscape-for-Electronic-Nicotine-Delivery-Systems-07102015.pdf>>, <<http://revenue.louisiana.gov/LawsPolicies/RIB15-023.pdf>>, and <<http://otr.cfo.dc.gov/release/vapor-products-subject-excise-tax-effective-october-1-2015-exempt-sales-tax>>.

(Sloan et al., 2004) Smokers bear a portion of these net costs themselves, but a portion equaling \$2,911 per female smoker and \$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. We lack detailed data on the financial effects of using newly deemed combusted tobacco products; we expect the financial effects would differ but may be qualitatively similar. The financial effects of using ENDS products are not known.

F. INTERNATIONAL EFFECTS

As stated above, the Bureau of Economic Analysis reports that \$108.0 billion worth of tobacco products were consumed in the United States in 2013. Table 29 in section III.C.6.a above estimates U.S. total tobacco product sales, and sales of tobacco products affected by this final rule using private data sources; the table also shows sales of individual product classes affected by this final rule. Of total U.S. tobacco product sales, the U.S. International Trade Commission (2015) reports that \$1.9 billion consisted of imported Tobacco and Manufactured Tobacco Substitutes. In 2014, imports of Tobacco and Manufactured Tobacco Substitutes were valued at \$1.8 billion. Of this total, cigarettes accounted for \$157.7 million and cigars and similar products accounted for \$738.4 million. The total value of imported cigars weighing more than 1.36 kg/1000 and valued at greater than \$0.76 each is about \$299.4 million. (Other manufactured tobacco and homogenized or reconstituted tobacco imports were valued at \$76.1 million; of this total, waterpipe tobacco imports accounted for \$7.6 million, pipe tobacco imports accounted for \$18.4 million, and roll-your-own tobacco imports accounted for \$2.4 million.) Import volume of ENDS products is unknown (GAO, 2015).

As with domestic manufacturers, foreign manufacturers continuing to market in the U.S. will experience an increase in costs as a result of this final rule. The increase in costs for participating in the U.S. market may encourage foreign manufacturers and U.S. importers to cease selling relatively low-volume products in the U.S. or consolidate products available to U.S. consumers. Foreign cigar producers' revenue would decrease if U.S. consumption of imported cigar products decreases as a result of this final rule.

Public comments asserted that the premium cigar industry accounts for around 350,000 jobs in Honduras, Nicaragua, and the Dominican Republic, relative to total employment of 10.8 million in these countries.⁷⁹ The United States is the primary importer of cigars from these countries, although a wide range of countries also import cigars from this region (i.e., 88 percent of Nicaragua's premium cigar exports, in terms of value, go to the United States (International Trade Centre, 2015)).

⁷⁹ The most recent statistics compiled by the International Labor Organization show employment to have been 4.2 million in the Dominican Republic in 2014, 3.5 million in Honduras in 2013, and 3.1 million in Nicaragua in 2013.

G. ASSESSMENT OF REGULATORY ALTERNATIVES

We have formally identified and assessed four alternatives to the final rule. The costs and benefits of exempting any major product class from regulation would be analyzed in a similar way as Alternative 1. Table 32, which shows costs disaggregated by product type, can aid the interested reader in determining the reduction in costs that would be associated with exempting any major class of tobacco products from this final rule.

1. EXEMPT PREMIUM CIGARS, AS DEFINED IN THE NOTICE OF PROPOSED RULE MAKING, FROM REGULATION

Under this regulatory alternative, which was Option 2 of the proposed rule, premium cigars would be exempted entirely from regulation. Therefore, all the costs of the final rule attributable to premium cigars would be eliminated; other costs would remain the same. Table 34 shows the present value of costs for this alternative.

Table 34 -- 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	703.2	959.4	1,271.8	580.9	793.6	1,051.4
Change in Costs	-19.1	-28.8	-42.6	-15.2	-22.9	-34.1

Under this alternative, none of the potential benefits associated with regulation of premium cigars would be realized. Manufacturers of premium cigars would not be subject to any of the FD&C Act's requirements. FDA would not obtain information about premium cigar manufacturers and premium cigar products through establishment registration, product listing, ingredient listing, health document submission, and harmful and potentially harmful constituents testing and reporting requirements. Unsubstantiated modified risk descriptors would not be removed from premium cigars. New premium cigar products would not be required to undergo premarket review. Therefore, FDA would not be able to prevent more harmful or addictive premium cigars from being introduced into the market. FDA would also lack the authority to take enforcement action against misbranded or adulterated premium cigar products. Premium cigars also would not be required to bear a health warning label, unless they already do so under the FTC consent decrees; the lack of a warning label when all other tobacco products bear a warning label could be taken to imply the premium cigars do not pose health risks, when in fact they do. Additionally, without this information on product packaging and advertising consumers would not be guaranteed to receive the same level of information about products' health risks. Finally, leaving a class of tobacco products unregulated could create a regulatory loophole insofar as some non-premium cigars might be altered to meet the definition of premium cigars in order to avoid regulation.

FDA did not choose this option based on the reasons described above and in the preamble to the final rule. By choosing to extend regulation to these currently unregulated tobacco products, FDA will also be correcting any possible misperception that, because they are not regulated, they must be safe.

2. CHANGE THE LABELING COMPLIANCE DATES

a. Extend the Compliance Period for Labeling Changes to 36 Months

b. Reduce the Compliance Period for Labeling Changes to 12 months

The cost of a labeling change to comply with the warning statement provisions and § 903(a)(2) and § 920(a) of the FD&C Act is dependent on the length of time the applicant has to comply (the “compliance period”).⁸⁰ Because manufacturers change their labels regularly, if a longer compliance period were provided, FDA expects that manufacturers would coordinate a greater proportion of the required labeling changes 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 FDA would expect to be coordinated with changes that would have been made for non-regulatory reasons, increasing incremental costs. For most costs, the FDA labeling cost model also estimates rush charges of 40 percent for compliance periods shorter than 18 months.

Table 35 shows the present value of costs of this rule under 36-month and 12-month labeling change compliance periods and the change in costs, compared with the final rule.

Table 35—Present Value of Costs for Regulatory Alternative 2 (\$ million)

	3 percent			7 percent		
	Lower Bound	Primary	Upper Bound	Lower Bound	Primary	Upper Bound
36-Month	712.4	968.4	1,278.3	586.0	796.6	1,049.2
Change in Costs	-9.9	-19.8	-36.1	-10.0	-20.0	-36.3
12-Month	749.3	1,043.2	1,415.6	623.0	871.2	1,185.7
Change in Costs	27.0	55.0	101.2	26.9	54.6	100.3

Extending the compliance period would provide additional time before FDA would intend to enforce certain misbranding provisions against newly deemed tobacco products, while delaying the accrual of benefits attributable to the warning statement provision. Shortening the compliance period would hasten the time at which FDA would intend to enforce certain misbranding provisions against newly deemed tobacco products, while hastening the accrual of benefits attributable to the warning statement provision.

⁸⁰ For § 903(a)(2) and § 920(a), the compliance period is the time period during which FDA does not intend to enforce those requirements. For the health warning statements, FDA intends to enforce on the effective date of part 1143.

FDA did not choose either of these options. While reducing the label change compliance period to 12 months would provide an earlier date at which FDA would intend to enforce certain misbranding provisions against newly deemed products, FDA determined the additional benefits did not justify the costs necessary to pursue this option. Choosing the 36 month alternative would reduce regulatory burden overall but would delay the date at which FDA intends to enforce certain misbranding provisions. In consideration of these options, FDA believes using a 24 month compliance period is appropriate.

3. DO NOT EXTEND THE PREMARKET REVIEW COMPLIANCE POLICY TO NEW FLAVORED TOBACCO PRODUCTS

Under this alternative compliance policy, the compliance policy described in Section III.C.3.b.(1) would not be extended to newly deemed flavored new tobacco products other than tobacco-flavored products. FDA, however, would not intend to enforce the requirements of premarket review for 90 days against retailers selling off any existing inventory of flavored (other than tobacco flavor) newly deemed products. Consequently, as of 180 days after publication of the rule, any non-grandfathered, newly deemed flavored tobacco products on the market would be subject to enforcement.

Table 36 shows available estimates of the breakdown between flavored (other than tobacco flavor) and non-flavored products. A recent study by Morris (2013) compiled evidence on proportions of cigars, pipe tobacco, and waterpipe tobacco products that are flavored. The study found wide variation across products: the share for cigars was around 10 percent while that for waterpipe tobacco was 86 percent.⁸¹ We estimate that 75-85 percent of e-liquids have a flavor other than a variant of tobacco or are non-flavored.⁸² Based on an analysis of 2014 Nielsen data on e-cigarette sales, which primarily cover major closed-systems brands, we estimate that 60 percent of disposable or cartridge products are flavored. We estimate that there would be approximately 4,500 to 9,300 non-grandfathered, newly deemed flavored tobacco products that we expect would be affected by this alternative compliance policy, including 3,750 to 8,500 e-liquids.

Table 36: Estimated Number of Flavored and Non-flavored Products

	Estimated Proportion Flavored	Flavored Product Formulations	Flavored Product-Package Combinations	Non-flavored Product Formulations	Non-flavored Product-Package Combinations
Cigars	9.5%	475	713	4,525	6,787

⁸¹ Note that we estimate the proportions of product formulations and product-packages that are flavored. This may differ greatly from the proportion of units sold that are flavored if the average number of units sold differs systematically between flavored and non-flavored products. For example, cigars described as “handmade” are less likely than other cigars to be flavored and have lower average unit sales volume; therefore, we would expect the proportion of cigar units sold that are flavored to differ from the proportion of unique products.

⁸² Burke (2015) finds that products with a “tobacco” flavor account for approximately 17 percent of e-liquids unit sales volume. We use a range for the proportion of products with a flavor other than tobacco because the proportion of products with a flavor other than tobacco need not equal the proportion of unit sales and because some e-liquids may be non-flavored.

Pipe Tobacco	16.8%	151	185	749	915
Waterpipe tobacco	86.1%	671	839	108	135
E-Liquids	75% to 85%	3,000 to 6,800	3,750 to 8,500	1,000 to 1,200	1,250 to 1,500
ENDS Delivery Systems	Closed Systems (disposable or cartridge products): 60% Open Systems: Not Defined ⁸³	Not Estimated	Not Estimated	Not Estimated	Not Estimated

Note: We assume that the vast majority of ENDS mixtures manufactured in vape shops are flavored.

The implications of this alternative compliance policy would be far reaching. We assume for this analysis that it would not be possible to obtain marketing authorization within 180 days of publication of this final rule. Therefore, we expect that newly deemed flavored non-grandfathered tobacco products would initially exit the market within 90 days after the effective date of this final rule. This would significantly impact the availability of flavored tobacco products at least in the short term. However, this exit would only be temporary for these products because such products could reenter the market after obtaining premarket authorization.

The ENDS market would be subject to the most severe disruption because flavors make up the majority of the market and there likely will not be any flavored grandfathered ENDS products. We expect that under this alternative compliance policy many or most vape shops would exit within 90 days after the effective date of the final rule as a result of ceasing to engage in manufacturing activities (rather than complying with the requirements of premarket review) and the initial exit of flavored ENDS products from the market. We expect that some vape shops might reenter the market as pure retailers after products receive marketing authorizations and the variety of products available increases. The timing of any such reentry would be uncertain and would depend on how quickly manufacturers obtain authorization for their products.⁸⁴

Under this alternative, we expect that there would be additional costs associated with exit of non-grandfathered newly deemed flavored tobacco products 90 days after the effective date of this final rule. These costs would include one-time consumer search costs, one-time market adjustment costs due to the exit of non-grandfathered flavored tobacco products, and the loss of producer surplus associated with those products while they are off the market. See Appendix 3 for a detailed description of these costs.

We assume that product exit among ENDS products would be higher under this alternative compliance policy than under the compliance policy described in the preamble to the final rule because FDA would intend to enforce the requirements of premarket review for newly deemed new flavored tobacco products shortly after the effective date. We assume the number of marketing applications submitted for e-liquids would decrease to 1,000 to 1,500 (compared with

⁸³ This value is not defined because open systems ENDS products can be used with flavored or non-flavored e-liquids, or they themselves may be flavored or non-flavored (e.g. a flavored mouthpiece).

⁸⁴ It is difficult to predict how long the application process would take and how quickly retailers would make decisions after product authorizations occur; however, for the purposes of our analysis we assume that that reentry might occur three or four years after publication of this final rule.

1,250 to 2,500 under the compliance policy described in the preamble to the final rule), while the number of applications submitted for delivery systems would decrease to 280 to 350 (compared with 360 to 450 under the compliance policy described in the preamble to the final rule).

Table 37 shows the present value of costs for this alternative.

Table 37 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	839.7	1,141.4	1,533.1	704.5	961.3	1,295.4
Change in Costs	117.4	153.2	218.6	108.4	144.8	209.9

Under this alternative, FDA would expect that non-grandfathered newly deemed flavored tobacco products would exit 90 days after the effective date of this final rule. We expect that some such products would seek marketing authorization to reenter the market. Only such products that could meet the applicable public health standard for marketing authorization could reenter.

In deciding on the compliance policy described in the preamble, FDA sought to balance three important public health considerations: concern about the extended availability of newly deemed new tobacco products without scientific review; concern about flavored products' youth appeal; and emerging evidence that some adults may potentially use such products to transition away from combusted tobacco use. Taking these factors into account, and based on currently available scientific evidence, FDA determined that the compliance periods described in the preamble strike an appropriate balance to protect public health. In addition, as with other tobacco products that will be regulated under this rule, FDA is cognizant of the transition that will be required for regulated entities. Several comments expressed concern that even the proposed 24-month compliance period was not sufficient to submit complete applications for all of their products. FDA notes that an even shorter period or no premarket review compliance policy would have an even greater impact on these businesses. Specifically, the agency expects that this alternative compliance policy would result in the likely closing of a number of small retail and manufacturing establishments (e.g., vape shops), with consequent economic impacts on the owners of those entities and any affected employees. The premarket review compliance policy described in the preamble to the final rule is not expected to have these significant impacts.

FDA did not choose this option based on the reasons described above and in the preamble to the final rule. FDA believes that a staggered compliance period for flavored products, as with other tobacco products, represents the exercise of its enforcement discretion in a way that strikes an appropriate balance between providing industry time to transition and protecting the public health.

4. SUMMARY OF REGULATORY ALTERNATIVES

Table 38 summarizes the present value of quantified costs of the final rule and several regulatory alternatives. Note that it is not possible to quantify how the benefits of the regulatory alternatives would differ from those of the final rule, nor is it straightforward to characterize qualitatively how they may differ. Benefits of the regulatory alternatives could differ to the extent that they result in different changes in consumption patterns.

Table 38--Summary Quantified Costs of Regulatory Alternatives (Present Values, \$ million)

Alternative		3%	7%
1 -- Exempt Premium Cigars from Regulation	Total	703 to 1,272	581 to 1,051
2a-- 36-month compliance period for labeling changes	Incremental	09 to 07	05 to -02
	Total	712 to 1,278	586 to 1,049
Final Rule and Compliance Period	Incremental	10 to 36	10 to 36
	Total	722 to 1,314	596 to 1,085
2b--12-month compliance period for labeling changes	Incremental	27 to 101	27 to 100
	Total	749 to 1,416	623 to 1,186
3 – Do not extend the premarket review compliance policy to new flavored tobacco products	Incremental	90 to 117	81 to 110
	Total	840 to 1,533	705 to 1,295

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

IV. SMALL ENTITY EFFECTS

FDA has examined the economic implications of this final rule for small entities as required by the Regulatory Flexibility Act. If a final 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 final rule will have a significant economic impact on a substantial number of small entities. Consequently, this analysis, together with other relevant sections of this analysis and the final rule (81 FR 28973), serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act. See Appendix Table 4 (in Appendix 1) for a detailed list showing where specific small business topics are discussed in the preamble and RIA. FDA also notes that we are announcing multiple compliance policies with this final rule including a compliance policy for “small-scale tobacco product manufacturers” discussed in section IV.D of the preamble to the rule. Also, FDA does not intend to take enforcement action against manufacturers who make tobacco blending changes without a marketing authorization if the tobacco blending changes are intended to address the natural variation of tobacco (e.g., due to variation in growing conditions) in order to maintain a consistent product. A full discussion of our considerations and specific relief can be found in those sections of the preamble.

A. DESCRIPTION AND NUMBER OF AFFECTED SMALL ENTITIES

This final rule would primarily affect domestic tobacco product manufacturers and importers as well as vape shops. 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.⁸⁵ Manufacturers of tobacco products covered by this final rule would be designated under the North American Industry Classification System (NAICS) as “tobacco product manufacturers.” 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 final rule, those most likely to import them are specialty tobacco shops and non-store retailers operating electronically or through the mail. Table 39 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 (SBA, 2016; Statistics of U.S. Businesses, 2012; U.S. Census, 2010b).⁸⁶ Within each category, the proportion of businesses found to be small will be underestimated because the Census size categories are lower than the SBA threshold.

⁸⁵ The Census data for tobacco product manufacturing are not sufficiently disaggregated to distinguish currently regulated tobacco product manufacturers from manufacturers of newly deemed tobacco products. Additionally, the Census establishment count for 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 (U.S. Census, 2007).

⁸⁶ Tobacco product manufacturers (and importers) are considered small under chapter IX of the FD&C Act if they employ fewer than 350 people. However, the Small Business Administration’s definition of small is applicable to the small entity analysis required under the Regulatory Flexibility Act.

Table 39--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)
Tobacco Product Manufacturers				
	312230	Tobacco Manufacturing	1,500	500
Potential Tobacco Product Importers				
Wholesalers				
	424940	Tobacco and Tobacco Product Merchant Wholesalers	250	100
Retailers				
	453991	Tobacco Stores	\$7.5	\$5.00
	454111	Electronic Shopping	\$32.5	\$25.00
	454113	Mail-Order Houses	\$38.5	\$25.00

FDA considers a "small-scale tobacco product manufacturer" to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of \$5,000,000 or less.⁸⁷ This is not the threshold for conducting a small entity analysis under the Regulatory Flexibility Act, but rather a threshold designed to align with the nature of the specific relief provided. We assume in estimating costs in this analysis of small entities that the typical small entity according to the Small Business Administration definition qualifies as a small-scale tobacco product manufacturer.

Table 40 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 2012 indicate that 89 percent of "tobacco manufacturing" businesses with employees are small. Note that the "tobacco manufacturing" category in NAICS 2012 includes cigarette manufacturing. These data also show that 92 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 (U.S. Census, 2010b).⁸⁸

Table 40--Estimated Percentage of Small Firms Among Firms With Employees

⁸⁷ FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with such manufacturer.

⁸⁸ The relevant 2012 census data that could be used to update these statistics have not yet been released.

NAICS	Description of NAICS Category	Number of Firms	Number of Firms Below Census Size Standard	Percentage of Small Firms (%)
312230	Tobacco Manufacturing	93	83	89%
424940	Tobacco and Tobacco Product Merchant Wholesalers	1,158	1,068	92%
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 all tobacco product manufacturing firms that are small, then 316 ($=355*0.89$) to 348 ($=391*.89$) newly deemed small manufacturing establishments and 19 ($=21*0.89$) currently regulated small manufacturing establishments will be affected by this final rule. For several reasons, these numbers are only an approximation: (1) the “tobacco manufacturing” Census category includes many firms that are not affected by this final rule, and those firms that will be affected may not necessarily be representative; (2) many ENDS manufacturers are likely too new to be reflected in 2012 data; (3) 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 (4) large firms are more likely to have multiple establishments, so the percentage of establishments belonging to small firms is smaller than the percentage of firms that are small.

Based on Table 40, 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, 251 ($=0.92*273$) small importers of newly deemed products and 19 ($=0.92*21$) small importers of currently regulated products will be affected by this rule.

Table 41 shows additional size detail for tobacco manufacturers and merchant wholesalers. Because these categories include currently regulated tobacco products, such as cigarettes and smokeless tobacco, the distribution of sizes of newly deemed tobacco manufacturers and merchant wholesalers may be different.

Table 41—Size Detail for Tobacco Manufacturers and Merchant Wholesalers

	Number of Firms						
	0 to 4 employees	5 to 9 employees	10 to 19 employees	20 to 99 employees	100 to 499 employees	500+ employees	Total
Tobacco Manufacturing ¹ — Number of Firms	34	8	5	27	9	10	93
Tobacco Manufacturing ¹ — Proportion of Firms	37%	9%	5%	29%	10%	11%	100%

Tobacco and Tobacco Product Merchant Wholesalers ² — Number of Firms	526	211	153	178	65	25	1,158
Tobacco and Tobacco Product Merchant Wholesalers— Proportion of Firms ²	45%	18%	13%	15%	6%	2%	100%

1 NAICS code 312230.

2 NAICS code 424940.

In addition to manufacturers and importers of tobacco products, vape shops will be affected by this final rule. We estimate in section III.C.1 above that there are 5,000 to 10,000 vape shops, 3,500 to 7,000 of which engage in activities that cause them to meet the definition of a manufacturer. Based on Table 40 above, 94 percent of tobacco stores are small. The proportion could differ somewhat for retailers that meet the definition of a manufacturer, but if it holds, 4,700 to 9,400 small vape shops would be affected by this final rule. Of these small vape shops, approximately 3,290 to 6,580 would meet the definition of manufacturer.

B. ECONOMIC EFFECT ON SMALL ENTITIES

We focus the quantitative analysis of this section on manufacturers and importers of cigars and ENDS products. We note that most pipe and waterpipe tobacco manufacturers and importers are also small, and we expect the impact on them to be similar to the impact on cigar manufacturers and importers, though perhaps less substantial.⁸⁹ Manufacturers and importers of ENDS products will be affected quite differently from manufacturers and importers of cigars, pipes, and waterpipe tobacco because of differences in the estimated costs of compliance with premarket review and the current applicability of user fees.

We calculate costs per small manufacturer or importer within a product category by dividing total costs by the number of manufacturing and importing establishments. This assumes that the costs of compliance for imported goods are borne by the importers and that the typical establishment is approximately equivalent to the typical small firm. (Most affected manufacturers and importers are small and there are few multi-establishment firms.) Because some establishments are part of multi-establishment firms, cost per establishment is less than cost per firm. However, because some establishments belong to large firms, average cost per establishment overstates average cost per establishment belonging to a small firm.

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. However, some manufacturers make multiple types of products and will pay less in user fees for currently

⁸⁹ The traditional segment of the cigar market, sometimes called handmade, may be more affected to the extent that it is characterized by a large number of low volume products.

regulated tobacco products going forward because the shares for cigars and pipe tobacco will no longer be reallocated to currently regulated products. Therefore, we include user fees in the estimated burden for small cigar manufacturers and importers but note this will be an overestimate for manufactures and importers who also manufacture currently regulated products. In addition, the amount of user fees paid is based on market share; therefore, the smaller a firm’s market share, the lower the amount of user fees paid. Because ENDS are not listed as a tobacco product class and are not subject to user fees under in Section 919 of the FD&C Act, this final rule does not automatically extend user fees to manufacturers and importers of ENDS products.

Table 42 summarizes the estimated cost per small domestic cigar manufacturer or importer under the final rule. Because the costs of the final rule depend more on the number of 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. This analysis does not take into account that some of these firms may already be manufacturing currently regulated products and would already be paying a portion of the user fees that will now be paid by cigar manufacturers. Estimated costs per entity are \$278,000 to \$397,000 in the first year, \$292,000 to \$411,000 in the second year, and \$235,000 to \$257,000 in the third year. 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 (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 (U.S. Census, 2010c). These establishments are generally among the smallest (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 final rule; some firms may exit the market.

Table 42--Estimated Costs per Small Cigar Manufacturer or Importer

	Year 1 (\$1,000)		Year 2 (\$1,000)		Year 3 ¹ (\$1,000)	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Regulation Review	1.33	1.33				
Costs of Premarket Review	26.17	26.17	26.17	26.17	8.96	17.95
Registration and Product Listing	0.05	0.16	0.01	0.04	0.01	0.04
Ingredient Listing			3.46	3.46	0.14	0.29
User Fees	198.41	198.41	210.34	210.34	222.60	222.60
Label Changes	51.78	171.27	51.78	171.27	3.34	16.08
Total Cost	277.75	397.35	291.76	411.29	235.06	256.96

¹ The only change from year 3 in years 4 through 20 is that the forecasted average user fee cost for cigar manufacturers and importers goes up to \$236,000.

Table 43 summarizes the estimated cost per small ENDS manufacturer or importer under the final rule. Estimated costs are \$827,000 to \$1.21 million in the first year, \$832,000 to \$1.21 million in the second year, and drop to \$22,000 to \$64,000 in subsequent years. Submission of premarket tobacco applications, discussed above in section III.C.3.b, is expected to a costly requirement for ENDS manufacturers. We expect to see adjustment through additional

consolidation and exit from the U.S. market, compared with what we would expect without regulation.

Table 43--Estimated Costs per Small ENDS Manufacturer or Importer

	Year 1 (\$1,000)		Year 2 (\$1,000)		Year 31 (\$1,000)	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Regulation Review	1.33	1.33				
Costs of Premarket Review	814.32	1,132.87	814.32	1,132.87	21.55	63.48
Registration and Product Listing	0.15	0.16	0.04	0.04	0.04	0.04
Ingredient Listing			5.81	9.20	0.07	0.24
Label Changes	11.61	70.75	11.61	70.75		
Total Cost	827.41	1,205.11	831.78	1,212.85	21.66	63.76

1 Years 4 through 20 are forecasted to be the same as year 3.

Vape shops that mix e-liquids will also be affected by this final rule. Although we do not quantitatively examine the effects on vape shops in this section, we note that during the initial 24-month compliance period for submission and FDA receipt of PMTAs, we expect many vape shops to continue to prepare some mixtures that they prepared and offered for sale as of the effective date; we also expect they will comply with other requirements for manufacturers, such as establishment registration, product listing, and ingredient listing. After the initial 24-month compliance period for the submission and FDA receipt of PMTAs expires, vape shops selling new newly deemed tobacco products, including e-liquid mixtures, for which neither they nor an upstream supplier has submitted an application for premarket review, will be subject to enforcement action. Therefore, we expect vape shops that mix e-liquids will overwhelmingly cease mixing. This does not necessarily imply closure of vape shops, but rather a change in business operations to pure retailing.

C. REGULATORY ALTERNATIVES FOR SMALL ENTITIES

Because approximately 90 percent of domestic entities affected by this rule are estimated to be small, the regulatory alternatives analyzed in section III.G that would reduce costs for affected manufacturers and importers also offer potential regulatory relief options for small businesses. Here, we show the possible reductions in costs per establishment under these alternatives, which would largely be channeled through small businesses. We also note that elimination of individual provisions would provide relief. Table 42 and Table 43 above can aid the interested reader in determining the relief that would be provided by eliminating specific provisions.

1. EXTEND THE COMPLIANCE PERIOD FOR LABELING CHANGES TO 36 MONTHS [REGULATORY ALTERNATIVE 2A]

FDA expects that under Alternative 2a, manufacturers would comply with labeling requirements within 36 months after the publication date, reducing upfront (labeling change) costs and effectively allowing small firms to spread the cost of label changes out over the 36-month period.

Table 44 shows costs for cigar manufacturers and importers under this alternative.

Table 44-- Cost Per Cigar Manufacturer or Importer Under Regulatory Alternative 3 [Extend the Compliance Period for Labeling Changes to 36 Months]

	Year 1(\$1,000)		Year 2 (\$1,000)		Year 3 (\$1,000) ¹	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Label Changes	28.77	95.87	28.77	95.87	28.77	95.87
Total Cost	254.75	321.95	268.76	335.88	260.49	336.75
Change in Costs	-23.00	-75.40	-23.00	-75.40	25.43	79.79

¹ There would be no change from the final rule and compliance period in years 4 through 20.

Table 45 shows costs for ENDS manufacturers and importers under this alternative.

Table 45- - Cost Per ENDS Manufacturer or Importer Under Regulatory Alternative 3 [Extend the Compliance Period for Labeling Changes to 36 Months]

	Year 1(\$1,000)		Year 2(\$1,000)		Year 3 (\$1,000) ¹	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Label Changes	5.80	37.17	5.80	37.17	5.80	37.17
Total Cost	821.59	1,171.53	825.96	1,179.27	27.45	100.93
Change in Costs	-5.81	-33.58	-5.81	-33.58	5.80	37.17

¹ There would be no change from final rule and compliance period in years 4 through 20.

2. EXEMPT PREMIUM CIGARS FROM REGULATION [REGULATORY ALTERNATIVE 1]

Exempting premium cigars from regulation would provide regulatory relief to all manufacturers and importers of premium cigars. Any tobacco product manufacturers or importers that completely specialize in premium cigars would not be subject to chapter IX of the FD&C Act and would bear none of the associated costs. Firms that manufacture or import premium cigars and other products covered by this final rule would receive partial relief. Because we do not know the number of manufacturers and importers of premium and non-premium cigars, we do not analyze these effects quantitatively.

V. REFERENCES

- Agaku, I. T., King, B. A., Husten, C. G., et al., "Tobacco Product Use Among Adults--United States, 2012-2013," *Morbidity and Mortality Weekly Report*, 63(25); 542-547, June 27, 2014, available at: <http://www.cdc.gov/mmwr/pdf/wk/mm6325.pdf>.
- Angeletos, G-M., D. Laibson, A. Repetto, J. Tobacman, and S. Weinberg. 2001. "The Hyperbolic Consumption Model: Calibration, Simulation, and Empirical Evaluation." *Journal of Economic Perspectives*. 15(3), 47-68.
- Arrazola, R.A., Singh, T., Corey, C.G., et al., "Tobacco Use Among Middle and High School Students - United States, 2011-2014," *Morbidity and Mortality Weekly Report*, 64(14); 381-385, April 17, 2015, available at: <http://www.cdc.gov/mmwr/pdf/wk/mm6414.pdf>.
- Ashley, E.M., C. Nardinelli and R.A. Lavaty. 2015. "Estimating the Benefits of Public Health Policies that Reduce Harmful Consumption," *Health Economics* 24(5): 617–624.
- Bernheim, B. Douglas and Antonio Rangel, "Addiction and Cue-Triggered Decision Processes," *American Economic Review* 94(5): 1558-90, December 2004.
- Bernheim, B. Douglas and Antonio Rangel. 2005. "Behavioral Public Economics: Welfare and Policy Analysis with Non-Standard Decision-Makers," NBER Working Paper No. 11518.
- Burke, Don. 23 April 2015. "Trends & Insights in the Nicotine Delivery Category." Management Science Associates, Inc. Presentation at NATO Show. Accessed June 2015.
- Callahan-Lyon, Priscilla. 2014. "Electronic cigarettes: human health effects," *Tobacco Control*, 23 (Suppl. 2): ii36-ii40.
- John Cawley, and Christopher J. Ruhm. 2012. "The Economics of Risky Behaviors". In Mark Pauly, Thomas McGuire and Pedro Barros, eds., *Handbook of Health Economics*, Vol. 2. Amsterdam: Elsevier/North Holland Press, pp.95-199.
- Centers for Disease Control and Prevention. 3 August 2012. "Consumption of Cigarettes and Combustible Tobacco—United States, 2000-2011." *MMWR* 61(30): 565-569.
- Centers for Disease Control and Prevention. 2015. "STATE System E-Cigarette Fact Sheet." State Tobacco Activities Tracking & Evaluation System. <<http://www.cdc.gov/statesystem/factsheets.html>>
- Chaloupka, Frank and Kenneth Warner. 2000. "The Economics of Smoking." In Anthony Culyer and Joseph Newhouse, eds., *Handbook of Health Economics*, Vol. 1B. Amsterdam: Elsevier/North Holland Press, pp. 1539-1627.
- Chang, Cindy M., Catherine G. Corey, Brian L. Rostron, and Benjamin J. Apelberg, "Systematic review of cigar smoking and all cause and smoking related mortality," *BMC Public Health* 2015, 15:390, DOI 10.1186/s12889-015-1617-5.
- Chetty, Raj. 2009. "Sufficient Statistics for Welfare Analysis: A Bridge between Structural and Reduced-Form Methods." *Annual Review of Economics*, 1: 451-488.

Chetty, Raj. 2015. "Behavioral Economics and Public Policy: A Pragmatic Perspective," *American Economic Review*, vol. 105(5), pages 1-33, May.

Cobb, C., Ward, K. D., Maziak, W., Shihadeh, A. L., & Eissenberg, T. 2010. Waterpipe Tobacco Smoking: An Emerging Health Crisis in the United States. *American Journal of Health Behavior*, 34(3): 275–285

Cutler, David, Amber Jessup, Donald Kenkel, and Martha Starr. 2015. "Valuing Regulations Affecting Addictive or Habitual Goods". *Journal of Benefit-Cost Analysis*, 6(2), Summer, pp 247-280.

Cutler, David, Amber Jessup, Donald Kenkel, and Martha Starr. 2016. "Economic Approaches to Estimating Benefits of Regulations Affecting Addictive Goods." *American Journal of Preventive Medicine*, forthcoming.

Darby, Michael R. and Edi Karni. 1973. "Free Competition and the Optimal Amount of Fraud." *Journal of Law and Economics*. 16(1), 67—88.

Delnevo, Cristine D. 2006. Smokers' Choice: What Explains the Steady Growth of Cigar Use in the U.S.? *Public Health Reports* 121(2): 116-119

Delnevo, Cristine D. and Mary Hrywna. 2007. "A Whole 'Nother Smoke" or a Cigarette in Disguise: How RJ Reynolds Reframed the Image of Little Cigars. *American Journal of Public Health* 97(8): 1368-1375.

Department of Health and Human Services (1988). The health consequences of smoking: nicotine addiction. A Report of the Surgeon General. Office on Smoking and Health, Rockville, Maryland. <<http://profiles.nlm.nih.gov/ps/retrieve/ResourceMetadata/NNBBZD>> Accessed July 2011.

Eastern Research Group, Inc. "Baseline of State and International Tobacco Laws" Final Report, Oct 27, 2011.

Etter, J., Zather, E, Svensson, S., "Analysis of Refill Liquids for Electronic Cigarettes," *Addiction*, 108(9):1671-1679, 2013.

Euromonitor International. "Cigarettes in the U.S." Passport. August 2014c.

Euromonitor International. "Cigars in the U.S." Category Briefing. 27 August 2014a.

Euromonitor International. "Smoking Tobacco in the U.S." Category Briefing. 27 August 2014b.

Euromonitor International. "Vapour Devices in the U.S." August 2015.

FDA, 2009. Guidance for Industry: Listing of Ingredients in Tobacco Products. <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM192053.pdf>

FDA, 2010. Guidance for Industry: Tobacco Health Document Submission. <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM208916.pdf>

FDA, 2011. Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products. <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM239021.pdf>

FDA, 2015a. Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2). <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf>

FDA, 2015c. Population Assessment of Tobacco and Health (PATH) Study: Preliminary Wave 1 (Baseline) Data on Flavored E-cigarettes. Unpublished analyses.

FDA, 2016. "FY 2016 Tobacco User Fee Yearly Allocation Formulation by Product Class Under section 919 of the Federal Food, Drug, and Cosmetic Act." <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM462190.pdf>

Federal Trade Commission. "Cigar Sales and Advertising and Promotional Expenditures for Calendar Years 1996 and 1997." Federal Trade Commission Report to Congress. 1999. <http://www.ftc.gov/os/1999/07/cigarreport1999.htm>, accessed July 22, 2011, and <http://www.ftc.gov/os/1999/07/cigarreporttable3.htm>, accessed July 28, 2011.

Fong, G., D. Hammond, F. Laux, M. Zanna, K. Cummings, R. Borland, and H. Ross. 2004. "The Near-Universal Experience of Regret among Smokers in Four Countries: Findings from the International Tobacco Control Policy Evaluation Survey," *Nicotine and Tobacco Research*, 6 (Suppl 3): S341-S351.

Friedman, Abigail. How Does Electronic Cigarette Access Affect Adolescent Smoking? *Journal of Health Economics* Volume 44, pages 300-308, 2015. <http://www.sciencedirect.com/science/article/pii/S0167629615001150>

Goniewicz, M., et al., "Levels of Selected Carcinogens and Toxicants in Vapour from Electronic Cigarettes," *Tobacco Control*, 23(2):133-139, 2014.

Government Accountability Office, United States. "Tobacco Taxes: Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes," GAO-12-475, www.gao.gov/assets/600/590192.pdf. April 2012.

Government Accountability Office, United States. "Electronic Cigarettes: Imports, Tariffs, and Data Collection," GAO-15-491R, <http://www.gao.gov/assets/680/670102.pdf>. May 2015.

Gruber, Jonathan. "Smoking's 'Internalities.'" *Regulation* 25 (4): 52-57. Winter 2002-2003.

Gruber, Jonathan and Botond Köszegi, "Is Addiction 'Rational'? Theory and Evidence," *Quarterly Journal of Economics*, 116(4): 1261-1303, November 2001.

Gul, Faruk and Wolfgang Pesendorfer. "Harmful Addiction." *Review of Economic Studies* 74: 147-172. 2007.

Henley, S. Jane, Michael J. Thun, Ann Chao, and Eugenia E. Calle. 2004. "Association Between Exclusive Pipe Smoking and Mortality From Cancer and Other Diseases." *Journal of the National Cancer Institute*, 96(11): 853-861.

Herzog, Bonnie, Jessica Gerberi, and Adam Scott. 14 April 2014b. "Vape Shops – Springing Up Across the Country." Wells Fargo Securities. http://www.vaporworldexpo.com/PDFs/Tobacco_%20Vape_Shop_Visit_Apri_2014.pdf

Herzog, Bonnie, Jessica Gerberi, and Adam Scott. 24 March 2014a. "Tobacco Talk: Vapors/Tanks Driving Next Wave of E-Vapor Growth." Wells Fargo Securities. <
http://www.vaporworldexpo.com/PDFs/Tobacco_Talk_Vapors_Tanks_%20March%202014.pdf
>

Herzog, Bonnie, Jessica Gerberi, and Adam Scott. 23 January 2015. "Tobacco Talk: Independent Vapor Mfr. Survey." Wells Fargo Securities.

Hughes, J.R. 2006. "Clinical Significance of Tobacco Withdrawal." *Nicotine and Tobacco Research* 8(2): 153-156.

Hughes, J.R. 2007. "Effects of Abstinence from Tobacco: Valid Symptoms and Time Course." *Nicotine and Tobacco Research* 9(3): 315-327.

Hughes, J.R., J. Keely, and S. Naud. 2004. "Shape of the Relapse Curve and Long-term Abstinence among Untreated Smokers." *Addiction* 99(1): 29-38.

Hutzler, C., Paschke, M., Kruschinski, S., et al., "Chemical Hazards Present in Liquids and Vapors of Electronic Cigarettes," *Archives of Toxicology*, 88(7):1295-1308, 2014.

Institute of Medicine of the National Academies, "Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths," 1994.

International Trade Commission, U. S. (2015). HTS - 24: Tobacco and Manufactured Tobacco Substitutes, Custom Values by Custom Values for ALL Countries, U.S. Imports for Consumption, Annual Data. Retrieved March 30, 2015, from USITC Interactive Tariff and Trade Database: <http://dataweb.usitc.gov>

Iribarren, C., I. Tekawa, S. Sidney, et al., "Effect of Cigar Smoking on the Risk of Cardiovascular Disease, Chronic Obstructive Pulmonary Disease, and Cancer in Men," *The New England Journal of Medicine*, 340(23):1773-1780, 1999.

Jin, L., D. Kenkel, F. Liu and H. Wang. 2015. "Retrospective and Prospective Benefit-Cost Analyses of U.S. Anti-Smoking Policies," *Journal of Benefit-Cost Analysis* 6: 154-186.

Joint Committee on Taxation, "Overview of Revenue Estimating Procedures and Methodologies Used by the Staff of the Joint Committee on Taxation," 2 February 2005. <<http://www.jct.gov/x-1-05.pdf>>

Joint Committee on Taxation, “The Income and Payroll Tax Offset to Changes in Excise Tax Revenues,” 23 December 2011.
<<https://www.jct.gov/publications.html?func=startdown&id=4378>>

Kadhun M, Sweidan A, Jaffery AE, Al-Saadi A, Madden B. 2015. “A review of the health effects of smoking shisha.” *Clinical Medicine* 15(3):263-6.
<<http://www.ncbi.nlm.nih.gov/pubmed/26031977>>

Kim, H. J., Shin, H. S., “Determination of Tobacco-Specific Nitrosamines in Replacement Liquids of Electronic Cigarettes by Liquid Chromatography-Tandem Mass Spectrometry,” *Journal of Chromatography A*, 1291:48-55, 2013.

Morris, Daniel. “Flavored Tobacco on Sale in Minnesota.” Tobacco Control Legal Consortium, April 2013. <<http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-Morris-MN-flavored-tobacco-sold-2013.pdf>>

National Conference of State Legislatures. 2015. Alternative Nicotine Products|E-cigarettes : State Actions 10/9/2015/. <http://www.ncsl.org/research/health/alternative-nicotine-products-e-cigarettes.aspx>

O'Connor, R. A. McNeill, R. Borland, D. Hammond, B. King, C. Boudreau, and K. Michael Cummings. 2007. “Smokers' Beliefs About the Relative Safety of Other Tobacco Products: Findings from the ITC Collaboration,” *Nicotine and Tobacco Research*, 9 (10): 1033-1042

Office of the Assistant Secretary for Planning and Evaluation. 2015. “Valuing Utility Offsets to Regulations Affecting Addictive or Habitual Goods”. Washington, DC: U.S. Department of Health and Human Services, working paper.
<<http://aspe.hhs.gov/sites/default/files/pdf/108471/addictivegood.pdf>> Accessed August 2015.

Ohta K, Uchiyama S, Inaba Y, et al. Determination of carbonyl compounds generated from the electronic cigarette using coupled silica cartridges impregnated with hydroquinone and 2,4-dinitrophenylhydrazine. *Bunseki Kagaku* 2011;60:791–7.

Orzechowski and Walker, “The Tax Burden On Tobacco: Historical Compilation,” Volume 49, 2014. <http://www.taxadmin.org/fta/tobacco/papers/tax_burden_2014.pdf>

Perelman's Pocket Cyclopedia of Cigars, 2010 Edition. Richard B. Perelman (Author), Ed Pioneer (Editor) <<http://www.cigarcyclopedia.com/webapp/content/view/930/36/>> Accessed January 2010.

Robinson, LA, Hammitt, JK (2011) “Behavioral Economics and the Conduct of Benefit-Cost Analysis: Towards Principles and Standards,” *Journal of Benefit-Cost Analysis*, 2(2).

Robinson, L. and J. Hammitt. 2015. “Valuing Reductions in Fatal Illness Risks: Implications of Recent Research,” *Health Economics*. Published online: 30 JUN 2015 (DOI: 10.1002/hec.3214).

Rousu, Matthew C. and James F. Thrasher 2014. "Examining the relationship between psychosocial and behavioral proxies for future consumption behavior: self-reported impact and bidding behavior in an experimental auction study on cigarette labeling." *Health Education Research* 29(2), pages 183-194.

RTI (Muth, M.K., Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela C. Coglaiti, and Shawn A. Karns), "2014 FDA Labeling Cost Model," Research Triangle Park, NC: RTI International, August 2015.

Schelling, Thomas C, 1978. "Economics, or the Art of Self-Management," *American Economic Review*, American Economic Association, vol. 68(2), pages 290-94, May.

Schelling, Thomas C, 1984. "Self-Command in Practice, in Policy, and in a Theory of Rational Choice," *American Economic Review*, American Economic Association, vol. 74(2), pages 1-11, May.

Shanks, Thomas G. and David M. Burns (1998). "Disease Consequences of Cigar Smoking." In: D. Burns, K. Cummings, & D. Hoffman (Eds.), *Cigars: Health effects and trends. Smoking and Tobacco Control Monograph No. 9*, pp. 105-160). Bethesda, MD: U.S. Department of Health and Human Services, National Institute of Health, National Cancer Institute. 1998 (NIH Pub. No. 98-4302). <http://cancercontrol.cancer.gov/tcrb/monographs/9/m9_complete.PDF> Accessed February 2010

Sloan, Frank A., Jan Ostermann, Christopher Conover, Donald H. Taylor, Jr., and Gabriel Picone, *The Price of Smoking*, Cambridge, MA: MIT Press, 2004.

Sloan, Frank A., V. Kerry Smith and Donald H. Taylor, Jr. (2003). *The Smoking Puzzle: Information, Risk Perception, and Choice*. Harvard University Press.

Tan, A. and C. Bigman. 2014. "E-Cigarette Awareness and Perceived Harmfulness," *American Journal of Preventive Medicine*, 47(2): 141–149.

Tverdal, Aage and Kjell Bjartveit. 2011. "Health Consequences of pipe versus cigarette smoking." *Tobacco Control*, 20(2): 123-130.

Uchiyama S, Inaba Y, Kunugita N. Determination of acrolein and other carbonyls in cigarette smoke using coupled silica cartridges impregnated with hydroquinone and 2,4-dinitrophenylhydrazine. *J Chromatogr A* 2010;1217:4383–8.

U.S. Census Bureau, American FactFinder. (2010c) "2007 Economic Census. Sector 31: Manufacturing: Summary Series: General Summary: Industry Statistics for Subsectors and Industries by Employment Size: 2007." <http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0731SG3&-NAICS2007=312229&-ib_type=NAICS2007&-geo_id=&-_industry=312229&-_lang=en&-fds_name=EC0700A1> Accessed July 2011.

U.S. Census Bureau, American FactFinder. 2010b. Establishment and Firm Size: Summary Statistics by Sales Size of Firms for the United States: 2007, 2007 Economic Census, Retail Trade, Subject Series. <http://factfinder.census.gov/servlet/IBQTable?_bm=y&-

ds_name=EC0744SSSZ4&-NAICS2007=453991|454111|454113&-ib_type=NAICS2007&-geo_id=&-_industry=454113&-_lang=en&-fds_name=EC0700A1>

U.S. Census Bureau, Statistics of U.S. Businesses (SUSB), Latest SUSB Annual Data, U.S., All Industries. 2012. <<http://www.census.gov/econ/susb/>>. Accessed May-June 2015.

U.S. Census Bureau. 1995. 1992 Census of Retail Trade. Subject Series. Merchandise Line Sales, United States. Table 1. Merchandise Lines by Kind of Business. <<http://www.census.gov/prod/1/bus/retail/92subj/rc92s03.pdf>>

U.S. Census Bureau. 2007 Economic Census Methodology: Manufacturing (sector 31-33). <http://www.census.gov/econ/census07/pdf/meth/meth_31.pdf> Accessed July 2011.

U.S. Census Bureau. 2012 Economic Census. Accommodation and Food Services: Subject Series: Product Lines Statistics by Kind of Business for the United States and States: 2012.

U.S. Census Bureau. 2012 Economic Census. Retail Trade: Subject Series: Product Lines Statistics by Kind of Business for the United States and States: 2012.

U.S. Census Bureau. 2012 Nonemployer Statistics. Retail Trade and Accommodation and Food Services. Available at <<http://censtats.census.gov/cgi-bin/nonemployer/nonsect.pl>>

U.S. Department of Agriculture, “2012 Census of Agriculture: United States Summary and State Data: Volume 1, Geographic Area Series, Part 51,” May 2014, available at <http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_US/usv1.pdf>.

U.S. Department of Agriculture, “Crop Production 2014 Summary,” January 2015, available at <http://usda.mannlib.cornell.edu/usda/current/CropProdSu/CropProdSu-01-12-2015_revision.pdf>.

U.S. Department of Health and Human Services. *Preventing Tobacco Use among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012. <<http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf>>

U.S. Department of Health and Human Services. *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2006. <http://www.ncbi.nlm.nih.gov/books/NBK44324/pdf/Bookshelf_NBK44324.pdf>

International Trade Centre. *Bilateral trade between Nicaragua and United States of America: Product: 2402 Cigars, cheroots, cigarillos & cigarettes*. Retrieved April 30, 2015, from ITC Trade Map - International Trade Statistics: http://www.trademap.org/tradestat/Bilateral_TS.aspx.

U.S. Small Business Administration, 2016, Table of Size Standards.
<https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf> Accessed March 2016.

Vending Times, 2011 Census of the Industry, 2011, <
<http://www.vendingtimes.com/Media/MediaManager/VTcensus11.pdf>>.

Zheng, Yuqing, Chen Zhen, James Nonnemaker, and Daniel Dench. "US Demand for Tobacco Products in a System Framework." In 2014 Annual Meeting, July 27-29, 2014, Minneapolis, Minnesota, no. 174110. Agricultural and Applied Economics Association, 2014.

Zhu, Shu-Hong, Jessica Y. Sun, Erika Bonnevie, Sharon E. Cummins, Anthony Gamst, Lu Yin, and Madeleine Lee. "Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation." *Tobacco Control* 2014; 23 (Suppl. 3), pages iii3-iii9.

VI. APPENDIX 1

Appendix Table 1--Summary of Benefits, Costs and Distributional Effects

Economic Data: Costs and Benefits Statement							
Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes
				Year Dollars	Discount Rate	Period Covered	
Benefits							
Annualized Monetized \$ millions/year							
Annualized Quantified							
Qualitative							Behavioral changes that could improve health or other welfare-enhancing changes from: deterrence of youth initiation, which may reduce morbidity and mortality from consuming these products; increased information about health risks associated with these products, which may change the level or composition of people's usage of tobacco products in ways that yield health benefits.
Costs							
Annualized Monetized \$ millions/year	77.1	56.3	102.5	2014	7%	2015-35	Registration, listing and various submissions; labeling changes performed to simultaneously satisfy statutory 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.
	66.4	48.5	88.3	2014	3%	2015-35	
Annualized Quantified					7%		All quantified costs are also monetized.
					3%		
Qualitative							Some consumer costs for users of the newly deemed products due to

							loss of product variety or higher prices; recordkeeping costs for exporters of deemed tobacco products; compliance costs for components and parts other than complete pipes, waterpipes, and ENDS delivery systems; the cost of testing and reporting for harmful and potentially harmful constituents; the cost of any clinical testing that may potentially be conducted to support substantial equivalence reports; market adjustment (friction) costs and lost producer surplus associated with product consolidation, exit of manufacturers (including some vape shops currently engaged in manufacturing activities), and the switch to pure retailing among retailers such as vape shops who currently engage in manufacturing activities.
Transfers							
Federal Annualized Monetized \$ millions/year							
From/To							
Other Annualized Monetized \$ millions/year							
From/To							
Effects							
State, Local or Tribal Government: If consumption of tobacco products is reduced, state governments would lose excise tax revenue each year. There would be additional changes in Medicaid and other government health insurance receipts and outlays.							
Small Business: The final rule would affect small entities in several industries, from							

tobacco farming to tobacco product manufacturing and importing to the retail industry. Tobacco product manufacturers and importers and vape shops are expected to be most affected. Most (at least 89%) are small, and the costs of this final rule could be a substantial share of annual receipts.	
Wages: No Estimated Effect	
Growth: No Estimated Effect	

Appendix Table 2 --Estimated Average Per-Establishment Costs to Remove Noncompliant Point-of-Sale Advertising

AT Kearney Business Category	Total Number of establishments ^a	Remove Cigarette Promotional Materials (\$) ^b		Remove Promotional Materials for Products Covered by Warning Statement Provisions (\$) ^c
		1996 dollars	Current dollars	Current dollars
General Merchandise	32,125	23	33	4
Supermarket & Grocery	113,008	125	174	19
Convenience Stores	22,880	150	208	23
Convenience Stores with Gas	89,647	146	203	22
Service Stations	7,131	36	50	6
Drug Stores	52,088	12	16	2
Specialty Tobacco Stores	8,937	123	171	19
Other establishments ^d	20,738	9	13	1
ENDS establishments ^e	5,000 to 10,000	123	171	19
Total	351,554 to 356,554			
Weighted Average ^f				14.88 to 14.93

a Source: Table 5 .

b Sources: 61 FR 44585, Table 8; 1996 to 2013 (most recent) GDP-deflator = 38.8%

c = ("current dollars" estimate of effort required to remove cigarette promotional materials in 1996) * 11.01%

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

e Cost to remove promotional material assumed to be the same as for a specialty tobacco store.

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

Appendix Table 3 Undiscounted Stream of Costs (\$mill)

Year	Low	Medium	High
1	212.5	295.8	393.9
2	203.7	277.0	365.2
3	25.0	33.9	45.3
4	25.0	33.9	45.3
5	25.0	33.9	45.3
6	25.0	33.9	45.3
7	25.0	33.9	45.3
8	25.0	33.9	45.3
9	25.0	33.9	45.3
10	25.0	33.9	45.3
11	25.0	33.9	45.3
12	25.0	33.9	45.3
13	25.0	33.9	45.3
14	25.0	33.9	45.3
15	25.0	33.9	45.3
16	25.0	33.9	45.3
17	25.0	33.9	45.3
18	25.0	33.9	45.3
19	25.0	33.9	45.3
20	25.0	33.9	45.3

Appendix Table 4: Discussion of Small Business Topics in the Preamble and Final RIA

SBA Item Number	Location in the Final Rule or RIA
(1) a statement of the need for, and objectives of, the rule	<p><u>Preamble:</u> Executive Summary, Purpose of the Rule Background VII. Regulation of Cigars and Selection of Option 1. A. Health Risks of Premium Cigars VII. Regulation of Cigars and Selection of Option 1. B. Youth and Young Adults Use Premium Cigars VIII. Regulation of Electronic Nicotine Delivery Systems (Including E-Cigarettes) and the Continuum of Nicotine-Delivering Products. B. Prevalence</p> <p><u>RIA:</u> III.A. Need for the Final Rule</p>
(2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments	<p><u>Preamble:</u> There are small business-related comments addressed throughout the rule. Examples of such discussions include: III. Use of Premarket Pathways for Newly Deemed Products. D. Impact of Premarket Requirements IV. Implementation. Compliance Periods for Certain Provisions IV. Implementation. Compliance Policy Regarding Certain Provisions and Small-Scale Tobacco Product Manufacturers IX. Regulation of Vape Shops. E. Office of Small Business</p>
(3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments	<p><u>RIA:</u> II.H. Comments About the Small Entity Analysis</p>
(4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available	<p><u>Preamble:</u> IV. Implementation. Compliance Policy Regarding Certain Provisions and Small-Scale Tobacco Product Manufacturers</p> <p><u>RIA:</u> II.D.1 Comments About the Number of Entities and Products Affected II.H Comments About the Small Entity Analysis III.C.1 Number of Affected Entities IV.A Description and Number of Affected Small Entities</p>
(5) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record	<p><u>Preamble:</u> The requirements are described throughout the rule. The Summary of Major Provisions provides a succinct description of the rule’s requirements. XI. Additional Automatic Provisions Applicable to Newly Deemed Products. A.-F.</p> <p><u>RIA:</u> II.D Comments About Costs II.H Comments About the Small Entity Analysis III.C Costs IV. Small Entity Effects</p>
(6) a description of the steps the agency has taken to minimize the significant economic impact on small entities	<p><u>Preamble:</u> FDA addresses small business related comments and concerns throughout the rule, along with discussions supporting FDA’s actions in the rule. Examples include:</p>

<p>consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected</p>	<p>II. Legal Authority IV. Implementation. Compliance Policy Regarding Certain Provisions and Small-Scale Tobacco Product Manufacturers VII. Regulation of Cigars and Selection of Option 1. A-D VIII. Regulation of Electronic Nicotine Delivery Systems (Including E-Cigarettes) and the Continuum of Nicotine-Delivering Products. A-K <u>RIA:</u> II.G Comments about the Analysis of Alternatives II.H Comments About the Small Entity Analysis III.G Assessment of Regulatory Alternatives IV Small Entity Effects</p>
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

VII. APPENDIX 2: PREMARKET TOBACCO APPLICATION ANALYSIS

FDA has made available draft guidance for public comment, which, when final, will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. FDA expects that the content of PMTAs will vary significantly, depending on factors such as product type, complexity, and novelty. Moreover, there is more than one way to show that marketing a new tobacco product is appropriate for the protection of the public health. For the purposes of estimating the costs in the RIA, the following types of studies were considered:

E-Liquids

Composition and Design:

Testing of e-liquids may include chemical and microbiological analysis. Engineering analysis would not likely be done for an e-liquid.

The extent of microbiological testing will depend, in part, on the sterility of chemicals obtained by manufacturers from chemical suppliers. For example, if the certificates of analysis (COAs) from chemical suppliers included results from microbiological testing done by the suppliers, the e-liquid manufacturer may not need to do any microbiological analysis of the e-liquid. On the other extreme, if the COAs from the chemical suppliers do not include any microbiological testing, then the e-liquid manufacturer may have to analyze their products for bacteria and fungi. In addition, in this scenario, the e-liquid manufacturer may have to conduct stability testing to determine the expiration date of the e-liquid based on bacterial and fungal growth in the e-liquid over time. It is expected that some manufactures may already do this as part of their own internal quality control procedures.

The extent of chemical testing will depend, in part, on the purity of chemicals obtained by manufacturers from chemical suppliers. For example, if the COAs from chemical suppliers demonstrate that the chemicals are of high purity (e.g., >99.0%), the e-liquid manufacturer may only need to conduct limited analysis of the e-liquid to verify the contents of the e-liquid. This analysis is likely currently being done as part of quality

control by the e-liquid manufacturer and, therefore, would not be an additional cost associated with PMTAs. If COAs from chemical suppliers do not demonstrate highly purified chemicals, the e-liquid manufacturer may need to conduct more extensive chemical analysis to identify and quantify impurities in the e-liquid. It is also possible that manufacturers will choose suppliers that can provide them with such information instead of conducting the testing themselves.

The extent of chemical testing will be somewhat proportional to the chemical complexity of the e-liquid. For example, simple e-liquid formulations may be limited to nicotine, propylene glycol, and glycerol. In contrast, flavored e-liquids may have more complex formulations that include these three ingredients plus additional flavorants. The costs of the chemical analysis by the e-liquid manufacturer of the simple formulation will likely be less than that for the complex formulation.

Toxicological Studies:

When addressing toxicology issues for a product, this may be done by using toxicity information for the ingredients in the e-liquid or constituents formed during use. The toxicology information submitted in support of a PMTA for e-liquids should not be viewed as identical to the development of information required to support an application for a new molecular entity drug. In addition, as these are not novel chemicals, it is possible that much or all of the relevant information may exist within the publically available literature. Available literature and data would be relevant provided that they cover comparable exposure levels and the route of administration that apply to the product as it is used by the consumer.

For some products, such as e-liquid products that include only ingredients and aerosol products well studied using the inhalation route, nonclinical studies may not need to be conducted as all the relevant information is available publically. If there are ingredients or constituents for which there are not sufficient, relevant data (publically available or internal to manufacturer), then nonclinical studies could fill that void. If such studies are needed, they could be on the individual ingredient instead of the product, potentially allowing that study to cover multiple products using that ingredient or constituent. The range of studies needed would depend on the extent of the data gap that is identified. However, it is also possible that manufacturers will choose not to seek authorization for products where large data gaps exist.

Human studies:

Human studies that are supportive of ENDS PMTAs include: perception evaluations, product use/misuse, labeling comprehension, abuse liability, and health impact. There is an increasing volume of research conducted and publically available such as evaluations of cross-sectional prevalence of ENDS product use across the U.S. and perceptions of ENDS by various populations, as well as short term health impact studies. For example, FDA is funding more than 70 studies related to ENDS products. This growing pool of publically available information can be used to help support an ENDS product PMTA. FDA is also developing a public docket to make such information more easily accessible.

If new studies are conducted, we anticipate that multiple products will be evaluated in each human study. It is typical that e-liquids produced by a common manufacturer are offered in numerous flavorings and multiple dose offerings per flavoring, and many or all products can be evaluated in one study. In addition, data from a single study may be able to address many of the clinical questions relevant to ENDS use and health impacts and be referenced across a wider spectrum of ENDS products.

The types of studies that applicants may need to supplement existing data might be specific to the perception and actual use of their product. These could be in the form of survey or observational studies. A range of small surveys or set of focus group studies to more expansive behavioral use studies might be conducted. Such studies may be used to support many ENDS product PMTAs. Formal clinical trials are well known to be several million dollars in cost but FDA does not expect that PMTAs will include randomized clinical trials (e.g., phase 3 trials) like those conducted to support drug approvals. Study emphasis will be on understanding actual use of ENDS products of different types, establishing the toxicological profile of ingredients, and acquiring sufficient clinical, nonclinical, and behavioral data to evaluate the products' health impacts. If there are ingredients that are unknown or have known risks, then further clinical evaluation may be needed to support the PMTA. However, manufacturers may decide not to submit applications for products where extensive additional evaluation is needed.

END Systems

Composition and Design:

Testing of END systems may include chemical, microbiological, and engineering analysis. A closed END system will always contain an e-liquid; therefore, chemical, engineering, and microbiological testing will likely be necessary to support the PMTA. An open ENDS system may not include an e-liquid and, therefore, may only require an engineering analysis.

The microbiological testing will likely be limited to analysis of the e-liquid for those "closed" device systems that used e-liquid cartridges or are disposable. Considerations for testing these are generally the same as discussed in the e-liquid section.

Similar to e-liquid chemical analysis, the extent of chemical testing of the aerosol produced by ENDS devices will depend, in part, on the purity of chemicals obtained by a manufacturer from a chemical supplier as well as the e-liquid formulation complexity. E-liquids with simple formulations such as vegetable glycerin and nicotine will often generate fewer chemicals in the aerosol. Therefore, chemical analysis will also depend on the number of chemical ingredients.

In addition, chemical testing will also be dependent on the apparatus design. For example, an apparatus that does not allow modification by the user (e.g., cigalike) can only generate aerosol under one set of apparatus settings/conditions. In contrast, an apparatus that allows user modification of settings (e.g., tank apparatus with variable

wattage and adjustable airflow openings) will likely include more analyses of the aerosol to understand the aerosol delivery under a range of different settings.

The extent of engineering analysis, like chemical testing, will be dependent on the apparatus design. For example, an apparatus that does not allow modification by the user (e.g., cigalike) will generally include a relatively simple design compared to an apparatus that allows user modification of settings or conditions (e.g., tank apparatus with variable wattage and adjustable airflow openings). A simpler design will generally have fewer design parameters to test.

Toxicological Studies:

Toxicology evaluation for the apparatus is similar to that described above for the e-liquid. When dealing with an END system, a toxicological evaluation of constituents in the aerosol that are formed due to the apparatus, in addition to those formed from the e-liquid, would likely be needed. Identification of these constituents would occur during the chemical testing, and as noted, that testing would vary dependent on the apparatus design. As with the e-liquid, there is potential that no new toxicology studies will need to be conducted. For example, available information on the constituents formed due specifically to the apparatus may already exist. This publically available information can be used in a toxicology evaluation; Generally, available literature and data would be relevant provided that they cover comparable exposure levels and the route of administration that apply to the product as it is used by the consumer.

While closed systems would likely require only the toxicological information or studies described in the paragraph above, an open system, without an accompanying e-liquid, would generally require only a toxicological assessment of any constituents that could be formed due to the apparatus and to which the user would be exposed. As discussed throughout, generally, if sufficient toxicology information is already available, and the information is relevant to both the exposure level and the route of exposure for the user, then additional studies may not be needed.

Human studies:

Human studies that are supportive of ENDS PMTA include: perception evaluations, product use/misuse, labeling comprehension, abuse liability, and health impact. Human studies for e-liquids and END systems will likely be similar; therefore, the discussion in the e-liquid section above is also relevant to the END system. Similar to e-liquids, there is an increasing volume of research conducted and publically available such as evaluations of cross-sectional prevalence of ENDS product use across the U.S. and perceptions of ENDS by various populations, as well as short term health impact studies. For example, FDA is funding more than 70 studies related to ENDS products. This growing pool of publically available information can be used to help support an ENDS product PMTA. FDA is also developing a public docket to make such information more easily accessible.

FDA expects that manufacturers will produce END systems with fewer variations than e-liquids so studies would likely cover fewer product variations. However, it is still the case

that a single study can broadly evaluate various aspects as perception, craving and biomarkers of exposure. Similarly, the data from a single study may be able to address many of the clinical questions relevant to ENDS use and potential health impacts.

Open END systems may require additional human study considerations compared to closed END system because of human factors that can lead to misuse. Specific human factor testing will likely be an important aspect for evaluating open systems due to increased variability in aerosol delivery.

Given the uncertainties regarding the percent of each type of END systems that will apply for premarket authorization, we conservatively applied the higher costs for open END systems to all the systems in this category.

VIII. APPENDIX 3: SEARCH, MARKET ADJUSTMENT, AND PRODUCER SURPLUS COSTS UNDER REGULATORY ALTERNATIVE 3 (DO NOT EXTEND THE PREMARKET REVIEW COMPLIANCE POLICY TO NEW FLAVORED PRODUCTS)

A. SEARCH AND MARKET ADJUSTMENT COSTS DUE TO EXPECTED EXIT OF NEWLY DEEMED FLAVORED NEW TOBACCO PRODUCTS

Under this compliance policy alternative, with the exception of a 90-day sell off period for retailers of newly-deemed flavored new tobacco products (other than tobacco flavored products), FDA would intend to enforce the requirements of premarket review for such products as of the effective date of the final rule. Therefore, we expect that newly deemed flavored new tobacco products would exit the market within 180 days of publication of this final rule. Newly deemed flavored new tobacco products might reenter the market in the future if they applied for and received marketing authorization. This exit and reentry would cause disruptions in the markets for flavored tobacco products, the extent of which would depend on the prevalence of flavors and the prevalence of grandfathered products (which are not subject to premarket authorization requirements). The ENDS market would be subject to the most severe disruption because flavors make up the majority of the market and there likely will not be any flavored grandfathered ENDS products.

We expect that consumers would incur search costs in order to look for replacements for products that exit the market within 180 days after publication of the final rule. In the case of flavored cigars and pipes, grandfathered flavored cigars and pipes are probable substitutes for non-grandfathered products in this category; we therefore assume that consumer search costs for these products would be small and do not estimate them here. Because there likely will not be any flavored grandfathered ENDS products, search costs would be expected to be more appreciable for consumers of flavored ENDS than for consumers of other flavored products. In

the absence of empirical evidence relevant to estimating what time or money consumers would allocate to searching for alternative products, but to account for the possible cost, we assume they would incur one-time search costs equal to between one-half of one percent and one percent of current annual sales of flavored ENDS products.

For producers and retailers, we expect that there would be one-time market adjustment costs due to exit of non-grandfathered flavored tobacco products. Regulation-induced product and firm exit would lead to one-time friction costs for the reallocation of labor and capital both within firms and across firms. We do not predict the number of (non-retailer) manufacturers that would shut down as a result of this alternative compliance policy, but we expect the majority of vape shops would shut down in the period after flavored ENDS products exit the market. Some vape shops might reopen after marketing authorizations are obtained and product variety broadens. Although we lack empirical evidence relevant to estimating the friction costs that firms would bear due to product and firm exit, to account for social costs of these frictions, we estimate they would equal between 1 percent and 2 percent of the value of total sales associated with flavored new products.

Appendix Table 5 shows our estimates of revenue associated with flavored products, as well as consumer search costs and market adjustment costs under this compliance policy alternative.

Appendix Table 5 –One-Time Consumer Search and Market Adjustment Costs

Product Category	Estimated total sales (\$) ¹	Proportion New and Flavored	Estimated total sales related to new flavored Products (\$)	Consumer Search Costs (\$)	Market Adjustment Costs (\$)
Cigars ²	7,979,700,000	10.34%	825,429,065	Not Estimated	8,254,291 to 16,508,581
Pipe Tobacco ³	1,763,200,000	11.87%	209,203,680	Not Estimated	2,092,037 to 4,184,074
ENDS ⁴	3,500,000,000	See note 4.	1.599 billion to 2.275 billion	7,995,000 to 22,750,000	15,990,000 to 45,500,000
Total				7,995,000 to 22,750,000	26,336,327 to 66,192,655

¹ Sources for dollar value of sales: Euromonitor, 2014a; Euromonitor, 2014b.; Herzog et al., 2015.

² In 2013, handmade cigars accounted for 48.9 percent of cigar revenue while machine-made cigars accounted for 51.1 percent (Euromonitor, 2014a). Within handmade and machine-made categories, we assume the proportion of revenue from flavored products is the same as the proportion of products that are flavored (see Table 36). Finally, we assume the proportion of products that are new (from Table 9) does not depend on the presence or absence of flavors.

³ We assume that waterpipe tobacco accounts for 10 percent of overall pipe tobacco revenue. Within these categories, we assume the proportion of revenue from flavored products is the same as the proportion of products that are flavored. (See Table 36.) Finally, we assume the proportion of products that are new (from Table 9) does not depend on the presence or absence of flavors.

⁴ We assume that all flavored ENDS product are new. Herzog et al. (2015) forecast that sales of e-cigarettes will be \$1.5 billion in 2015 and sales of open systems will be \$2.0 billion. Euromonitor (2015) estimates that approximately 40 percent of open systems sales are attributable to e-liquid and the remaining 60 percent to delivery systems. We assume that flavored products represent 45 percent of total sales of e-cigarettes, based on analysis of 2014 Nielsen data on sales of e-cigarettes sold through convenience stores and food, drug and mass-merchandise channels. We assume flavored e-liquids represent 66 to 80 percent of total e-liquid sales; 66 percent reflects preliminary data from the out Population Assessment of Tobacco and Health (PATH) Study (FDA, 2015c) showing that two-thirds of regular adult users of e-cigarettes say their usual brand is a flavored product, and 80 percent reflects a finding from Burke (2015) that tobacco e-liquids represent 17 percent of the volume of unit sales of e-liquids (where we adjust this figure up to allow for sales of non-flavored e-liquids). It is uncertain whether the proportion of revenue for open delivery systems that would disappear when flavors exit is equal to the proportion of e-liquids that are flavored. We generate a wide range to account for this uncertainty; on the low end, we assume the proportion is half as large (33 percent), while on the high end, we assume it is equal (80 percent). We note that the extremes values are possible but unlikely.

B. ESTIMATING THE LOSS OF PRODUCER SURPLUS IN THE MARKET UNDER THIS REGULATORY ALTERNATIVE

Under this compliance policy alternative, the expected exit of non-grandfathered flavored ENDS products within 90 days after the effective date of the final rule would lead to additional costs. Although we would expect that some flavored ENDS products would submit premarket applications, receive authorization, and eventually enter the market, declining to extend the premarket compliance policy described in the preamble to the final rule to new newly deemed flavored tobacco products would imply that different types of exit costs would be borne by consumers and producers. One social cost would be forgone producer surplus during the time non-grandfathered flavored ENDS products would be off the market; given that there likely will not be any flavored grandfathered ENDS products, we expect that all flavored ENDS products would initially exit the market. Producer surplus, which is the difference between the prices producers receive for their products and the minimum price they would accept, is a measure of net benefit to producers. We include lost producer surplus as an exit cost.

To estimate the change in producer surplus, we separate flavored ENDS products from the other part of the market and use a simple linear model of supply and demand. We can think of the exit of flavored ENDS products as a result of this compliance policy alternative as analogous to a tax-induced change in market price sufficient to cause the quantity supplied to drop to zero. Treating a regulatory restriction as a change in price in a market with linear supply and demand generates an approximation for the broad market change associated with this compliance policy alternative.

We can compute the change in producer surplus as a simple triangular area between the prevailing product price and the supply curve equal to one-half of the change in price times the change in quantity. The calculation of lost producer surplus for flavored ENDS products in this simulation is based on the estimated value of total revenues from sales of flavored products, estimates of the price elasticity of demand, and the assumption that the elasticity of supply of these products is significantly greater than the elasticity of demand.

Without any real-world experience of product disappearance in this market, we model the effects as having ranges of uncertainty. For revenue from flavored ENDS products, we used a uniform distribution ranging between \$1.599 billion and \$2.275 billion per year. Based on Zheng et al. (2014), and other recent research, we model the price elasticity of demand as having a triangular distribution (-2.1, -2.0, -1.8). A key parameter for this model is the price elasticity of supply. We expect the price elasticity of supply of flavored ENDS products to be considerably larger in absolute value than the demand elasticity, but how much larger is unknown. We use a uniform distribution assuming the supply elasticity is 3 to 7 times greater than the demand elasticity, which encompasses a range of about 6 to 14. With linear supply and demand, the initial market price can be arbitrary (quantity is determined by total revenue divided by price). Using these assumptions, we simulated the results using a Monte Carlo simulation with 100,000 iterations.

The measured change in producer surplus is based on the change in supply price, $P_o - P_n$. P_o is the initial price and P_n is the new supply price that would occur after the regulation is introduced (in effect, the price at which the supply curve crosses the horizontal axis because Q falls to zero), so $P_o - P_n$ is the change in supply price. The producer surplus change equals $0.5 * (P_o - P_n) * Q_o$, with Q_o being the initial quantity sold. The linear model reduces to the following calculation of producer surplus:

$$0.5 * P_0 Q_0 * (1/\epsilon),$$

where ϵ is the supply elasticity.

We compute the loss of producer surplus over 10 years. In the first year, we expect that products would exit within 90 days after the effective date of the final rule (180 days after the publication date), so we estimate the loss as 50 percent of a year. For that reason, we treat the loss in year one as 50 percent of the annual loss. In year 2, we calculate the full loss. Starting in year 3, we also assume that ordinary product entry or turnover, assumed in the RIA to be 5 to 10 percent per year, would reduce the loss in producer surplus loss by the same amount (5 to 10 percent per year).

The calculation in year 3, then, would be

$$PS = (1 - \text{uniform}(0.05, 0.1)) * 0.5 * P_0 Q_0 * (1/\epsilon).$$

We assume most entry of flavored or other varieties of products to compensate for the lost sales resulting from the initial product exit would occur by the 4th year after the rule takes effect, dramatically reducing the net producer surplus loss. Therefore, we model re-entry in year 4 as offsetting nearly all, 90 to 99 percent, of producer surplus that would previously be lost.

We further assume the small remaining effects of the initial exit of flavored ENDS products would disappear after year 10.

For years 4-10, the general formula would be

$$PS = (1 - \text{uniform}(0.05, 0.1))^{t-2} * (1 - \text{uniform}(0.9, 0.99)) * 0.5 * P_0 Q_0 * (1/\epsilon), \text{ where } t \text{ is the year.}$$

Finally, we assume that complete adjustment would occur after year 10 and therefore there would be no subsequent producer surplus loss.

Appendix Table 6 shows the annual estimated losses of producer surplus, starting with the year the final rule becomes effective. As the table shows, almost all of the loss would occur in the first 3 years after the final rule takes effect.

Appendix Table 6 -- Simulation of Lost Producer Surplus, years 1-20 (\$ Millions)

Year	Mean	5 th percentile	95 th percentile
1	52.2	33.8	79.3
2	104.4	67.6	158.5
3	97.4	63.1	148.0
4	5.0	1.2	10.3
5	4.7	1.1	9.6
6	4.3	1.1	9.0
7	4.1	1.0	8.4
8	3.8	0.9	7.8
9	3.5	0.9	7.3
10	3.3	0.8	6.9

11	0.0	0.0	0.0
12	0.0	0.0	0.0
13	0.0	0.0	0.0
14	0.0	0.0	0.0
15	0.0	0.0	0.0
16	0.0	0.0	0.0
17	0.0	0.0	0.0
18	0.0	0.0	0.0
19	0.0	0.0	0.0
20	0.0	0.0	0.0

In order to calculate the present value and annualized present value of the lost surplus, we run the model for both 3 percent and 7 percent rates of discount. Appendix Table 7 shows present and annualized values of lost producer surplus over 20 years.

Appendix Table 7-- Simulations Results for Present Value of Lost Producer Surplus (In \$ millions over 20 years)

	Mean	5 th	95 th
Present value, 3 percent discount	261.8	168.4	399.2
Annualized value, 3 percent discount	17.6	11.3	26.8
Present value, 7 percent discount	237.8	153.3	362.2
Annualized value 7 percent discount	22.5	14.5	34.2