DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports; Final Rule

Docket No. FDA-2016-N-3818

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

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Office of Policy, Legislation, and International Affairs
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I. Introduction and Summary

A. 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 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). 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. Because we have determined that the compliance costs are less than 0.2 percent of revenues, we certify that the rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary

This final rule will impose compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, keep records, and fill out a form for SE Reports. We estimate that the present value of industry compliance costs ranges from $0.4 million to $3.4 million, with a primary estimate of $1.9 million at a 3 percent discount rate, and from $0.4 million to $2.9 million, with a primary estimate of $1.6 million at a 7 percent discount rate over 10 years. Annualized industry compliance costs over 10 years range from $0.05 million to $0.39 million, with a primary estimate of $0.22 million at a 3 percent discount rate and from $0.06 million to $0.42 million, with a primary estimate of $0.23 million at a 7 percent discount rate. The costs to industry range from around $200 to around $1,400 per affected entity per year, with a primary estimate of around $800 per entity per year.

The benefits of this final rule are potential time-savings to industry and cost-savings to FDA. The final rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product. Certifying may save applicants time in preparing their SE Reports. In this final rule, we intend to shorten review times for SE Reports. In addition, based on our experience with prior SE Reports, we believe this final rule will lead to higher quality SE Reports, saving us time in review and requiring fewer staff to review SE Reports, which will result in cost-savings. We estimate that the present value of

government cost-savings ranges from $15.1 million to $150.6 million, with a primary estimate of $50.2 million at a 3 percent discount rate, and from $12.4 million to $124 million, with a primary estimate of $41.3 million at a 7 percent discount rate over 10 years. Annualized government cost-savings over 10 years range from $1.8 million to $17.7 million, with a primary estimate of $5.9 million at both 3 and 7 percent discount rates. The FDA cost-savings per report ranges from around $17,700 to around $58,800, with our best estimate at around $29,400.

The non-quantified benefits of this final rule include additional clarity to industry about the requirements for the content and format of SE Reports. The final rule will also establish the general procedures we intend to follow in reviewing and communicating with applicants. In addition, this final rule will make the SE pathway more predictable.

The present value of net benefits due to this final rule ranges from $14.6 million to $147.2 million, with a primary estimate of $48.3 million at a 3 percent discount rate, and from $12.0 million to $121.0 million, with a primary estimate of $39.7 million at a 7 percent discount rate. The estimated annualized net benefits range from $1.72 million to $17.3 million, with a primary estimate of $5.67 million at a 3 percent discount rate. The estimated annualized net benefits range from $1.71 million to $17.23 million, with a primary estimate of $5.65 at a 7 percent discount rate.

Table 1 summarizes the benefits and costs of the final rule.

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

Category		Low Estimate	Primary Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$1.8 million	$5.9 million	$17.7 million	2018	7%	10 years	Cost-savings to government
		$1.8 million	$5.9 million	$17.7 million	2018	3%	10 years	Cost-savings to government
	Annualized Quantified				2018	7%	10 years	
					2018	3%	10 years	
	Qualitative							Greater certainty for SE applicants
Costs	Annualized Monetized $millions/year	$0.06 million	$0.23 million	$0.42 million	2018	7%	10 years	
		$0.05 million	$0.22 million	$0.39 million	2018	3%	10 years	
	Annualized Quantified				2018	7%	10 years	
					2018	3%	10 years	
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year				2018	7%	10 years	
					2018	3%	10 years	
		From:			To:			
	Other Annualized				2018	7%	10 years	
					2018	3%	10 years	

Category		Low Estimate	Primary Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Monetized $millions/year	From:			To:			
Effects	State, Local or Tribal Government: No effect Small Business: No effect Wages: No effect Growth: No effect							

C. Definitions

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

- Originally regulated tobacco product: tobacco products that the Family Smoking Prevention and Tobacco Control Act gave FDA immediate authority to regulate under Chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act). These products are cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco.

- Deemed tobacco product: tobacco products subject to Chapter IX of the FD&C Act, as a result of regulations enacted by FDA (Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 FR 28974, May 10, 2016 ("Deeming Rule")). These products include cigars, pipe tobacco, waterpipe tobacco, electronic nicotine delivery systems (ENDS), and other novel tobacco products.

- Predicate tobacco product: The product that the new tobacco product is compared to in SE Reports. A predicate tobacco product is either a product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that FDA previously found substantially equivalent.

- New tobacco product: As defined in section 910(a)(1)(A) of the FD&C Act; 21 U.S.C. 387j(a)(1)(A)), "new tobacco product" means (1) any tobacco product (including those in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

- "Premium" cigars: A type of cigar that: (1) is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar); (4) is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); (5) has no filter, nontobacco tip, or nontobacco mouthpiece; (6) does not have a characterizing flavor other than tobacco; (7)

contains only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weighs more than 6 pounds per 1,000 units[1].

- Substantial equivalence or substantially equivalent: As defined in section 910(a)(3)(A) of the FD&C Act (21 U.S.C. 387j(a)(3)(A), the term "substantially equivalent" or "substantial equivalence" means, with respect to a new tobacco product being compared to a predicate tobacco product, that FDA by order has found that the new tobacco product:
    (1) Has the same characteristics as the predicate tobacco product; or
    (2) Has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to require premarket review under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health.

- Exemption Request: A request for an exemption from a substantial equivalence report for tobacco products that are modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of an existing tobacco additive (section 905(j)(3) of the FD&C Act and the Tobacco Products, Exemptions From Substantial Equivalence Requirements final rule (76 FR 38961)). We may exempt from the requirements relating to the demonstration of substantial equivalence tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if we determine 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.

- Substantial Equivalence (SE) Report: the initial SE Report submission under section 905(j)(1)(A)(i) of the FD&C Act (21 U.S.C. 387e(j)(1)(A)(i)) and all subsequent amendments to the initial submission.

- Review cycle: the time FDA reviews the initial SE Report or response to a deficiency letter. The review cycle ends with the issuance of an action letter (e.g., an Advice/Information Request letter, Preliminary Finding letter, Substantially Equivalent order, Not Substantially Equivalent order). FDA intends to review initial SE Reports within 90 calendar days of determining that the predicate is eligible, and subsequent responses to deficiency letters within 90 calendar days of receipt.

- Marketing order: an order authorizing a new tobacco product to be introduced or delivered for introduction into interstate commerce for commercial distribution in the United States. FDA may issue a marketing order under the premarket tobacco product application (PMTA) pathway or substantial equivalence (SE) pathway.

[1] As defined under the court's order in *Cigar Ass'n of Am., et al. v. Food and Drug Admin., et al.*, Case No. 1:16-cv-01460 (APM), (D.D.C. Aug. 19, 2020), Dkt. No. 214 (*Cigar Ass'n of America*). For further discussion of the court's decision, see below.

- Substantially Equivalent (SE) order: an order finding a product substantially equivalent to a predicate tobacco product and in compliance with the requirements of the FD&C Act.

- Not Substantially Equivalent (NSE) order: an order finding that (1) the applicant did not demonstrate that its new tobacco product is substantially equivalent to a predicate tobacco product and/or (2) the new tobacco product is not in compliance with the requirements of the FD&C Act.

- FDA/we/us/our: used to refer to the Food and Drug Administration.

D. Comments on the Preliminary RIA and Our Responses

We received many comments on our preliminary regulatory impact analysis (PRIA) (Ref. [1]) for the proposed rule (Ref. [2]). For ease of use, we group together comments that address the same subject. We assign a single number for each grouping even though the group may contain several comments. Please see the Appendix for comments and responses that apply to the Appendix.

1. Out of scope comments

(Comment 1) Many commenters commented on the Deeming final rule and Deeming Final RIA. They state that we excluded many of the costs to prepare and submit SE Reports for deemed tobacco products such as cigars, premium cigars, and pipe tobacco and didn't account for any benefits. Commenters discussed impacts for deemed tobacco products including: testing costs; environmental assessments; reduced product variety; impacts on businesses, including impact on profitability and potential for exit from the market; costs for deciding whether they will exit or remain market participants; costs to develop implementation and compliance approaches if they remain on the market; impacts on the price of cigars; creation of a monopoly market; particular impacts on small businesses; impacts on domestic and foreign tobacco growers; job losses in domestic and foreign tobacco manufacturing and retailing; and FDA resources to review SE Reports for deemed tobacco products. Commenters requested that these effects be part of the economic analysis of the SE Rule.

(Response 1) The Deeming Final Rule (May 2016) extended FDA's regulatory authority to all tobacco products (excluding accessories of such products), and thus all premarket requirements apply to deemed tobacco products. Because this final rule does not change who is required to prepare and submit an SE Report, we consider some aspects of these comments out-of-scope. However, the marketing clearance system established for originally-regulated products by the Tobacco Control Act and extended to deemed tobacco products by the Deeming Final Rule has been characterized by trial-and-error inefficiencies that are consistent with the public feedback and that form the government failure this final rule is intended to address with the term "government failure" used in the sense of economic conceptual analysis, indicating a gap between the status quo and the theoretical ideal. For this final RIA, we assume that SE reports

will be prepared and submitted even without this final rule and estimate the incremental impact of this final rule.

2. Comments on baseline

(Comment 2) We received comments on our Paperwork Reduction Act (PRA) estimates. Several commenters stated that our estimate of 87 to 300 hours to prepare and submit an SE Report is too low. Several comments suggest that, based on their experience, it will take approximately 900-1,000 hours to prepare an SE Report for one product, and other comments estimate that it may take 15-28 months to prepare an SE Report depending on the scientific testing required. These commenters believe that it will take longer, especially for deemed products, because some information may not be readily available. Another commenter states that they believe our estimated burden for an environmental assessment (EA) is too high as a proportion of the time to prepare and submit an SE Report. They state that our estimate of 52 to 80 hours for an EA is potentially more than our estimated burden for an SE Report at 35 to 220 hours.

(Response 2) Please see the preamble to the final rule, section IX, for responses to comments on the PRA estimates.

(Comment 3) A commenter stated that our estimated burden of "bundled" SE Reports is significantly lower than our estimate for a single product. They believe that this is wrong because the bundled applications cover multiple products and should therefore be greater than the burden associated with preparing a report for a single product.

(Response 3) We agree that the total time to submit a bundled SE Report is greater than the time to submit a report for a single product. Our estimates for "bundled" SE Reports should have said that it was the time associated with submitting for each *additional* product in the bundle. Meaning, we anticipate that the time it takes to submit each additional report in the bundle will be less than the time it takes to submit the report for the first product in the bundle. Therefore, the total cost for submitting a bundle of 3 products would be the full SE burden for the first product, plus two times the burden to submit a bundled report. We have clarified this in the final analysis.

(Comment 4) A commenter stated that we may have failed to undertake a proper economic analysis by not focusing on the cost to manufacturers of having to generate the data that the rule, but not the statute, requires companies to submit. The commenter believes that we have grossly underestimated costs to industry because we have not included the cost of preparing and submitting extensive data as part of the SE Report.

(Response 4) As we state in the 'Baseline' section of the PRIA, "this analysis uses the state of the world where manufacturers routinely submit SE Reports as the baseline." Therefore, we assume that the costs to prepare, submit and review SE Reports will be undertaken even without this rule. This rule does not change the cost per SE Report, except for the costs to submit an electronic form with the Report. We also included an Appendix where we considered the impacts of an alternative baseline prior to the Family Smoking Prevention and Tobacco Control Act. The

estimates in the Appendix include the impact of the SE provisions as currently interpreted by the Agency.

3. Comments on estimates of number of products and SE Reports

(Comment 5) Several commenters stated that their trade association reports that there are 51,000 different premium cigar items on the market today. Another commenter also stated that there are nearly 51,000 separate types of premium cigars as measured by stock keeping units or SKUs. These estimates are based on a report by EConsult that was commissioned by the trade association. Other commenters state that we missed counting foreign products by relying on our domestic tobacco product listing database.

(Response 5) We agree that there are several limitations to our estimate of the total number of tobacco products from our tobacco listing module as we discussed in the PRIA. For the final RIA, we have changed the method used to estimate the number of deemed SE reports we expect to receive. We describe the methodology used to make this calculation below.

Note that a recent court decision in *Cigar Ass'n of America* enjoined FDA from enforcing the premarket review requirements against "premium" cigars until the Agency has completed its review of commenters' suggestions to the proposed deeming rule that the FDA create a streamlined substantial equivalence process for "premium" cigars. Therefore, at this time, FDA is not finalizing the proposed SE rule with respect to "premium" cigars. As such, the estimated number of deemed SE reports we expect to receive is likely an overestimate as it includes "premium" cigars, which are excluded from the scope of this final rule.

(Comment 6) A few commenters disagree with our assumption that the majority of cigar products on the market as of the effective date for the Final Deeming Rule were commercially marketed in the United States as of February 15, 2007 ("Pre-Existing tobacco products").[2]

(Response 6) The RIA for the Final Deeming Rule assumed that the majority of cigar products were Pre-Existing tobacco products. For analysis of this final rule, we combine our estimate of the number of voluntary, standalone Pre-Existing tobacco product requests (voluntary, standalone determination requests) for deemed products to date with our estimate that SE Reports for originally regulated tobacco products average two to five times the count of established, originally regulated Pre-Existing tobacco products. We use this combination to estimate the number of initial and annual SE Reports manufacturers will submit under the baseline.

(Comment 7) A few commenters believe that FDA's estimate of initial cigar SE Reports is too low. They note that FDA relied on the number of cigars that FDA has determined are Pre-Existing tobacco products through voluntary, standalone determination requests, but that number has increased since the proposed rule. In addition, they note that, because these requests are

[2] In this final regulatory impact analysis, as well as the final rule, we have changed the term from "grandfathered tobacco product" to "Pre-Existing tobacco product" because Pre-Existing tobacco product more appropriately describes these products.

voluntary, this number underestimates the number of cigars that are Pre-Existing tobacco products, since manufacturers may not have submitted standalone determination requests for all cigars that are Pre-Existing tobacco products. In addition, this estimate excludes pending submissions. Several commenters stated that FDA should expect to receive thousands of SE Reports for deemed products, including around 30,000 initial SE Reports for cigars and around 10,000 each subsequent year.

(Response 7) We have updated our estimate of the number of deemed products that are Pre-Existing tobacco products to include tobacco products that FDA has recently determined, through voluntary, standalone determination requests, are Pre-Existing tobacco products. In addition, we have updated this estimate to include pipe tobacco products and waterpipe tobacco products. We use our estimate that SE Reports for originally regulated tobacco products average two to five times the count of originally regulated products that FDA has determined through voluntary, standalone determination requests are Pre-Existing tobacco products. We also estimate that the number of initial SE Reports received for deemed tobacco products will be an average of two to five times the count of deemed Pre-Existing tobacco products. Moreover, this final rule will publish after the deadline for manufacturers to submit initial SE Reports for deemed tobacco products. Therefore, this rule will only cover subsequent SE Reports. We now estimate that manufacturers may submit between 600 and 1,650 annual SE Reports for deemed products each year from 2021 onwards, noting that this range has a tendency toward overestimation as it includes "premium" cigars, which are excluded from the scope of this final rule.

(Comment 8) Several commenters stated that we have substantially underestimated the number of SE Reports we will receive annually as calculated in the PRA analysis of the proposed rule. The commenters state that FDA should expect tens of thousands of SE Reports, much higher than the proposed rule estimates of 683 standalone SE Reports and 456 bundled SE Reports each year, as calculated in the PRA analysis of the proposed rule. In addition, a commenter notes that it expects to submit well over 100 reports per year as opposed to the FDA estimates of one application per year.

(Response 8) For analysis of this final rule, we have changed the method used to estimate the number of deemed SE reports we expect to receive and updated our estimate of deemed products FDA has determined through standalone determination requests were commercially marketed in the United States as of February 15, 2007, to include more recent counts in our calculations. We describe the methodology used to make these calculations, as well as the resulting estimates, in later sections. Additionally, these comments refer to the PRA estimates for the rule. Please see the preamble to the final rule, section IX, for responses to comments on the PRA estimates. We also note that the estimated number of deemed SE reports we expect to receive is likely an overestimate as it includes "premium" cigars, which are excluded from the scope of this final rule.

(Comment 9) A commenter stated that FDA's estimate of the number of pipe tobacco products and SE Reports is wrong because we rely on internal subject matter experts for our estimates.

(Response 9) In response to comments, we have revised our approach in the final RIA of this rule and use the number of deemed tobacco products FDA has determined through voluntary, standalone determination requests are Pre-Existing tobacco products, along with relationships estimated from SE Report submissions for originally regulated tobacco products, to estimate the number of deemed SE Reports we expect to receive.

4. Comments on estimates of incremental cost or burden

(Comment 10) Several commenters discussed the proposed requirement for manufacturers, upon request, to fully characterize the original predicate product regardless if the SE Report references a predicate product that was previously given an SE Order. Commenters stated that this requirement is inefficient and will impose an undue burden on entities. A few commenters believe that it will be impossible to refer to the original predicate tobacco product because the firm may no longer manufacture the original predicate tobacco product and may not have tested the original predicate tobacco product or kept the records that we will require to compare the original predicate tobacco product to the new tobacco product. Another commenter stated that this requirement will require that manufacturers have the ability to manufacture original predicate tobacco products indefinitely. Two commenters noted that FDA's requirement to keep all records supporting an SE Report for four years understates the actual burden. If FDA requires records related to the original predicate tobacco product for each new tobacco product, manufacturers will have to keep records in perpetuity.

(Response 10) We disagree with the comment that this requirement will require manufacturers to have the ability to manufacture original predicate tobacco products indefinitely. We believe that this requirement is a recordkeeping burden. The first SE Report in a chain must use a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, as a predicate product for the SE Report. Therefore, we believe that given this fact, most manufacturers as part of usual business practices will have kept and still have access to those records for the predicate products which were the subject of the initial SE report. In the absence of this final rule, we believe a small number of manufacturers may not continue to maintain such records or will be a different manufacturer than the one that initially submitted the first report in the chain. Based on this assumption, this requirement could lead to manufacturers keeping records for a longer time. In response to comments, we have increased the upper-bound recordkeeping burden in our final RIA. We have retained the lower-bound estimate of zero recordkeeping hours because not all entities will submit SE Reports. In addition, some entities may keep records without this final rule. We estimate the recordkeeping burden of this final rule is zero to ten hours per entity each year.

(Comment 11) A commenter states that FDA should include costs estimates related to reading, understanding, and studying the regulations.

(Response 11) We included costs to read and understand the rule in the PRIA. The commenter did not comment on our specific estimates, so we have retained our methodology to read and understand the rule in our final RIA.

(Comment 12) One commenter believes that FDA has underestimated the time to complete the electronic form.

(Response 12) We have changed our estimates to complete the electronic form in the final RIA. We now estimate that initially it will take 45 minutes per product to fill out the form, and subsequent reports may take 10 minutes.

5. Comments on entities and the initial regulatory flexibility analysis

(Comment 13) A commenter states that FDA underestimated the number of affected entities because we relied only on the domestic establishment registration database.

(Response 13) We did not use our registration database to estimate the number of affected entities, but rather used data from the Alcohol and Tobacco Tax and Trade Bureau (TTB). We have updated our estimate of affected entities with TTB data from 2017. We use counts of importers of tobacco products from this data source as a proxy for the number of foreign firms that will submit SE reports under this final rule, but acknowledge that this estimate may not fully capture the number of foreign entities who will submit SE Reports. The commenter did not provide any additional information on the number of entities or other data sources to use for us to change our estimate.

(Comment 14) A commenter discusses the threshold for small businesses under the Small Business Act. They state that a business engaged primarily in cigarette manufacturing is considered small if its annual receipts do not exceed $1 billion, and a business engaged primarily in manufacturing tobacco products other than cigarettes is considered small if its annual receipts do no exceed $500 million.

(Response 14) In our small business analysis, we comply with the requirements of the Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement Fairness Act (SBREFA) and we use the Small Business Administration (SBA) Table of Small Business Size Standards to determine the size threshold for small businesses. SBA classifies Tobacco Manufacturing (NAICS 312230) businesses with less than 1,500 employees as a small business. In addition, SBA classifies Tobacco and Tobacco Product Merchant Wholesalers (NAICS 424940) as small businesses if they have fewer than 250 employees.

(Comment 15) A commenter does not believe we should certify that the rule will not have a significant impact on small entities. The commenter states that the SE Rule will have a significant impact on small entities.

(Response 15) We disagree with this comment. The Deeming Final Rule (May 2016) extended FDA's regulatory authority to all tobacco products (except accessories of deemed products), and thus all premarket requirements apply to deemed tobacco products. Because this final rule does not change who is required to prepare and submit an SE Report, we assume that these reports will be prepared and submitted even without this final rule and estimate the incremental impact of this final rule. Any impacts of the SE program on small businesses, besides those discussed in the main analysis of this RIA, will occur without this final rule.

(Comment 16) A commenter stated that tobacco growers and their workers, will be impacted by the rule and that we should have included these impacts on small tobacco farms in our small entity analysis. Another commenter stated that we should account for impacts on retailers, particularly for single store operations.

(Response 16) This final rule does not change the scope of manufacturers required to submit SE Reports. Any indirect impacts of the SE program on tobacco growers or retailers will occur without this final rule. Therefore, we do not consider these indirect impacts as an incremental impact of this final rule.

E. Summary of Changes

We have made several changes to this final RIA to reflect updated estimates as well as information provided in comments on the proposed rule. These changes include:

- Wages from 2018
- Number of entities based on TTB data from 2017
- Estimates for originally regulated SE Reports based on Tobacco Product User Fees Reports and internal data
- Updated estimated number of deemed tobacco product SE Reports based on estimates of the number of deemed products FDA has determined through standalone determination requests are Pre-Existing tobacco products
- Updated timing of SE Reports due to court decision on Deeming compliance dates[3]
- Updated the time to read and understand the rule
- Kept the estimates for establishing standard operating procedures, but treat them as a range rather than as estimates applying to small and large firms
- Updated the time for recordkeeping based on comments about the requirement to submit material on the original predicate tobacco product

II. Final Economic Analysis of Impacts

A. Background

1. Statutory pathways to obtain marketing authorization

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) of 2009, which amends the FD&C Act, gave us the authority to regulate tobacco products under Chapter IX of the FD&C Act. Tobacco products (including those products in test markets)

[3] *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18-cv-883 (PWG), 2019 WL 3067492 (D. Md. July 12, 2019); *see also American Academy of Pediatrics, et al. v. Food and Drug Administration, et al*., Case No. 8:18-cv-883 (PWG), (D. Md. Apr. 22, 2020), Dkt. No. 182.

commercially marketed in the United States as of February 15, 2007, are not "new." Manufacturers may market these tobacco products without receiving authorization from us as long as they have not made any modifications to the tobacco product.[4] However, under the FD&C Act, manufacturers must generally receive premarket authorization for new tobacco products before introducing the new tobacco product into interstate commerce in the United States.

Manufacturers of new tobacco products generally must obtain premarket authorization of their products through one of three pathways prior to marketing: a premarket tobacco product application (PMTA)[5], a Substantial Equivalence Report[6], or an Exemption Request.[7]

Manufacturers may submit a PMTA for any new tobacco product, including new tobacco products that may not qualify for the SE pathway or the Exemption Request pathway. To receive marketing authorization through the PMTA pathway, a manufacturer must show that the marketing of the new tobacco product would be appropriate for the protection of public health, among other things.

Manufacturers may submit an Exemption Request for certain modifications of tobacco products. To receive marketing authorization through the Exemption Request pathway, a manufacturer must show that the modification was minor, an SE Report is not necessary to show that permitting the tobacco product to be marketed would be appropriate for the protection of public health, and an exemption is appropriate. A manufacturer must then submit an abbreviated report and wait 90 days before introducing the new product to market.

The SE pathway is an alternative to the PMTA pathway. A manufacturer can use the SE pathway to obtain a marketing order for a new product that either has the same characteristics as a predicate tobacco product, or has different characteristics than a predicate product and the applicant has provided information demonstrating that a PMTA is not necessary because any differences in characteristics do not cause the new product to raise different questions of public health.

Manufacturers who submit SE Reports for new tobacco products must receive a marketing order from us before they can legally market their new tobacco products. An SE Report must include:

- information on the new tobacco product,
- information on an eligible predicate tobacco product, and
- information to support that the characteristics are the same between the new and predicate tobacco products, or if there are different characteristics between the

[4] Manufacturers sometimes co-package tobacco products. Co-packaging refers to packaging two or more products together. If each product in a co-package is a legally marketed product and there are no changes to the products, including no changes to their respective container closure systems, the co-packaging does not result in a new product.
[5] Under section 910 of the FD&C Act.
[6] Under section 905(j) of the FD&C Act.
[7] Under section 905(j)(3) of the FD&C Act.

new and predicate tobacco products, information that demonstrates the new tobacco product does not raise different questions of public health.

2. SE pathway

The Tobacco Control Act amended the FD&C Act and immediately subjected cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own tobacco to FDA's tobacco authorities while the deeming rule extended those authorities to newly deemed products. There are three premarket review pathways, one of which is the SE pathway. The SE pathway, and other premarket authorization pathways, are required in the absence of this rule. FDA began receiving SE Reports in 2010. Manufacturers incur costs to prepare and submit SE Reports and FDA incurs costs to review these reports. OMB Circular A-4, which provides guidance on implementing the analytic requirements of EO 12866, suggests the use of multiple baselines in some situations. For transparency we have estimated the impacts of the SE provisions as applied to originally-regulated tobacco products, as currently interpreted by the Agency. These estimates together with the estimates in the main analysis represent an alternative baseline with the costs and benefits relative to a baseline prior to the Tobacco Control Act. See the Appendix for detailed calculations and discussion.

3. SE pathway guidances and court decisions

We have issued guidance documents on the substantial equivalence pathway, which include recommendations on what information should be included in an SE Report and the kind of changes that make a new tobacco product. First, we issued a final guidance to industry on demonstrating substantial equivalence in January 2011.[8] We also issued an SE FAQ guidance in September 2015, which explained, in part, that "the 'same characteristics' prong of the SE criteria describes products whose physical attribute are identical to those of the predicate. . . . Products that carry new names or label modifications that render the product distinct, but otherwise have the same physical attributes as a predicate product fall into this category." However, a decision in the United States District Court for the District of Columbia disagreed with the 2015 SE FAQ guidance's interpretation of "same characteristics", finding that changes to an existing tobacco product's label do not result in a "new tobacco product." (Philip Morris USA Inc. v. United States Food and Drug Administration, 202 F. Supp. 3d 31 (D.D.C. 2016)). We issued a revised SE FAQ guidance in December 2016 to reflect the decision.[9] As such, products with a changed label are not required to receive premarket authorization. Thus, the baseline reflects FDA's current interpretation that manufacturers need not submit SE Reports for label changes.

The Deeming Rule extended our authority under Chapter IX of the FD&C Act to cover additional tobacco products (e.g., cigars, pipe and waterpipe tobacco, ENDS, etc.) The Deeming Rule was effective on August 8, 2016, with an initial compliance date of February 8, 2018, for submission of SE Reports for new deemed tobacco products on the market as of the effective date. We issued guidance in May 2017 extending the compliance date to May 8, 2018. We revised this guidance in August 2017 to extend the compliance date for products on the market as

[8] https://www.fda.gov/media/79702/download
[9] https://www.fda.gov/media/90811/download

of August 8, 2016, to August 8, 2021, for combustible tobacco products and August 8, 2022, for noncombustible tobacco products.[10] On July 12, 2019, the United States District Court for the District of Maryland ordered the FDA to require manufacturers of e-cigarettes, cigars and other deemed new tobacco products that were on the market as of August 8, 2016, to submit applications for premarket review by May 12, 2020.[11] This submission date was later updated to September 9, 2020, when the court granted FDA's request for a 120-day extension of the deadline due to the coronavirus pandemic.[12] Furthermore, as discussed above, a recent court decision in *Cigar Ass'n of America* enjoined FDA from enforcing the premarket review requirements against "premium" cigars until the Agency has completed its review of commenters' suggestions to the proposed deeming rule that the FDA create a streamlined substantial equivalence process for "premium" cigars.

4. Purpose of the final rule

Although the statute created the SE pathway, this final rule codifies the specific format and content of substantial equivalence reports. If the new tobacco product has some characteristics that are identical to a valid predicate, but some characteristics are not identical, the applicant may submit an SE Report and choose to certify that certain characteristics are identical (e.g., product quantity changes). The final rule will clarify when manufacturers can certify that certain characteristics are identical. While not required, we expect many applicants will use certifications given the decreased burden on the applicants.

B. Market or Government Failure Requiring Federal Regulatory Action

Tobacco products have many characteristics that contribute to health outcomes. These characteristics are generally not listed on labels or provided to the consumer. This leads to an information asymmetry where manufacturers know more than consumers about what characteristics are present in each tobacco product and know what differs about new tobacco products compared with other marketed products. For example, consumers may not know if a manufacturer changed certain ingredients in the tobacco product. However, even if this information was provided to consumers for each product, consumers may have difficulty interpreting this information or using it to compare tobacco products to each other. The substantial equivalence pathway allows us to review new tobacco products before they enter the market. Because consumers cannot reliably evaluate the potential health risks of new tobacco products, we receive information from the manufacturer to make a determination as to whether the new product has the same characteristics as the predicate tobacco product or has different characteristics that would raise different questions of public health than the predicate tobacco product. Thus, requiring premarket authorization through the SE pathway reduces the

[10] The guidance document has been withdrawn because the compliance deadlines contained therein have passed, have been vacated or stayed, or are otherwise described in other guidance. Please see the notice of withdrawal (85 Federal Register 23968, April 30, 2020) available at https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/withdrawnreplaced-guidances.

[11] *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18-cv-883 (PWG), 2019 WL 3067492 (D. Md. July 12, 2019).

[12] *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al*., Case No. 8:18-cv-883 (PWG), (D. Md. Apr. 22, 2020), Dkt. No. 182.

information asymmetry faced by consumers about the potential health risks of newly marketed tobacco products.

This final rule provides additional clarity about the requirements for the content and format of SE Reports and establishes the general procedures FDA intends to follow in reviewing and communicating with applicants. By explaining what information applicants must include in their SE Reports and the general procedures we intend to follow in reviewing and communicating with applicants, we believe that the rule will make our review process more efficient.

C. Baseline Conditions

Manufacturers generally must receive premarket authorization through one of three premarket pathways prior to introducing a new tobacco product into interstate commerce for commercial distribution in the United States. The Deeming Final Rule (May 2016) extended FDA's regulatory authority to all tobacco products (except accessories of deemed products), and thus all premarket requirements apply to deemed tobacco products. New tobacco products that have an eligible predicate tobacco product, are otherwise in compliance with the requirements of the FD&C Act, and have either the same characteristics as the predicate product or have different characteristics but the information submitted demonstrates that the new tobacco product does not raise different questions of public health, may obtain marketing authorization through the substantial equivalence pathway.

A report demonstrating substantial equivalence must provide sufficient information to enable us to determine whether the new tobacco product is substantially equivalent to an appropriate predicate product.[13] For FDA to make a determination where the new tobacco product has different characteristics than the predicate tobacco product, the report must provide a comparison of the new tobacco product with its predicate tobacco product (or certify that the values are identical between the new tobacco product and the predicate) for every identified design feature, ingredient, material, heating source, composition, and other features, including harmful or potentially harmful constituents (HPHC).[14] 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.

As discussed previously, products with only a changed label are not new tobacco products, and thus are not required to receive premarket authorization. Thus, the baseline reflects the fact that manufacturers need not submit SE Reports for label changes. We do not expect a change in the number of SE Reports that will be received under the final rule.

Therefore, this analysis uses the state of the world where manufacturers routinely submit SE Reports as the baseline.

1. Number of Substantial Equivalence Reports

[13] Substantially equivalent is defined in section 910(a)(3)(A) of the FD&C Act.
[14] *See also* section 910(a)(3)(B) of the FD&C Act.

a) Originally Regulated Tobacco Product SE Reports

As of December 2019, we have received thousands of substantial equivalence reports for cigarettes, cigarette tobacco, roll-your-own and smokeless tobacco products (*i.e.*, originally regulated tobacco products).[15] To estimate the number of SE Reports for originally-regulated products that we expect to receive in the future, we use the number of reports we received in fiscal years 2016 to 2019 to create a range. We use reports submitted in 2016 and after because the reports submitted in these years reflect the types of SE Reports we expect to receive in the future. For counts of SE Reports by tobacco product category, we use Tobacco Product User Fees reports from fiscal years 2018 (Ref. [3]) and 2019 (Ref. [4]), as well as updated estimates through December 31, 2019. For cigarettes, roll-your-own, and smokeless tobacco products, manufacturers submitted 271 reports in fiscal year 2016, 112 in fiscal year 2017, 101 in fiscal year 2018, and 284 from October 2018 to December 2019. We use a range from 100 to 300 based on the past stream of SE Reports for cigarettes, cigarette tobacco, roll-your-own, and smokeless tobacco products.

b) Deemed Tobacco Product SE Reports

As of December 2019, we have received a total of approximately 380 SE Reports for cigar, pipe, waterpipe, and ENDS products. However, recent counts of SE Reports for deemed tobacco products do not offer sufficient historical data to estimate the number of deemed SE Reports FDA will receive in future years. Therefore, we use information about products FDA has determined through voluntary, standalone determination requests are Pre-Existing tobacco products, and assumptions from our subject matter experts, to estimate the number of deemed tobacco product SE Reports we expect to receive. While we used information on tobacco products on the market listed in our tobacco product listing database for the PRIA, we have decided to use information about deemed products that are Pre-Existing tobacco products, to estimate SE Reports for this final RIA.

We updated our estimate of expected annual SE Reports in this final analysis based on comments on the PRIA, recent counts of initial SE Reports for deemed products and products FDA has determined through voluntary, standalone determination requests are Pre-Existing tobacco products, as well as additional experience with deemed tobacco products.

To estimate the number of SE Reports we expect to receive initially and in subsequent years, the Center for Tobacco Products' (CTP) subject matter experts used their best professional judgment in considering internal data sources, assumptions and comments from the Deeming Rule, experience with other products, and estimates of the number of products that were likely commercially marketed in the United States as of February 15, 2007.

Applicants may reference a Pre-Existing tobacco product that was not exclusively in a test market as a predicate product in an SE Report. Firms may choose to request a voluntary,

[15] FDA-TRACK: Total number of product submissions received or filed in the month, https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-regular-SE-since-Program-Inception&fy=All

standalone determination from us that a tobacco product is a Pre-Existing tobacco product. If such a product was not exclusively commercially marketed in a test market, firms may reference such as a product as a predicate in an SE report. Alternatively, firms may choose to file an SE Report referencing a predicate product that the applicant identifies as commercially marketed (other than for test marketing) in the United States as of February 15, 2007, without first requesting a voluntary, standalone determination from us. Voluntarily requesting a standalone determination from us provides a means of demonstrating that a product was commercially marketed in the United States as of February 15, 2007. Not every voluntary, standalone determination will be used by a firm to support an SE Report and certain standalone determinations may be referenced in multiple SE Reports. Along with other information, the number of standalone requests for a determination that a product is a Pre-Existing tobacco product for deemed products may serve as a predictor of the number of SE Reports applicants will submit.

To estimate the number of initial SE Reports, we first analyze the relationship between SE Reports for originally regulated products (cigarettes, cigarette tobacco, roll-your-own and smokeless tobacco products) and the number of products FDA has determined through voluntary, standalone determination requests are Pre-Existing tobacco products (1,561 originally regulated products have been established through this process as of March 11, 2020).[16] We use this relationship, in addition to FDA's past experience with SE Reports for originally regulated products, subject matter expertise on tobacco manufacturing, and the amount of variation in deemed tobacco products, to estimate that the number of SE Reports received for deemed tobacco products during the initial submission period will be an average of two to five times the number of products that FDA has determined through voluntary, standalone determination requests are Pre-Existing tobacco products.

As of April 29, 2020, we have determined via voluntary, standalone determination requests that 4,021 cigar, pipe tobacco products and waterpipe tobacco products are Pre-Existing tobacco products. This includes 3,345 cigar products, 524 pipe tobacco products, and 152 waterpipe tobacco products.

As a lower bound estimate, we use these 4,021 deemed tobacco products and the assumption of an average of two times the number of products FDA has determined through voluntary, standalone determination requests are Pre-Existing tobacco products to estimate that manufacturers will submit roughly 8,000 initial SE reports.[17] This estimate includes initial SE Reports for 6,690 cigars, 1,048 pipe tobacco products, and 304 waterpipe tobacco products. Our upper bound estimate of the number of initial SE Reports for cigars, pipe tobacco and waterpipe tobacco products is roughly 20,100.[18] This estimate includes initial SE Reports for 16,725 cigars, 2,620 pipe tobacco products, and 760 waterpipe tobacco products. This creates a range of around 8,000 to 20,100 initial SE Reports for cigars, pipe tobacco, and waterpipe tobacco products. This

[16] Voluntary, standalone determinations for Pre-Existing tobacco products can be accessed at https://www.accessdata.fda.gov/scripts/ctpGnd/.

[17] 2 x 4,021 cigar, pipe tobacco, and waterpipe tobacco products that FDA has determined are Pre-Existing tobacco products = 8,042 initial SE reports, or roughly 8,000.

[18] 5 x 4,021 cigars, pipe tobacco, and waterpipe tobacco products that FDA has determined are Pre-Existing tobacco products = 20,105 initial SE reports, or roughly 20,100.

is likely an overestimate as it includes "premium" cigars, which are excluded from the scope of this final rule.

Assuming the estimate of 8,000 to 20,100 initial SE Reports represents changes[19] that have been made to cigar, pipe tobacco, and waterpipe tobacco products in the thirteen years since February 15, 2007, we assume a linear trend and estimate that 619 (= 8,042/13) to 1,547 (= 20,105/13) SE reports will be submitted for these products in each subsequent year after the initial period. We estimate a range of 515 to 1,287 for cigars, 81 to 202 for pipe tobacco products, and 23 to 58 for waterpipe tobacco products.

We retain the assumption from the Final Deeming Rule that eight to ten ENDS devices are potentially Pre-Existing tobacco products, and, as such, could be available for reference as predicate products in SE Reports. We use this as our starting point for the estimates below.

To estimate the number of initial SE Reports for ENDs devices, we assume 25 to 50 SE Reports will reference each ENDS devices that is potentially a Pre-Existing tobacco product as a predicate, and estimate that as many as 200 to 500 ENDS devices may submit SE reports initially (8 x 25 = 200, 10 x 50 = 500).

We use this estimate of 200 to 500 initial SE Reports for ENDS devices and the assumed ten to twenty percent relationship between initial and annual SE Reports from the Final Deeming Rule to generate an estimate of the number of SE Reports for ENDS devices expected annually in subsequent years. With these assumptions, we estimate that roughly 20 to 100 SE Reports will be submitted for ENDS Devices annually after the initial period.

For the purposes of this analysis, we assume that this final rule will be finalized in or shortly after 2020 and call this Year 1. We expect that the deeming SE Reports submitted on or before the September 9, 2020, deadline will not be subject to this final rule. From 2021 onward, we estimate the number of deemed SE Reports from the annual SE Reports. We expect to receive between 639 and 1,647 annual SE Reports covering all deemed products, noting that this is likely an overestimate as it includes "premium" cigars, which are excluded from the scope of this final rule.

2. Number of Findings Related to Substantial Equivalence Reports

As of December 2019, we have issued around 1,200 SE orders and issued around 400 NSE orders for new tobacco products.[20] We have also issued around 300 refuse to accept letters for SE Reports. As of December 2019, over 2,100 substantial equivalence reports have been withdrawn by manufacturers.

3. Review cycles

[19] As stated in the preamble to the Final Deeming Rule, we do 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) to maintain a consistent product.

[20] Tobacco Product Marketing Orders, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-marketing-orders#2.

In the final rule, a review cycle for an SE Report is 90 calendar days for our review. For some SE Reports we may need more than one review cycle to reach a final action. For example, for two review cycles our time would be 180 days (= 90 x 2). Our final action on SE Reports includes issuing an SE order or issuing an NSE order. Other actions to end the review cycle include issuing deficiency letters, cancellation or administrative closure of the SE Report by us, or withdrawal of the report by the applicant.

Currently most SE Reports take between two and five cycles for us to review. Our CTP estimates that it takes, on average, around 349 calendar days to review SE Reports in the absence of the final rule.[21] We convert calendar days into business days to capture the number of working days spent on a report.[22] Without the rule, we estimate that our average review time for SE Reports equals around 249 business days.

4. Time to prepare and submit substantial equivalence reports

Based on originally regulated products and in the absence of the final rule, our CTP estimates that it will take an applicant 35 hours to prepare a Product Quantity Change SE Report (referred to as the "low-end" estimate) and 220 hours to prepare a full SE Report (referred to as the "high-end" estimate).[23] Our high-end burden estimate of 220 hours for preparing an SE Report includes the time necessary to gather information regarding product characterization, studies, and comparative information with predicate products. Product characterization includes but is not limited to: ingredients, design features, heating source, materials, composition, and other features such as harmful and potentially harmful constituents, as well as general information relating to consistency of a product, such as stability testing, protocols and related data (Ref. [5]).

Manufacturers may bundle groups of substantial equivalence reports for their new products where the proposed modifications are the same; when a group of similar reports are bundled, we expect the initial SE Report to take the same amount of time as a stand-alone SE Report. However, we expect the additional reports in the bundle to take less time to prepare than the initial report. This further reduces costs as shown in Table 2 below.

Table 2. Time Cost per Substantial Equivalence Report

	Low (in hours)	High (in hours)
SE Report	35	220
SE environmental assessment	52	80
Total, Initial SE	**87**	**300**
Bundled SE Report (other than the initial SE Report)	10	10

[21] That is, it has taken us about 349 calendar days, on average, to issue an SE or NSE order for SE Reports. These review cycle timelines represent the time for us to issue an SE or NSE order.
[22] Business days are calculated by multiplying calendar days by 5/7.
[23] This estimate is based on the PRA burden estimates published in the *Federal Register* (84 FR 26121) on June 5, 2019. The hours referenced in the PRA are higher (at 300 and 87 respectively) because they included time to prepare and submit environmental assessments, which are not impacted by this rule.

Bundled SE environmental assessment (other than the initial SE Report)	52	80
Total, Bundled SE (other than the initial SE Report)	**62**	**90**

Note: The final rule will not change the requirements for environmental assessments; we estimate no incremental burdens to prepare and submit environmental assessments.

D. Number of Affected Entities and Reports

1. Affected Entities

This final rule applies to domestic and foreign manufacturers of tobacco products that were originally regulated under, or later deemed subject to, Chapter IX of the FD&C Act. Because we do not currently require foreign establishments to register and list their products with us, we do not have enough information to count foreign manufacturers. We use counts of importers of tobacco products as a proxy for the number of foreign firms that will submit SE reports under this final rule.

Based on aggregate information from the TTB[24], in 2017 there were 32 domestic manufacturers of cigarettes, 15 manufacturers of roll-your-own tobacco, 17 manufacturers of smokeless tobacco products, 80 manufacturers of cigars, and 64 manufacturers of pipe (including waterpipe) tobacco. In addition, there were 27 importers of cigarettes, 20 importers of roll-your-own tobacco, 13 importers of smokeless tobacco products, 120 importers of cigars, and 33 importers of pipe (including waterpipe) tobacco.[25] However, many manufacturers and importers currently make or import more than one type of tobacco product. The baseline number of manufacturers and importers of ENDS products is uncertain.[26] In general, we expect that few ENDS products will be able to go through the substantial equivalence pathway due to the difficulty in finding a valid predicate product. Therefore, since we do not know how many firms only manufacture ENDS products, we do not include estimates of ENDS-only manufacturers subject to this rule.

Summing TTB's counts of entities over-estimates the number of affected establishments because an establishment could be counted more than once. TTB estimates that there are 143 domestic manufacturers and 175 importers in total, including both originally regulated and deemed tobacco products. We use these TTB estimates to exclude dual manufacturing and importing entities from our primary estimate of the number of affected entities.

Table 3 summarizes information about the current number of manufacturers and importers potentially affected by this final rule. However, we do not know if every manufacturer will attempt to market a new tobacco product through the substantial equivalence pathway.

[24] TTB classifications of tobacco product categories do not necessarily match FDA classifications of tobacco product categories due to differences in definitions.

[25] Note that the estimated number of cigar manufacturers and importers is likely an overestimate as it includes manufacturers and importers of "premium" cigars, which are excluded from the scope of this final rule.

[26] ENDS products that do not contain tobacco do not satisfy the definition of "tobacco products" in the Internal Revenue Code (IRC), 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.

Table 3. Number of Manufacturers and Importers Potentially Affected

Domestic Manufacturing Entities	Count
Cigarettes	32
Roll-Your-Own Tobacco	15
Smokeless Tobacco Products	17
Cigars	80
Pipe and Waterpipe Tobacco	64
ENDS	0
Total manufacturing entities	208
Total accounting for dual manufacturing	143
Importers	
Cigarettes	27
Roll-Your-Own Tobacco	20
Smokeless Tobacco Products	13
Cigars	120
Pipe and Waterpipe Tobacco	33
ENDS	0
Total importers	213
Total accounting for dual importing	175

2. Affected Substantial Equivalence Reports

The final rule will cover SE Reports received on or after the effective date of the rule. Based on past SE Report submissions, we estimate that manufacturers will submit 100 to 300 SE Reports each year for new cigarette, roll-your-own tobacco, and smokeless tobacco products. Based on the number of deemed, pre-existing tobacco products and CTP's expert judgment, we estimate that manufacturers will submit between 640 to 1,650 SE Reports for newly deemed tobacco products each year after the first year. However, this final rule will not cover any pending SE Reports received before the effective date of any final rule. In addition, provisional SE Reports are not covered by this final rule.

E. Costs of the Rule

All entities manufacturing or importing tobacco products who expect to receive premarket authorization through the SE pathway may be affected by this final rule. Without this rule manufacturers will routinely submit SE Reports for new tobacco products. This analysis estimates the incremental impacts of this final rule, for these manufacturers and their SE Reports.

1. Administrative One-Time Costs

The one-time compliance activities associated with this final rule include reading and understanding the rule, and establishing or revising procedures for preparing substantial

equivalence Reports. We use the time required to complete these activities to estimate this burden.

All entities affected by this final rule will need to devote time to reading and understanding this rule. To understand this rule, affected entities will read the current preamble, codified regulatory text and instructions for filling out an electronic form required with each report. The preamble, codified regulatory text, and instructions for filling out an electronic form are approximately 75,000 words combined. Assuming average reading speed of 200 to 250 words per minute, we estimate that the average time to read the regulation will be 5.0 hours to 6.3 hours per person. We assume that one to four people read the rule at each entity manufacturing or importing affected products.

To value the time for complying with these provisions, we use composite wages calculated from the Bureau of Labor Statistics' (BLS) national industry-specific occupational employment and wage estimates for the tobacco manufacturing industry (Ref. [6]).[27,28] To value the time associated with reading and understanding the rule, 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 $65.25.[29] We double this to account for benefits and overhead, yielding an hourly labor cost of $130.49.

We estimate the cost for one reviewer to read the rule ranges from $652 to $816. For each affected entity, these costs range from $652 to $3,262. As previously discussed in section II.D.1, we estimate that the final rule will affect 295 entities manufacturing or importing tobacco products. The total costs for reading and understanding the rule range from around $0.2 million to around $1.0 million. Table 4 includes a summary of these costs.

Table 4. One-time costs for reading and understanding the rule

	Low	High
Reading time (Hours)	5.0	6.3
Wage ($ per hour)	$130.49	$130.49
Affected entities	295	295
Number of people reading per entity	1	4
Total Cost ($ million)	**$0.2**	**$1.0**

Affected entities may respond to the final rule by establishing or revising procedures related to substantial equivalence reports, even though this is not required by the rule. This is a one-time cost. We estimate that this activity will take between four and eight hours. In the PRIA we applied the four hour estimate to small entities and the eight hour estimate to large entities. For this analysis, we use four to eight hours as a range and apply this estimate to all entities.

[27] May 2018 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200 – Tobacco Manufacturing. <http://www.bls.gov/oes/>

[28] The BLS did not publish wage estimates for legal occupations within the tobacco manufacturing industry in 2018. We use instead, the legal occupation wage reported for beverage and tobacco manufacturing (NAICS 312000).

[29] The calculation is 0.5*($65.23) + 0.5*($65.26) = $65.25.

To value the time to establish or revise procedures for SE submission, we use a mix of 20 percent upper management occupations (occupation code 11-1000), 70 percent middle management occupations (occupation code 11-1021), and 10 percent administrative occupations (occupation code 43-0000). This mix yields a composite wage of $67.19.[30] We double this to account for benefits and overhead, yielding an hourly labor cost of $134.38.

The total costs for establishing or revising procedures attributable to the rule are estimated to range between $0.16 million and $0.32 million. Table 5 shows the estimated costs for these affected entities to establish or revise submission procedures.

Table 52. One-time costs for establishing or revising procedures

	Low	High
Total hours	4	8
Wage ($ per hour)	$134.38	$134.38
Number of entities	295	295
Total cost ($ million)	**$0.16**	**$0.32**

Note: This is not a requirement of the final rule and not all manufacturers may submit SE Reports

2. Recordkeeping costs

The final rule will require applicants to maintain records related to their SE Reports. We do not know how long applicants currently keep SE Report records, or how much time they devote to these records at baseline. However, manufacturers or importers may want to use information from previously submitted Reports, such as predicate information, and may already be keeping their own records. We do not attempt to estimate the current amount of recordkeeping. This will result in an overestimate of costs for this requirement if many already keep their own records. We assume that applicants will keep electronic records.

The final rule states that if the applicant is comparing the new tobacco product to a predicate product that we previously found substantially equivalent, we may request that the applicant include information related to the original predicate tobacco product. We believe that this will result in increased recordkeeping for records related to tobacco products beyond the four years required by the rule. Therefore, we have increased our estimate of the amount of time each applicant will spend maintaining records. We estimate that each applicant will spend between 0 hours to 10 hours each year maintaining these records and deleting records that no longer need to be kept.

Preparing SE Reports takes a mix of expertise. Scientists and engineers provide information and data to support the scientific basis for the applicant's determination that the new tobacco product that is the subject of the SE Report is substantially equivalent to the identified predicate tobacco product, lawyers provide input on legal issues, and administrative staff may compile and submit the report. In valuing this time, we use a mix of 30 percent life, physical, and social science occupations (occupation code 19-0000); 20 percent architecture and engineering

[30] The calculation is 0.2*($75.32) + 0.7*($71.55) + 0.1*($20.39) = $67.19.

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 $37.96.[31] We double this to account for benefits and overhead, yielding an hourly labor cost of $75.92.

We estimate that each applicant will incur between $0 and $759 for annual recordkeeping costs. Total annual recordkeeping costs range from $0.11 million to $0.22 million. Table 6 summarizes estimated annual recordkeeping costs for SE Reports.

Table 63. Annual Recordkeeping Costs

	Low	Medium	High
Recordkeeping time (Hours)	0	5.0	10
Labor cost ($ per hour)	$75.92	$75.92	$75.92
Affected entities	295	295	295
Annual cost for affected entities ($ million)	$0.00	$0.11	$0.22

3. Electronic form

This final rule will require manufacturers to use the FDA forms when submitting each SE Report. These forms will provide general information to us about each report, which will help us categorize reports and manage workload. The forms will be electronic and will be filled out when the applicant submits their SE Report. Additionally, these forms will help each applicant in the organization of their report as it will provide a general checklist to help ensure the report meets the requirements for content as provided in the final rule.

Applicants will fill out this form each time they submit a new SE Report, although applicants may bundle SE Reports for certain new tobacco products. Our CTP estimates that it will take about 45 minutes per product to fill out the form for the first product in a bundle. However, subsequent reports may only take 10 minutes because applicants will be able to cut and paste from previous forms. We convert these estimates into hours and estimate that it will take 0.75 hours (= 45/60) for each product in the first year and 0.17 hours (= 10/60) for each product in subsequent years.

Our estimates of time to complete the form reflect the time for the first SE report. For bundled SE Reports, we expect that the form will take less time to complete for the additional bundled SE Reports than the first SE report. Depending on the number of bundled SE Reports, we will over-estimate the costs for the electronic form because we do not include shorter time estimates for bundled SE Reports.

Preparing SE Reports takes a mix of expertise. Scientists and engineers provide information and data to support the scientific basis for the applicant's determination that the new tobacco product that is the subject of the SE Report is substantially equivalent to the identified predicate tobacco product, lawyers provide input on legal issues, and administrative staff may compile and submit the report. In valuing the time to comply with this provision, we use a mix of

[31] The calculation is 0.3*($32.75) + 0.2*($44.84) + 0.3*($20.39) + 0.2*($65.26) = $37.96.

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 $37.96.[32] We double this to account for benefits and overhead, yielding an hourly labor cost of $75.92.

Table 7 summarizes the annual incremental costs for filling out the required electronic form for each SE Report.

Table 74. Annual costs for the electronic form

	Low	Medium	High
SE Reports for originally regulated tobacco products - Year 1	100	200	300
SE Reports for originally regulated tobacco products - Subsequent years	100	200	300
SE Reports for deemed tobacco products - Year 1	0	0	0
SE Reports for deemed tobacco products - Subsequent years	639	1,143	1,647
Electronic form - first year (hours)	0.75	0.75	0.75
Electronic form - Subsequent years (hours)	0.17	0.17	0.17
Labor cost ($ per hour)	$75.92	$75.92	$75.92
Cost for reports for originally regulated tobacco products - Year 1 ($ million)	$0.006	$0.011	$0.017
Cost for reports for originally regulated tobacco products - Subsequent years ($ million)	$0.001	$0.003	$0.004
Cost for deemed tobacco products - Year 1 ($ million)	$0.000	$0.000	$0.000
Cost for deemed tobacco products - Subsequent years ($ million)	$0.008	$0.014	$0.021

Note: Numbers may not sum or multiply due to rounding. These costs are likely an overestimate as they include estimates for SE Reports for "premium" cigars, which are excluded from the scope of this final rule.

4. Other costs

The additional clarification provided by the rule will lead to the submission of more complete SE Reports, reducing the average number of review cycles for SE Reports overall. Over time, fewer review cycles and gained understanding of the type of staff expertise required to review SE Reports allows us to review SE Reports more efficiently, saving time and labor. However, some portion of SE Report costs may be incurred several months sooner with the final rule than in the absence of rulemaking.

F. Benefits of the Rule

[32] The calculation is 0.3*($32.75) + 0.2*($44.84) + 0.3*($20.39) + 0.2*($65.26) = $37.96.

1. Quantified benefits

a) Time Savings for Industry

Over time, FDA and industry have gained experience with SE Reports. This experience has helped us write this final rule which clarifies to industry when to submit SE Reports, and what information to include in those SE Reports. The rule will clarify when manufacturers of tobacco products can certify that certain product characteristics between the new and predicate product are identical. While the final rule will not require an applicant to use certifications, we expect that many applicants will use certifications given the decreased burden on applicants.

It takes applicants less time to prepare an SE Report with certifications than to prepare an SE Report without certifications. Assuming that a Product Quantity Change SE Report represents the maximum potential savings from the inclusion of certifications, we estimate that an applicant may save as much as 185 hours by using certifications (=220 hours for a full SE Report – 35 hours for a Product Quantity Change SE Report). The actual time saved may be less than 185 hours and will depend on the number and type of characteristics that are not identical between the new and predicate products and thus not covered by the certification statement in the SE Report. At an hourly wage rate of $75.92, the maximum amount saved for including certifications equals about $14,000 (= 185 hours x $75.92 per hour) per SE Report. Applicants may also save time in preparing the environmental assessment (EA) that accompanies the SE Report and may save money by not providing certain testing data.

We do not have enough information to estimate the number of SE Reports that may include certifications as a result of this final rule.

b) Cost Savings for FDA

The quantified benefits of this final rule are cost-savings to government. Our CTP estimates that this final rule will lead to cost-savings for us to review SE Reports. These cost-savings will be realized due to both fewer review cycles, as well as fewer staff per SE review.

We expect that applicants will submit more complete SE Reports, meaning that we will require fewer review cycles to obtain all the information needed for a determination on the SE Report. Therefore, as described in the preamble of this final rule, if fewer review cycles are needed, FDA anticipates decisions in a shorter time period, and we expect that this rule will result in a decrease in the average number of review cycles needed to issue an order. In addition, we believe that more complete and clearer SE Reports will allow us to more easily identify the type of staff expertise required to review the SE Reports when we receive the SE Report. Therefore, we estimate that this rule will also reduce the average number of staff we assign to review each SE Report. Overall, this will make our review of SE Reports more efficient and save time and labor costs.

Our CTP provided estimates on the number of staff that will be involved with SE reviews without and with the rule. In addition, this final rule explains that we intend to shorten review times as measured by the number of review cycles. CTP estimates that with the rule we intend to

review SE Reports in one to three review cycles. In the final rule, we explain that we intend for FDA's review to be 90 calendar days per cycle (i.e., each review cycle will be 90 calendar days). We convert calendar days into business days to capture the average number of working days spent on a report.[33] Table 8 summarizes the number of staff and review times for SE Reports both with and without the rule.

Table 8. FDA review cycles and staff without and with the rule

	Without Rule	With Rule	Net change
Staff reviewing each SE Report	5.6	5.0	(0.6)
Review time (business days)	249	99	(150)

Note: Values in parentheses are negative numbers (i.e., reductions in time or staff spent after the rule).

CTP estimates that each reviewer may be reviewing 15 to 50 SE Reports at one time, with most reviewing around 30 reports. We convert this into an estimate of staff time per SE Report. That is, at the low end one SE Report will take 0.02 (=1/50) of a full-time equivalent employee (FTE), and at the high end one SE Report will take 0.07 (=1/15) of an FTE. We estimate labor hours by multiplying the number of staff per SE Report by the portion of an FTE per SE Report and then multiplying by the number of business days and 8 hours (for example, 5.6 staff x 0.02 staff time per SE Reports x 249 business days x 8 hours per day = 224 hours). Table 9 summarizes our review times in labor hours.

Table 9. FDA review times in labor hours without and with the rule.

	Without Rule: Hours Low	Without Rule: Hours Medium	Without Rule: Hours High	With Rule: Hours Low	With Rule: Hours Medium	With Rule: Hours High	Net Change: Hours Low	Net Change: Hours Medium	Net Change: Hours High
Staff time per SE Report	0.02	0.03	0.07	0.02	0.03	0.07	0	0	0
Labor hours per SE Report	224	374	748	80	133	265	(145)	(241)	(483)

Note: Values in parentheses are negative numbers (i.e., reductions in labor hours).

In valuing our time, we use a wage based on FTE employees. We use a fully-loaded cost per FTE of $121.83 per hour. We assume that there are 100 to 300 SE Reports to review each year. Thus, we estimate cost-savings of around $1.8 million to $17.7 million annually. These cost-savings come from fewer staff on average needed to review each SE Report as well as following the intended faster review timelines contained in the final rule. The cost-savings per report range from about $18,000 to about $59,000, with our best estimate at $29,000. Table 10 summarizes these cost-savings.

Table 10. Annual FDA Review Costs

	Low	Medium	High
Annual SE reports	100	200	300
Labor hours saved per SE Report	145	241	483
Review time cost-savings ($ millions)	$1.8	$5.9	$17.7

[33] Business days are calculated by multiplying calendar days by 5/7.

We will only realize these cost-savings if we meet our intended goal for shorter review times. If we do not meet these intended shorter review times, then we have over-estimated the cost-savings to government due to this final rule.

We note, however, that these cost-savings will not affect the total amount of user fees or the size of the federal budget because our regulation of tobacco products is fully funded by industry user fees, which are fixed by statute.

Given the uncertainty about report submissions, we have not been able to quantify incremental cost-savings for us related to SE Reports for deemed products here.[34]

2. Non-quantified benefits

This final rule will provide additional clarity to industry about the requirements for the content and format of SE Reports. The final rule will also establish the general procedures we intend to follow in reviewing and communicating with applicants. In addition, this final rule will make the SE pathway more predictable.

Currently, if a manufacturer wants to market a new tobacco product in the United States, they have three options: (1) submit a PMTA, (2) submit a SE Report, and/or (3) submit a request for an exemption from a SE Report. The type of report available to a manufacturer to introduce a new product into interstate commerce may depend on the modification made to the product and whether a valid predicate tobacco product exists.

This final rule does not change what is required to be included in a PMTA or an SE exemption request.

We do not estimate any health benefits or related impacts on consumer experience due to this final rule. The FD&C Act, and not this final rule, establishes the standard that a tobacco product is substantially equivalent to its predicate. A tobacco product is substantially equivalent to its predicate tobacco product if it has the same characteristics, or has different characteristics but the differences do not cause the new tobacco product to raise different questions of public health.

G. Summary of Benefits and Costs

This final rule will impose incremental burdens on industry such as administrative and recordkeeping costs, and incremental costs to fill out a form with each SE Report. The present discounted value of costs to industry ranges from $0.4 million to $3.4 million, with a primary estimate of $1.9 million at a 3 percent discount rate and from $0.4 million to $2.9 million, with a primary estimate of $1.6 million at a 7 percent discount rate over 10 years. The annualized costs

[34] In the Final RIA for the Deeming Rule, we estimated that the percentage of each deemed product that will use the SE pathway in the initial compliance period ranges from 0 percent to around 75 percent depending on the tobacco product category. This wide range in the estimated use of the SE pathway is driven by the number of predicates that may be available for each product type.

to industry over 10 years range from $0.05 million to $0.39 million, with a primary estimate of $0.22 million at a 3 percent discount rate and from $0.06 million to $0.42 million, with a primary estimate of $0.23 million at a 7 percent discount rate.

The benefits of this final rule are potential time savings to industry in preparing some SE Reports and cost-savings to us from fewer numbers of review cycles and fewer staff per SE Report. The present discounted value of this cost-savings ranges from $15.1 million to $150.6 million, with a primary estimate of $50.2 million at a 3 percent discount rate and from $12.4 million to $124.0 million, with a primary estimate of $41.3 million at a 7 percent discount rate over 10 years. The annualized cost-savings ranges from $1.8 million to $17.7 million at both 3 and 7 percent discount rates. The primary estimate of annualized cost-savings is $5.9 million at both 3 and 7 percent discount rates.

Overall, this final rule will lead to a present discounted value of net social benefits ranging from $14.6 million to $147.2 million, with a primary estimate of $48.3 million at a 3 percent discount rate and from $12.0 million to $121.0 million, with a primary estimate of $39.7 million at a 7 percent discount rate. Table 11 summarizes the present discounted value of the incremental costs and benefits of this final rule.

Table 51. Present discounted value of benefits and costs over 10 years

	Low (3%)	**Medium (3%)**	**High (3%)**	**Low (7%)**	**Medium (7%)**	**High (7%)**
Reading the rule	$0.2	$0.5	$0.9	$0.2	$0.5	$0.9
Establish or revise procedures	$0.2	$0.2	$0.3	$0.1	$0.2	$0.3
Recordkeeping	$0.00	$1.0	$1.9	$0.0	$0.8	$1.6
Electronic form	$0.1	$0.1	$0.2	$0.1	$0.1	$0.2
Total costs	$0.4	$1.9	$3.4	$0.4	$1.6	$2.9
Total benefits	$15.1	$50.2	$150.6	$12.4	$41.3	$124.0
Net Benefits	$14.6	$48.3	$147.2	$12.0	$39.7	$121.0

Overall, this final rule will lead to an annualized net social benefits in the form of cost savings over 10 years ranging from $1.7 million to $17.2 million at both 3 and 7 percent discount rates. The primary estimate of annualized net social benefits is $5.7 million at a 3 percent discount rate and $5.7 million at a 7 percent discount rate. Table 12 summarizes the annualized incremental costs and benefits of this final rule.

Table 62. Annualized value of incremental benefits and costs over 10 years

	Low (3%)	**Medium (3%)**	**High (3%)**	**Low (7%)**	**Medium (7%)**	**High (7%)**
Reading the rule	$0.02	$0.06	$0.11	$0.03	$0.07	$0.13
Establish or revise procedures	$0.02	$0.03	$0.04	$0.02	$0.03	$0.04

Recordkeeping	$0.00	$0.11	$0.22	$0.00	$0.11	$0.22
Electronic form	$0.01	$0.02	$0.02	$0.01	$0.02	$0.02
Total costs	$0.05	$0.22	$0.39	$0.06	$0.23	$0.42
Total benefits	$1.8	$5.9	$17.7	$1.8	$5.9	$17.7
Net Benefits	$1.7	$5.7	$17.3	$1.7	$5.7	$17.2

The non-quantified benefits associated with this final rule include clarification of what we expect to be contained in SE Reports submitted by industry for new tobacco products. We do not estimate any health benefits related to this final rule because the requirements for authorizing the marketing of a new tobacco product through the SE pathway are statutory requirements. Our review of SE Reports requires a determination that the new tobacco product has the same characteristics as the predicate tobacco product or that there are different characteristics but the differences do not cause the new tobacco product to raise different questions of public health.

H. Analysis of Regulatory Alternatives to the Rule

We analyze several alternatives to the final rule, including extending the effective date of the rule, providing for more deficiency letters and review cycles, and issuing NSE orders rather than deficiency letters. We summarize these alternatives based on the change in annualized costs for industry, benefits (measured as cost-savings for government), net benefits, and comparison to the final rule. We use primary estimates for the annualized costs over 10 years. Table 13 summarizes the final rule and alternatives in order from least costly to most costly.

Table 73. Annualized costs and benefits for the final rule and alternatives

Description	Annualized costs (3%)	Annualized benefits (3%)	Annualized net benefits (3%)	Change in annualized net benefits from final rule (3%)	Annualized costs (7%)	Annualized benefits (7%)	Annualized net benefits (7%)	Change in annualized net benefits from final rule (7%)
One review cycle for all SE Reports	$0.2	$7.0	$6.8	$1.1	$0.2	$7.0	$6.8	$1.1
Final Rule	$0.2	$5.9	$5.7	NA	$0.2	$5.9	$5.7	NA
Extend the effective date of the rule	$0.2	$5.2	$5.0	($0.7)	$0.2	$5.1	$4.9	($0.8)
Allow more review cycles	$0.2	$0.7	$0.5	($5.2)	$0.2	$0.7	$0.5	($5.2)

Note: Values in parentheses are negative values (i.e., less net benefits than the final rule). All annualized costs are for the primary estimates over 10 years.

1. One review cycle for all SE Reports with no deficiency notifications

Under this alternative, our CTP will review all SE Reports in one review cycle and issue a not substantially equivalent (NSE) order for deficient reports. Initially, this will result in more NSE orders for industry, but reduced use of our resources per report. This differs from the final rule, in which we intend to issue a deficiency letter for incomplete SE Reports and allow the applicant to submit additional information as amendments, instead of issuing an NSE order for a deficient report and having the applicant submit a new SE Report for the tobacco product. Over time, we expect that industry will submit more complete reports. We do not have estimates for costs to industry of this alternative, as we do not know how many SE Reports may receive an NSE order under this alternative and submit a new SE Report to seek marketing authorization for the tobacco product. If industry costs increase with this alternative, then we will under-estimate the costs associated with this alternative; if industry costs decrease, then we will over-estimate the costs associated with this alternative.

To provide quantitative estimates for this alternative, we estimate the change in our review costs. We assume that the same number of staff will be reviewing SE Reports as under the final rule. However, we now only account for one review cycle for all SE Reports instead of up to three review cycles estimated for the final rule. Table 14 summarizes the staff and review times under the final rule, and under this alternative.

Table 84. FDA staff and review time for reviewing all SE Reports in one review cycle

	With Rule	Alternative - 1 review cycle	Net change from final rule
Staff reviewing each SE Report	5.0	5.0	0.0
Review time (business days)	99.0	64.3	(34.7)

Note: Values in parentheses are negative numbers.

This alternative could lead to an increase or decrease in the number of SE Reports submitted. There could be more SE Reports if in response to an NSE order, the applicant corrects deficiencies and submits a new SE Report. However, there could also be fewer SE Reports if applicants wait longer to submit an SE Report to gather more information, or chose not to submit an SE Report if they think they would receive an NSE order. Because we are uncertain about the number of SE Reports submitted under this alternative, we assume no change in the number of SE Reports we receive and review each year.

We use the estimates for reduced review time in Table 14 along with estimates for the number of reports and number of reports per reviewer to estimate the cost-savings under this alternative. The estimated annualized cost-savings to government of this alternative compared to the final rule are between $0.3 million and $3.4 million, with a primary estimate of $1.1 million. Given the uncertainty about report submissions, we do not quantify incremental cost-savings for us related to SE Reports for deemed products here; we assume there are 100 to 300 SE Reports for originally regulated tobacco products to review each year. Table 15 summarizes our review costs under this alternative.

Table 95. FDA review costs when reviewing all SE Reports in one review cycle

	Low	Medium	High
Number of SE Reports	100	200	300
Labor hours saved per SE Report	27.9	46.5	93.0
Review time cost-savings ($ millions)	$0.3	$1.1	$3.4

When we compare to our review times without the rule, our annualized review cost-savings increase from around $5.9 million under the final rule to around $7.0 million with this alternative at both 3 and 7 percent discount rates. However, this alternative is also expected to initially result in more NSE orders for industry. Once an NSE order is issued, the applicant would need to resubmit an application seeking marketing authorization for the tobacco product.

2. Extend the effective date of the rule

Extending the effective date of the final rule will shift some industry costs later, but also shift associated benefits, calculated as FDA cost-savings, to a later period. For this alternative, we extend the effective date of the rule by 12 months. We assume that industry will still read and understand the rule and establish or revise procedures (although not specifically required by the rule) before the rule comes into effect, and then only incur annual costs after the effective date of the rule. We assume we will experience no cost-savings prior to the effective date of the rule, and then will experience the same annual cost-savings as estimated for the final rule in each year after the effective date.

The annualized costs to industry under this alternative would be around $0.20 million at a 3 percent discount rate and around $0.21 million at a 7 percent discount rate using the primary estimates over 10 years. The annualized cost-savings to government falls from around $5.9 million to around $5.2 million at a 3 percent discount rate and to around $5.1 million at a 7 percent discount rate. Overall, this alternative would be associated with less benefits (measured as government cost-savings) than the final rule. This alternative reduced net benefits by around $0.66 million at a 3 percent discount rate and $0.77 million at a 7 percent discount rate.

3. Provide more than three review cycles and deficiency notifications for some SE Reports

Another alternative would be for us to provide more than three review cycles for SE Reports, and issue additional deficiency letters rather than NSE orders. This alternative will provide industry with more time to gather the information they need for each SE Report. However, the overall effort to prepare and submit an SE Report will remain unchanged. We do not have enough information to estimate how this alternative might affect other industry costs. If industry costs increase, then we have under-estimated costs for this alternative; if industry costs decrease, then we have over-estimated costs for this alternative.

This alternative would require additional resources from us as it would lengthen review times and increase back-and-forth with industry. We estimate our review costs under this alternative by assuming that we would review all SE Reports in four review cycles. This alternative would increase our review time for SE Reports compared to the final rule. We assume

that the number of staff reviewing each SE Report would not change under this alternative. Table 16 summarizes the staff and review times at baseline, under the final rule, and under this alternative.

Table 106. FDA staff and review time for reviewing SE Reports with more review cycles and deficiency letters

	With Rule	Alternative - more review cycles	Net change from final rule
Staff reviewing each SE Report	5.0	5.0	0.0
Review time (business days)	99.0	257.1	158.1

We assume no change in the number of SE Reports we receive and review each year. We use the estimates for increased review time in Table 16 along with estimates for the number of reports and number of reports per reviewer to estimate the costs under this alternative. Overall, this alternative would be associated with higher government costs than the final rule. The estimated annualized costs to government of this alternative are between $1.5 million and $15.5 million, with a primary estimate of $5.2 million compared to the final rule. Table 17 summarizes our review costs under this alternative.

Table 117. FDA review costs when reviewing SE Reports with more review cycles and deficiency letters

	Low	Medium	High
Number of SE Reports	100	200	300
Labor hours per SE Report	127.1	211.9	423.8
Review time cost-savings ($ millions)	($1.5)	($5.2)	($15.5)

Note: Numbers in parentheses represent less cost-savings compared to the final rule.

When we compare to our review times without the rule, our primary annualized review cost-savings decrease from around $5.9 million under the final rule to around $0.7 million under this alternative at both 3 and 7 percent discount rates.

I. Uncertainty Analysis

One area of uncertainty is the annual number of SE Reports received by us and how these numbers will change over time. If the number of SE Reports we receive is lower than we estimated, then industry costs will be lower. However, our cost-savings will also be lower. If the number of SE Reports we receive is higher than we estimated, then industry costs will be higher but our cost-savings will also be higher.

As discussed previously, we assume that applicants already incur the costs to prepare and submit SE Reports for new products as the baseline for our analysis. We include the one-time administrative costs and the incremental costs for new requirements beyond current industry practice. In addition, industry may receive some benefit from our intention to shorten our review times, such as faster time to market for new products. To estimate this cost savings, we would

need information about the current cost of longer review times. However, we lack information sufficient to estimate the potential net benefits of shorter review times that may occur.

Also, we are uncertain about the number of bundled SE Reports we may receive in the future. In our main analysis, we estimated the time to fill out the electronic form for the first SE Report without allowing a shorter amount of time for subsequent bundled SE Reports. We may have over-estimated industry costs for this requirement; however, the magnitude of this overestimation is uncertain.

We are uncertain about current industry practices related to keeping records for SE Reports. In our main analysis, we assume that manufacturers are not currently keeping records related to their SE Reports. If manufacturers are currently keeping records for their SE Reports, then we have over-estimated industry costs related to this requirement. We have added costs in our main analysis because we believe that applicants may keep records for longer times on predicate tobacco products for potential use in future SE Reports. However, we are uncertain of the recordkeeping burden associated with this requirement. In addition, we are uncertain about how many entities may establish or revise procedures related to SE Reports. If not all entities establish or revise procedures, then we have over-estimated industry costs for this activity.

J. International Effects

The requirements of the final rule are the same whether the manufacturer of the new tobacco product is a domestic firm or a foreign firm. We do not have enough information to estimate the number of SE Reports that only foreign firms will submit.

III. Final Small Entity Analysis

We have examined the economic implications of this final rule for small entities as required by the Regulatory Flexibility Act. If a final rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that will lessen the economic effect of the rule on small entities. We certify that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this is the only rulemaking on content and format of SE Reports. Therefore, there are no duplicative, overlapping, or conflicting rules. Consequently, this analysis, together with other relevant sections of this document and the preamble of the final rule, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

To assess the rule's economic impact on small entities, we compare the rule-related costs to each establishment's revenues.

A. Description and Number of Affected Small Entities

This final rule may potentially apply to any small manufacturer of tobacco products whose products were originally regulated under or deemed subject to Chapter IX of the FD&C Act.

This final rule will primarily affect domestic manufacturers of tobacco products and importers. Although U.S. Census data are not ideal for estimating the total number of such entities that will be affected, they offer the best available insight into the proportion that may be small.[35] Manufacturers of tobacco products that could be affected by this final rule are 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 are classified as "tobacco and tobacco product merchant wholesalers." Table 18 shows the SBA size thresholds for small businesses in each of these categories, as well as the most comparable size categories available from the U.S. Census (Ref. [7] [SBA, 2016]; Ref. [8][Statistics of U.S. Businesses, 2012 – detailed employment sizes]).[36] For tobacco and tobacco product merchant wholesalers the proportion found to be small will be underestimated because the Census size category is lower than the SBA threshold.

Table 128. SBA Size Standards and Census Size Categories for Manufacturers of Tobacco Products and Importers

	NAICS	Description of NAICS Category	SBA Size Standard (employees)	Census Size Category (employees)
Potential Manufacturers of Tobacco Products				
	312230	Tobacco Manufacturing	1,500	1,500
Potential Tobacco Product Importers (Wholesalers)				
	424940	Tobacco and Tobacco Product Merchant Wholesalers	250	200

Note: These counts are likely an overestimate as they include manufacturers and importers of "premium" cigars. "Premium" cigars are excluded from the scope of this final rule.

Table 19 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 96 percent of

[35] 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).

[36] 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 SBA's definition of small is applicable to the small entity analysis required under the Regulatory Flexibility Act.

"tobacco manufacturing" businesses with employees are small (Ref. [8]).[37] These data also show 96 percent of "tobacco and tobacco product merchant wholesalers" qualify as small. For several reasons, these numbers are only an approximation: (1) 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; and (2) because the Census manufacturing category excludes manufacturers without payroll, which would by definition be small, the Census understates the percentage of manufacturing firms that are small.

Table 19. Estimated Percentage of Small Firms among Firms with Employees

NAICS	Description of NAICS Category	Number of Firms	Number of Firms Below Census Size Standard	Percentage of Small Firms (%)
312230	Tobacco Manufacturing	93	89	96%
424940	Tobacco and Tobacco Product Merchant Wholesalers	1,158	1,110	96%

Without other information, we assume that the percentage of tobacco product manufacturing establishments in the TTB data that are small is the same as the percentage of tobacco manufacturing firms that are small; thus 137 (=143 x 0.96) small manufacturing establishments will be affected by this final rule. Neither the Census data nor the TTB data include ENDS-only manufacturers. Given that we expect only a small number of ENDS devices to use the SE pathway, we do not expect this assumption will greatly affect our estimates.

Based on Table 19 we also expect that most of the importers affected by this rule will be small. Using the proportion of tobacco and tobacco product merchant wholesalers that are small, 168 (=0.96 x 175) small importers will be affected by this rule.

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

We use detailed data from the 2012 Statistics of U.S. Businesses on U.S. 6-digit NAICS detailed employment sizes to analyze the potential impacts of the final rule on small entities (Ref. [8]). This detailed data allows us to more closely match the SBA size standards to the Census employment categories.

The upper-bound estimate for the largest single-year of costs experienced by industry is approximately $1,476,262. We divide these compliance costs among manufacturers and importers based on their frequency in the TTB entity data. Around $663,854 of the estimated annualized compliance costs are assigned to domestic manufacturers, and the other $812,408 of

[37] The TTB data only captures firms that pay tobacco excise taxes. The NAICS data may be capturing entities that are not responsible for paying excise taxes, especially in the wholesaler category. As described below, we use the TTB data for our estimates, as it seems likely that entities that are responsible for paying tobacco taxes would also take responsibility for submitting SE Reports, but we do not know for sure that this is the case.

the estimated annualized costs are assigned to importers (= $1,476,262 x 143/(143+175) and = $1,476,262 x 175/(143+175)). Next, we distribute these compliance costs among firm size categories based on the detailed 2012 Statistics of U.S. Businesses (SUSB) data. Finally, we compare these compliance costs to the estimated revenues from the 2012 SUSB data. Table 20 summarizes the potential impacts for small domestic manufacturers and importers. These estimates provide an average cost per manufacturer or importer but we note that costs depend on how many SE Reports they file annually. For example, a small manufacturer that does not seek to introduce many new products will have much lower costs.

Table 130. Compliance costs and estimated revenues for small businesses

NAICS	Employees	Census Number of Firms	% of Firms	TTB Number of Entities	Estimated Revenues ($ million)	Estimated compliance cost in size category	Compliance as a % of Estimated Revenues
312230	0 to 19	47	50.5%	72	$190.4	$335,496	0.18%
	20 to 99	27	29.0%	42	$1,351.1	$192,732	0.014%
	100 to 499	9	9.7%	14	$838.7	$64,244	0.008%
	500 to 1,000	3	3.2%	5	N.A.	$21,415	N.A.
	1,000 to 1,500	3	3.2%	5	$2,294.3	$21,415	0.0009%
	0 to 1,500	89	95.7%	137	$4,674.5	$635,301	0.014%
	Total	93	100.0%	143	$41,049.5	$663,854	
424940	0 to 19	890	76.9%	134	$6,420.4	$624,390	0.010%
	20 to 99	178	15.4%	27	$10,569.3	$124,878	0.0012%
	100 to 199	42	3.6%	6	$6,585.0	$29,466	0.0004%
	200 to 499	23	2.0%	3	$7,565.9	$16,136	0.0002%
	500+	25	2.2%	4	$89,060.0	$17,539	0.00002%
	0 to 200	1,110	95.9%	168	$23,574.8	$778,733	0.003%
	Total	1,158	100.0%	175	$120,200.7	$812,408	

Note: The estimated compliance costs are likely an overestimate as they include estimated costs for "premium" cigars, which are excluded from the scope of this final rule.

As shown in Table 20, the upper-bound estimate for the largest single-year of costs experienced by small entities fall below 0.2 percent of their annual revenues. Therefore, we certify that this final rule will not have a significant economic impact on a substantial number of small entities.

IV. References

The following references have been placed on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the *Federal Register*.)

[1] "Preliminary Regulatory Impact Analysis. Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports," [Online]. Available: https://www.fda.gov/media/122850/download.

[2] "84 FR 12740. Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports: Proposed Rule," 2 April 2019. [Online]. Available: https://www.federalregister.gov/documents/2019/04/02/2019-05787/content-and-format-of-substantial-equivalence-reports-food-and-drug-administration-actions-on.

[3] U.S. Food and Drug Administration, "Report to the House Committee on Appropriations, Tobacco Product User Fees. Report in Response to FY 2018 Consolidated Appropriations Act," 2018. [Online]. Available: https://www.fda.gov/media/114914/download.

[4] U.S. Food and Drug Administration, "Report to the House Committee on Appropriations, Tobacco Product User Fees. Report in Response to FY 2019 Consolidated Appropriations Act," 2019. [Online]. Available: https://www.fda.gov/media/131981/download.

[5] FDA, Center for Tobacco Products, Office of Regulations, *SE Burden Captured Under Deeming Rule [Memorandum],* 2016.

[6] U.S. Bureau of Labor Statistics, "May 2018 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200 - Tobacco Manufacturing," May 2018. [Online]. Available: http://www.bls.gov/oes/. [Accessed October 2019].

[7] U.S. Small Business Administration, "Table of Size Standards," 2019. [Online]. Available: https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf. [Accessed November 2019].

[8] U.S. Census Bureau, "Statistics of U.S. Businesses (SUSB). Historical Data, SUSB Annual Data, U.S., 6-digit NAICS, Detailed Employment Sizes," 2012. [Online]. Available: http://www.census.gov/econ/susb/data/download_susb2012.html. [Accessed March 2016].

V. Appendix

This Appendix analyzes the benefits and costs of the SE pathway for originally regulated products (cigarettes, smokeless tobacco products, and roll-your-own tobacco) assuming a baseline in which the Tobacco Control Act does not require premarket review.

A. Comments on the Appendix to the Preliminary RIA and our responses

(Comment 1) Several commenters stated that FDA's preliminary regulatory impact analysis (PRIA) was flawed because it only accounted for the costs of filling out a form and not testing costs required by the rule such as, comparative design testing, HPHC testing, and potentially stability testing. A commenter stated that the burden hours do not account for the testing costs. Several commenters stated that HPHC testing per SKU may be $18,000 based on FDA's lowest estimates from the Deeming Final Rule, and with legal fees at least $50,000 per product. A commenter references a comment submitted on February 5, 2018 that testing for HPHCs will cost as much as $20,000 per SKU. Several commenters estimated that testing costs, based on similar tests for cigarettes and smokeless tobacco, could average between $80,000 to $100,000 per product.

(Response 1) To the extent these comments are about deemed tobacco products, we have addressed those comments above (section I.D). For commenters that are generally addressing the costs associated with submitting an SE Report, we disagree that the PRIA only accounted for costs related to filling out a form. The estimated time and burden to develop, compile, prepare, and submit a Substantial Equivalence Report for a new tobacco product includes the time necessary to gather information regarding product characterization, studies, and comparative information with predicate products; however, as we explain further below, certain costs (e.g., third-party HPHC testing costs for laboratory and test method validation) may not be fully captured. The RIA estimates, in dollars, the cost of submitting an SE Report using, among other things, estimated burden hours multiplied by a composite wage per hour and consultation with agency experts experienced in the substantial equivalence program. In order to calculate the composite wage per hour, the RIA assumes the preparation of an SE Report will involve life, physical, and social science occupations; architecture and engineering occupations; office and administrative support occupations; and legal occupations. In order to capture average costs, the composite wage provides a general estimate of the time each of these occupations may contribute. We also note that some of the costs highlighted in these comments will not be incurred for every SE Report, or the costs may be shared across multiple SE Reports, e.g., applicants may use the same predicate product for several SE Reports and can rely on HPHC testing information for the predicate product for numerous SE applications. Furthermore, the amount of HPHC data needed to support an SE report – and thus the costs related to gathering the needed HPHC data – will vary depending on the number and type of modifications between the predicate and new tobacco products. As a reminder, the applicant determines which predicate tobacco product to use as a comparison with their new tobacco product. If there are very few differences between the new and predicate tobacco products, there would be minimal, if any, HPHC testing costs. Additional discussion on baseline testing cost can be found in comment 4 of this RIA.

(Comment 2) Several commenters provided estimates for the hours needed for preparing and submitting SE Reports of between 900 hours and 28 months. Based on these hours, the commenters estimate that the cost per SE Report could be between $250,000 and $2,000,000, although they state there may be some economies of scale in submitting multiple reports.

(Response 2) We believe some commenters have confused cost estimates from the RIA and burden hours from the PRA. Although these concepts are similar and account for some corresponding items, they ultimately serve different purposes and separate functions. The PRA estimates burden in hours on an annual basis generally for three years; while the RIA uses these estimated burden hours on an annual basis, along with an estimate of wage per hour, to estimate a cost in terms of dollars over a long-term horizon. See comment 4 of this RIA and comment 1 in the appendix of this RIA for a further discussion regarding costs and see comments 2 and 3 of this RIA for discussion on burden hours.

B. Summary of Changes

We have made several changes to this Appendix to reflect updated estimates as well as information provided in comments on the proposed rule. These changes include:

- Wages from 2018
- Estimates for originally regulated SE Reports based on Tobacco Product User Fees Reports and internal data
- Due to the updated data sources, we now provide estimates by fiscal year rather than calendar year

C. Benefits

Prior to the enactment of the Tobacco Control Act, manufacturers of tobacco products could introduce new products onto the market without any review by FDA. After the enactment of the Tobacco Control Act, new tobacco products generally must receive premarket authorization from FDA prior to introduction into interstate commerce. There are three premarket review pathways, one of which is the SE pathway.

Some manufacturers that submit SE Reports receive an SE order. We expect that these products would have been on the market in the absence of the Tobacco Control Act. However, products that receive an NSE order, unless they have otherwise received premarket authorization, cannot be introduced into interstate commerce or, in certain circumstances, must be removed from the market (e.g., provisional tobacco products). For the approximately 400 new tobacco products for which we have issued NSE orders, we assume that these products would have been on the market without the statute. Some products receive NSE orders because we have determined that the products raise different questions of public health, while other products receive NSE orders because we do not have enough information to determine that the differences between the new and predicate products do not cause the new products to raise different questions of public health. In addition, given the requirements of premarket review,

manufacturers may decide against modifying a product. We assume that without the statute they would have otherwise introduced these new tobacco products into interstate commerce.

The SE pathway enables FDA to monitor product development and prevent more harmful products as compared to their respective predicates from coming to market. We do not have enough information to quantify these benefits or associated impacts on consumer experience.

D. Costs

Number of originally regulated tobacco product SE Reports

As of December 2019, we have received thousands of substantial equivalence reports for cigarettes, cigarette tobacco, roll-your-own and smokeless tobacco products (*i.e.*, originally regulated tobacco products). These include over 3,500 provisional SE Reports and around 2,750 regular SE Reports, as reflected in our tracking system.[38]

In 2015, we started tracking two categories of regular SE Reports: full and streamlined. Streamlined SE Reports referred to Same Characteristics SE Reports (as described in 2015, an SE Report for a product with identical characteristics to, but a modified label that rendered it distinct from, the predicate product) and Product Quantity Change SE Reports. Consistent with a 2016 court decision, premarket review is not required where there is a modification to an existing tobacco product's label.

CTP stopped tracking full and streamlined SE Reports separately in 2018. In addition, in fiscal year 2016, we started receiving SE Reports for deemed tobacco products. For this section, we only want to count the number of SE Reports for originally regulated products. So, we use Tobacco Product User Fees reports from fiscal years 2018 and 2019, as well as updated estimates through December 31, 2019. For cigarettes, roll-your-own, and smokeless tobacco products, manufacturers submitted 271 reports in fiscal year 2016, 112 in fiscal year 2017, 101 in fiscal year 2018, and 284 from October 2018 to December 2019.

Table 21 summarizes the number of SE Reports we received from fiscal year 2011 to December 2019 for originally regulated tobacco products, and Table 22 summarizes the number of streamlined SE Reports we received from April 2015 to September 2015.

Table 141. Number of provisional and full SE Reports submitted for originally regulated tobacco products from fiscal year 2011 to December 2019

Fiscal year	Provisional SE	Regular SE
2011	3,599	200
2012	0	391
2013	0	267
2014	0	92

[38] FDA-TRACK: Total number of product submissions received or filed in the month, https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-product-submissions-received&fy=All

2015	0	101
2016	0	271
2017	0	112
2018	0	101
2019	0	284

Note: The 2015 data only covers January through March. CTP divided Regular SE Reports into two categories and began tracking them separately in April 2015.
Source for reports from 2011 to 2015:
https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-product-submissions-received&fy=All
Source for reports from 2016 to 2019: Tobacco Product User Fees Reports for FY18 and FY19 (Ref. [3], Ref. [4]) and estimates through December 31, 2019. Counts for 2019 cover October 2018 through December 2019.

Table 152. Number of streamlined SE Reports submitted for originally regulated tobacco products from April 2015 to September 2015

Fiscal year	Full SE	Streamlined SE
2015	42	824

Note: The 2015 data only covers April through September. CTP divided Regular SE Reports into two categories (full SE and streamlined SE) and began tracking them separately in April 2015, but stopped tracking them separately in 2018. https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-regular-SE-since-Program-Inception&fy=All

To estimate the number of SE Reports for originally-regulated products that we expect to receive in the future, we use the number of reports we received for originally regulated products in fiscal years 2016 to 2019 to create a range. We use reports submitted in 2016 and after because the reports submitted in these years reflect the types of SE Reports we expect to receive in the future. We use Tobacco Product User Fees reports from fiscal years 2018 and 2019, as well as internal estimates through December 31, 2019. For cigarettes, roll-your-own, and smokeless tobacco products, applicants submitted 271 reports in fiscal year 2016, 112 in fiscal year 2017, 101 in fiscal year 2018, and 284 from October 2018 to December 2019. We use a range from 100 to 300 based on the past stream of SE Reports for cigarettes, cigarette tobacco, roll-your-own and smokeless tobacco products.

Time Costs to Industry to prepare and submit SE Reports

Based on originally regulated products and in the absence of the final rule, our CTP estimates that it will take an applicant 35 hours to prepare a Product Quantity Change SE Report (referred to as the "low-end" estimate) and 220 hours to prepare a full SE Report (referred to as the "high-end" estimate).[39] The high-end burden estimate of 220 hours for preparing an SE Report includes the time necessary to gather information regarding product characterization, studies, and comparative information with predicate products. Product characterization includes but is not limited to: ingredients, design features, heating source, materials, composition, and other features such as harmful and potentially harmful constituents, as well as general information relating to consistency of a product, such as stability testing, protocols and related

[39] Some streamlined SE Reports were Same Characteristics SE Reports. We estimate that industry may have only spent 20 hours per such SE Report. Therefore, our estimates for industry time may be overestimated.

data (Ref. [5]). We also expect manufacturers will submit comparative information, including testing data, for full SE Reports. We do not believe that manufacturers will submit testing data with Product Quantity Change SE Reports.

Manufacturers may bundle groups of substantial equivalence reports for their new products in the same product category and sub-category where the proposed modifications are the same; when a group of similar reports are bundled, the initial SE Report is expected to take the same amount of time as a stand-alone SE Report. However, the subsequent bundled reports are expected to take less time to prepare than the initial report. This further reduces costs as shown in Table 23 below.

Table 163. Time Cost to Industry per Substantial Equivalence Report

	Low (in hours)	High (in hours)
SE Report	35	220
SE environmental assessment	52	80
Total, Initial SE	**87**	**300**
Bundled SE Report (other than the initial SE Report)	10	10
Bundled SE environmental assessment (other than the initial SE Report)	52	80
Total, Bundled SE (other than the initial SE Report)	**62**	**90**

Note: The final rule will not change the requirements for environmental assessments; we estimate no incremental burdens to prepare and submit environmental assessments.

FDA costs: Review cycles and staff

Currently most SE Reports take between two and five cycles for us to review. Our Center for Tobacco Products estimates that it takes, on average, around 349 calendar days to review SE Reports in the absence of the final rule.[40] We convert calendar days into business days to capture the number of working days spent on a report.[41] Without the rule, we estimate that our average review time for SE Reports equals around 249 business days.

Our CTP also provided estimates on the number of staff that will be involved with SE reviews without the rule. We estimate that without the rule, an average of 5.6 staff will review each SE Report. Our CTP estimates that each reviewer may be reviewing 15 to 50 SE Reports at one time, with most reviewing around 30 reports. That is, at the low end one SE Reports will take 0.02 (=1/50) of an FTE, and at the high end one SE Report will take 0.07 (=1/15) of an FTE. We use this estimate, along with the estimated staff and review cycles to calculate the number of labor hours to review each SE Report without the rule. We estimate labor hours by multiplying the number of staff per SE Report by the portion of an FTE per SE Report and then multiplying by the number of business days and 8 hours (for example, 5.6 staff x 0.02 staff time per SE

[40] That is, it has taken us about 349 calendar days, on average, to issue an SE or NSE order for SE Reports. These review cycle timelines represent the time for us to issue an SE or NSE order.
[41] Business days are calculated by multiplying calendar days by 5/7.

Reports x 249 business days x 8 hours per day = 224 hours). Table 24 summarizes our review times in labor hours.

Table 174. FDA review times in labor hours without the rule

	Labor Hours Without Rule – Low	Labor Hours Without Rule – Medium	Labor Hours Without Rule - High
Staff time per SE Report	0.02	0.03	0.07
Labor hours per SE Report	224	374	748

Costs of the SE pathway for Originally Regulated Products

In this section, we estimate the costs of preparing, submitting and reviewing SE Reports for originally regulated products. Originally-regulated tobacco products were immediately subject to our tobacco product authorities (including the requirement of premarket review), while the Deeming Rule in 2016 extended those authorities to newly deemed tobacco products. FDA began receiving SE reports for originally regulated products in fiscal year 2011.

To estimate past, current and future industry costs for SE Reports for originally regulated products, we use the hours burden for preparing SE Reports in Table 23.[42] Specifically, we use a range of hours from 35 to 220 to prepare SE Reports. We also use the number of SE Reports submitted from Table 21 and Table 22. We also use the number of future SE Reports estimated above. For SE Reports that are listed as streamlined, we use our low-end 35 hours to value the time to prepare the report.[43] For full SE Reports, we use our high-end value of 220 hours. We also use the full range of hours to estimate the cost of submitting SE Reports into the future. Our medium estimates are the midpoint of the low and high estimated costs.

Preparing SE Reports takes a mix of expertise. Scientists and engineers provide information and data to support the scientific basis for the applicant's determination that the new tobacco product that is the subject of the SE Report is substantially equivalent to the identified predicate tobacco product, lawyers provide input on legal issues, and administrative staff may compile and submit the report. In valuing the time to prepare SE Reports, 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 $37.96.[44] We double this to account for benefits and overhead, yielding an hourly labor cost of $75.92. Table 25 summarizes costs to industry to prepare SE Reports in each year.

[42] In 2015, FDA issued a final rule, National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions. The final RIA for that rule accounted for the costs of preparing environmental assessments in accordance with 21 CFR part 25 for SE Reports for originally-regulated products. *See* [https://www.fda.gov/media/94818/download] Since this piece of the baseline has already been calculated, we do not include the costs to prepare and submit environmental assessments in this analysis.

[43] Some streamlined SE Reports were Same Characteristics SE Reports. We estimate that industry may have only spent 20 hours per such SE Report. Therefore, our estimates for industry time may be overestimated.

[44] The calculation is 0.2*(44.84) + 0.3*($32.75) + 0.2*($65.26) + 0.3*($20.39) = $37.96.

Table 185. Industry costs for preparing SE Reports

Year	Rule Year	Low	Medium	High
2011	-8	$10,095,235	$36,775,498	$63,455,761
2012	-7	$1,039,020	$3,785,001	$6,530,982
2013	-6	$709,510	$2,584,643	$4,459,776
2014	-5	$244,475	$890,589	$1,536,702
2015	-4	$4,578,217	$4,578,217	$4,578,217
2016	-3	$720,139	$2,623,364	$4,526,589
2017	-2	$297,622	$1,084,195	$1,870,767
2018	-1	$268,391	$977,711	$1,687,031
2019	0	$754,685	$2,749,208	$4,743,732
2020	1	$265,734	$2,638,359	$5,010,984
2021	2	$265,734	$2,638,359	$5,010,984
2022	3	$265,734	$2,638,359	$5,010,984
2023	4	$265,734	$2,638,359	$5,010,984
2024	5	$265,734	$2,638,359	$5,010,984
2025	6	$265,734	$2,638,359	$5,010,984
2026	7	$266,574	$2,638,359	$5,010,984
2027	8	$266,574	$2,638,359	$5,010,984
2028	9	$266,574	$2,638,359	$5,010,984
2029	10	$266,574	$2,638,359	$5,010,984

To estimate FDA costs to review SE Reports, we use the range of hours for review in Table 24. In valuing FDA time, we use a wage based on FTE employees. We use a fully-loaded cost per FTE of $121.83 per hour. We assume that FDA reviews regular SE Reports in the year in which the regular SE Report is submitted. This is a simplifying assumption. FDA costs may be incurred later than the calendar year in which the regular SE Report is submitted.

As of December 2019, we have taken actions on around 2,000 provisional SE Reports. Because FDA review of these reports can extend across multiple years, we assume that FDA costs are incurred in the year in which the action occurs. Some FDA costs may be incurred earlier than the calendar year in which action on provisional SE Reports was taken. In general, this would lead to us understating the costs related to FDA review of provisional SE Reports. We announced a new approach to our review of the approximately 2,500 remaining provisional SE Reports in April 2018.[45] We will continue to review approximately 1,000 pending provisional SE Reports that were determined to have the greatest potential to raise different questions of public health; we will remove from review approximately 1,500 provisional SE Reports that were determined to be less likely to do so.[46] We use our tracking system as well as the Tobacco

[45] https://www.fda.gov/TobaccoProducts/NewsEvents/ucm583226.htm

[46] Our Tobacco Product User Fee Reports for fiscal year 2018 and 2019 state that we removed 929 reports from review as of April 30, 2018, and 1,390 reports from review as of June 30, 2019 (Ref. [3], Ref. [4]).

Product User Fees reports from fiscal year 2018 (Ref. [3]) and 2019 (Ref. [4]), and updated estimates through December 31, 2019 to determine the number of actions for provisional SE Reports in each fiscal year. In fiscal years 2018 and 2019, we report the number of additional actions for provisional SE Reports minus those that we removed from review. As of December 31, 2019, there were 550 pending provisional SE Reports. To capture all of the costs for our review of provisional SE Reports in this analysis, we spread out our review costs for the remaining 550 provisional SE Reports from 2020 to 2029.[47] These are simplifying assumptions. Table 26 summarizes the number of actual and estimated provisional SE Report actions by year.

Table 196. Number of provisional SE Report actions by year

Year	Provisional SE Report Actions
2011	0
2012	0
2013	0
2014	399
2015	132
2016	248
2017	220
2018	613
2019	93
2020	55
2021	55
2022	55
2023	55
2024	55
2025	55
2026	55
2027	55
2028	55
2029	55

[1] Our tracking system indicates that we took action on 399 provisional SE Reports before July 2015. We put these reports in 2014 for simplicity.

Our medium estimate of costs is the midpoint of the low and high cost estimates. We summarize FDA costs for reviewing SE Reports in Table 27.

Table 207. FDA costs for reviewing SE Reports for Originally Regulated Products

Year	Rule Year	Low	Medium	High
2011	-8	$5,469,875	$11,851,396	$18,232,917
2012	-7	$10,693,606	$23,169,479	$35,645,352

[47] This may be an underestimate of the provisional SE Reports we will review because products that are removed from review will be returned to the review queue if certain, limited criteria are met.

2013	-6	$7,302,283	$15,821,614	$24,340,944
2014	-5	$13,428,543	$29,095,177	$44,761,811
2015	-4	$39,182,538	$43,394,342	$47,606,146
2016	-3	$43,449,041	$51,362,127	$59,275,212
2017	-2	$15,497,979	$22,517,652	$29,537,325
2018	-1	$16,765,167	$36,324,528	$55,883,890
2019	0	$2,543,492	$5,510,899	$8,478,306
2020	1	$4,239,153	$18,301,290	$32,363,427
2021	2	$4,239,153	$18,301,290	$32,363,427
2022	3	$4,239,153	$18,301,290	$32,363,427
2023	4	$4,239,153	$18,301,290	$32,363,427
2024	5	$4,239,153	$18,301,290	$32,363,427
2025	6	$4,239,153	$18,301,290	$32,363,427
2026	7	$4,239,153	$18,301,290	$32,363,427
2027	8	$4,239,153	$18,301,290	$32,363,427
2028	9	$4,239,153	$18,301,290	$32,363,427
2029	10	$4,239,153	$18,301,290	$32,363,427

In addition to the caveats related to timing of reviewing SE Reports discussed above, we also have some uncertainty about how many SE Reports may be bundled. We do not track the number of SE Reports that are submitted to us as bundled reports. Therefore, for simplicity, for this analysis we assume that no SE Reports would be bundled. This would lead us to overestimate the costs to industry of preparing SE Reports if some reports are bundled. When we receive SE Reports that are bundled, we unbundle them, although we review information that is common across bundled reports at one time. Our assumption that no SE Reports are bundled would therefore also cause us to overestimate the costs for FDA review.

We also note that we have refused to accept and canceled some SE Reports, and applicants have withdrawn some of their SE Reports before we complete our review; these actions may also occur with pending and future SE Reports. In these cases, FDA review times would be shorter than we estimated above. We do not account for these shorter review times because we do not have good estimates of how much time this may save us in review. In general, this would lead us to overestimate costs for FDA review.

We treat 2020 as Year 1 to match our main analysis of this final rule. Therefore, 2011 is Year -8 and 2029 is Year 10. We estimate the costs of preparing and reviewing SE Reports for the 19 years from 2011 to 2029. The present discounted value of costs of SE Reports for originally regulated products ranges from around $233 million to $797 million, with a primary estimate of $514 million at a 3 percent discount rate, and from around $259 million to $836 million, with a primary estimate of $548 million at a 7 percent discount rate. The annualized cost over this period ranges from around $16 million to $56 million, with a primary estimate of $36 million at a 3 percent discount rate, and from around $25 million to $81 million, with a primary estimate of $53 million at a 7 percent discount rate.