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; Proposed Rule

Docket No. FDA-2016-N-3818

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

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed rule is not an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have determined that the compliance costs are less than 0.1 percent of revenues, we propose to certify that the rule would 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 $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary

This proposed rule would impose compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, and fill out a form for SE Reports. We estimate that the present value of industry compliance costs ranges from $0.60 million to $2.64 million, with a primary estimate of $1.61 million at a 3 percent discount rate, and from $0.56 million to $2.32 million, with a primary estimate of $1.43 million at a 7 percent discount rate over 10 years. Annualized industry compliance costs over 10 years range from $0.07 million to $0.31 million, with a primary estimate of $0.19 million at a 3 percent discount rate and from $0.08 million to $0.33 million, with a primary estimate of $0.20 million at a 7 percent discount rate. The costs to industry range from around $200 to around $800 per affected entity per year, with a primary estimate of around $500 per entity per year.

The benefits of this proposed rule are potential time-savings to industry and cost-savings to FDA. The proposed 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 proposed rule, we intend to shorten review

times for SE Reports. In addition, based on our experience with prior SE Reports, we believe this proposed rule would lead to better SE Reports, saving us time in review and requiring fewer staff to review SE Reports, which would result in cost-savings. We estimate that the present value of government cost-savings ranges from $15 million to $198 million, with a primary estimate of $62 million at a 3 percent discount rate, and from $12 million to $163 million, with a primary estimate of $51 million at a 7 percent discount rate over 10 years. Annualized government cost-savings over 10 years range from $1.7 million to $23.2 million, with a primary estimate of $7.2 million at both 3 and 7 percent discount rates. The cost-savings per report ranges from around $17,000 to around $58,000, with our best estimate at around $29,000.

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

The present value of net benefits due to this proposed rule ranges from $14.2 million to $195.1 million, with a primary estimate of $60.2 million at a 3 percent discount rate, and from $11.7 million to $160.5 million, with a primary estimate of $49.5 million at a 7 percent discount rate. The estimated annualized net benefits range from $1.7 million to $22.9 million at both 3 and 7 percent discount rates. The primary estimate of annualized net benefits is $7.1 million at a 3 percent discount rate and $7.0 million at a 7 percent discount rate.

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

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

Category		Low Estimate	Primary Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$1.7 million	$7.2 million	$23.2 million	2016	7%	10 years	Cost-savings to government
		$1.7 million	$7.2 million	$23.2 million	2016	3%	10 years	Cost-savings to government
	Annualized Quantified				2016	7%	10 years	
					2016	3%	10 years	
	Qualitative							Greater certainty for SE applicants
Costs	Annualized Monetized $millions/year	$0.08 million	$0.20 million	$0.33 million	2016	7%	10 years	
		$0.07 million	$0.19 million	$0.31 million	2016	3%	10 years	
	Annualized Quantified				2016	7%	10 years	
					2016	3%	10 years	
	Qualitative							
Transfers	Federal Annualized				2016	7%	10 years	
					2016	3%	10 years	
		From:			To:			

Category		Low Estimate	Primary Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Monetized $millions/year							
	Other Annualized Monetized $millions/year				2016	7%	10 years	
					2016	3%	10 years	
		From:			To:			
Effects	State, Local or Tribal Government: No effect Small Business: No effect Wages: No effect Growth: No effect							

In line with Executive Order 13771, in Table 2 we estimate present and annualized values of costs and cost-savings over an infinite time horizon. Our primary estimate of the present value over an infinite time horizon of net costs due to this proposed rule is -$101.4 million at a 7 percent discount rate, and -$237.7 million at a 3 percent discount rate. Our primary estimate of the annualized net costs is -$7.1 million at a 7 percent discount rate and -$7.1 million at a 3 percent discount rate. Table 2 summarizes the costs, cost-savings and net costs of this proposed rule. Based on these cost-savings this proposed rule, if finalized, would be considered a deregulatory action under EO 13771.

Table 2. EO 13771 Summary Table (in $ Millions 2016 dollars, over infinite time horizon)

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	$2.06	$0.59	$3.58	$3.77	$0.71	$6.94
Present Value of Cost Savings	$103.49	$24.84	$331.18	$241.48	$57.96	$772.75
Present Value of Net Costs	($101.4)	($24.2)	($327.6)	($237.7)	($57.2)	($765.8)
Annualized Costs	$0.14	$0.04	$0.25	$0.11	$0.02	$0.21
Annualized Cost Savings	$7.24	$1.74	$23.18	$7.24	$1.74	$23.18
Annualized Net Costs	($7.1)	($1.7)	($22.9)	($7.1)	($1.7)	($23.0)

Note: Values in parentheses denote net negative costs (i.e. cost-savings).

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 Tobacco Control Act gave FDA immediate authority to regulate under the Chapter IX of the Federal Food, Drug & Cosmetics 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 the SE Reports. A predicate tobacco product is either a product that was commercially marketed 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.

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

- 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

- We/us/our: used to refer to the Food and Drug Administration

II. Preliminary Economic Analysis

A. Background

1. Statutory pathways to obtain marketing authorization

The Family Smoking Prevention and Tobacco Control Act (TCA) of 2009, which amends the Federal Food, Drug and Cosmetic Act (FD&C Act), gave us the authority to regulate tobacco products under Chapter IX of the FD&C Act. We consider tobacco products commercially marketed (other than for test marketing) in the United States on February 15, 2007 to be "grandfathered tobacco products." Manufacturers may market a grandfathered tobacco product without receiving authorization from us as long as they have not made any modifications to the tobacco product.[1] 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.

[1] 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.

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) under section 910, a Substantial Equivalence Report under section 905(j), or an Exemption Request under section 905(j)(3).

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.

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.

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

2. SE pathway

The TCA 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 TCA. 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.[2] 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.[3] 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.[4]

4. Purpose of the proposed rule

Although the statute created the SE pathway, this proposed rule, if finalized, would codify 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 proposed rule would clarify when manufacturers can certify that certain characteristics are identical. While not required, we expect many applicants would use certifications given the decreased burden on the applicants.

B. Market 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

[2] http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM239021.pdf
[3] http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf
[4] In addition, we issued a draft guidance on manufacturer requests for extensions and changes to predicate products in July 2014 (79 FR 41292, July 15, 2014), which, when final, will reflect our current thinking on these topics.

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 would raise different questions of public health than the predicate tobacco product. Thus, requiring premarket authorization through the SE pathway reduces the information asymmetry faced by consumers about the potential health risks of newly marketed tobacco products.

This proposed rule would provide additional clarity about the requirements for the content and format of SE Reports and would establish 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 would make our review process more efficient.

C. Baseline

Manufacturers are generally required to 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. 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.[5] For FDA to make a determination, 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).[6] 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.

Under the FD&C Act, manufacturers of tobacco products generally have to submit a premarket submission to us and must receive marketing authorization before a new tobacco product can be introduced or delivered for introduction into interstate commerce. As discussed previously, products with a changed label are not thereby required to receive premarket authorization. Thus, the baseline reflects the fact that manufacturers need not submit SE Reports

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

for label changes. We do not expect a change in the number of SE Reports that would be received under the proposed rule. We request comment on this assumption.

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

1. Number of Substantial Equivalence Reports

a) Originally Regulated Tobacco Product SE Reports

As of December 2017, 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).[7] 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 2016 and 2017 to create a range. We use 2016 and 2017 because the reports submitted in these years reflect the types of SE Reports we expect to receive in the future. The average number of SE Reports submitted each month in 2017 is around 10; the number of full SE Reports submitted each month in 2016 is around 30. Therefore, between 120 (= 10 x 12) and 360 (= 30 x 12) SE Reports have been submitted each year. We use a range from 100 to 400 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

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 and revised this guidance in August 2017.[8] The new compliance date to submit SE Reports for products on the market as of August 8, 2016, is August 8, 2021 for combustible tobacco products and August 8, 2022 for noncombustible tobacco products.

Because the compliance date for manufacturers to submit premarket authorizations for new deemed products is not until 2021, we do not have a history of receiving SE Reports for new deemed tobacco products. Therefore, we use the baseline number of deemed tobacco products on the market, information about grandfathered determinations, and assumptions from our subject matter experts to estimate the number of deemed tobacco product SE Reports. We estimate the baseline number of deemed tobacco products using product listing information.[9]

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[7] 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

[8] https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf

[9] Note: Listing of a product does not constitute a jurisdictional determination, or an agency review or determination that the product is in compliance with FDA regulatory requirements.

(1) Registration and Listing Data Submitted to FDA

Owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product or products are required to register with us and to list their tobacco products. Although we have received listing information on cigarettes, roll-your-own and smokeless tobacco products for several years, we have only recently begun receiving registration and listing information from owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of deemed tobacco products.[10]

Our internal Tobacco Registration and Listing Module (TRLM) captures and maintains establishment registration information and associated product listings, including labels, advertising, and consumer information. As of December 15, 2017, two months after the compliance date for the registration and listing of deemed products on the market prior to August 8, 2016, TRLM contained approximately 16.5 million listings. Additional registration and listing submissions are still being scanned and uploaded into the TRLM system; the grand total may equal hundreds of millions of listings, although without analyzing the listings for redundant entries we cannot know how many unique products have been entered. We expect to complete an analysis of the full TRLM data set for the final rule.

There are several caveats associated with using the product listing data. The currently available product listing data may undercount the number of products. We use data on product listings that have been added to the module as of December 15, 2017. However, we are still processing product listing submissions, including some electronic media and paper submissions. We expect the number of product listings to change once we process and enter all submissions. The sample we use is not a random sample of the total product listing data, but rather a convenience sample based on the listings added to the module as of December 2017. We may also undercount the number of products because foreign firms are not yet required to list products. Finally, some establishments may submit one listing for multiple products with different package quantity. However, in our registration and listing guidance we state that each product included in a product listing should be clearly identified and distinguished. Products that differ in any way, including by package quantity, should be listed separately.

The currently available raw product listing data may overcount the number of products. Multiple entities may list the same product because the registrant must submit a list of all tobacco products that are being manufactured, prepared, compounded, or processed by the registrant for commercial distribution. Although we strongly encourage owners to act as the agent for all operators within a given business structure, not all owners may choose to do so. The same product may also be listed multiple times due to slight misspellings or other factors. Technical difficulties and capacity restrictions with the TRLM system at the registration compliance date also led to duplicate listings in the data. The same product may be sold under

[10] The statute requires that establishments engaged in the manufacture, preparation, compounding, or processing of deemed tobacco products register and list by December 31, 2016, provided that such establishments were engaged in such activities prior to August 8, 2016. Our registration and listing guidance explains that we do not intend to enforce this requirement, provided we received the registration and listing information before October 12, 2017.

multiple labels and therefore have multiple product listings. However, because manufacturers need not receive premarket authorization for existing products that are the subject of a label change only, there is not a one-to-one link between the number of products listed with multiple labels, and the number of products requesting marketing authorization. Additionally, the same product may be sold in multiple packaging configurations (*e.g.*, a tin of smokeless tobacco sold in red, plastic shrinkwrap and blue, plastic shrinkwrap) and may have multiple listings. However, under the proposed rule, only modifications to the subset of packaging that is the container closure system can result in a new product subject to premarket review. Therefore, counting the number of product-package combinations from the TRLM data overestimates the number of products subject to premarket review. Finally, some products that are initially listed in error may later be removed from the system by the registrant.

Manufacturers sometimes co-package tobacco products. Some co-packages can be identified in the TRLM data because they are identified as "kits." Without further analysis of the TRLM data, we do not know if entities listed both the kit and the individual tobacco products sold in the kit. For a kit co-packaging legally marketed tobacco products, where there are no changes to the tobacco products (including their respective container closure systems), the kit is not a new tobacco product and thus the kit is not subject to premarket review. For kits co-packaging two or more tobacco products (in their respective container closure systems), while the kit is not a new tobacco product subject to premarket review, premarket review is required for any new tobacco product that is intended to be included in the kit. In addition, for kits where two or more tobacco products are co-packaged in the same container closure system, the kit is a new tobacco product subject to premarket review, unless such a kit is grandfathered.

Some of the limitations of the current data will be resolved as we process the remaining submissions into the TRLM system. We will continue to examine the data to better understand the information it provides about deemed tobacco products. Over time, we expect better submissions as the tobacco industry gets more experience with submitting registration and listing data, and as we resolve technical issues with the registration and listing website and TRLM system. We expect to use the full registration and product listing data, as well as other pertinent information, to inform product counts in our Final Regulatory Impact Analysis. We solicit comments on how best to estimate the total number of affected products.

(2) Estimated Product Counts by Product Category for Deemed Tobacco Products

We use the tobacco product listing data submitted by industry and uploaded into our internal TRLM system. As discussed in the previous section, we have identified several limitations of the internal data. However, only registrants can revise the data submitted to the TRLM. To produce a data set that we can use to generate product counts, we use a copy of the TRLM data and apply several data cleaning steps to create an analytical file. With this file, we can estimate the baseline number of unique product-package-label combinations.

We use the count of observations as the raw count for each deemed tobacco product category. [11] We do not adjust counts from our convenience sample to account for the total number of product listings received. Our adjustments address some of the issues of overcounting and misclassifications discussed above. First, we remove non-finished tobacco products (identified in the listing as for further manufacturing use), any products identified in the listing as introduced to the market after August 8, 2016 (the effective date of the Deeming Rule)[12], and products marked as canceled or discontinued. For simplicity, we also exclude co-packaging identified as "kits."

Next, we remove observations that appear to be duplicate listings. As noted above, several factors can generate duplicates in the raw data. Thus, we identify duplicate listings in several ways. First, we remove observations when all the information provided by the registrant is the same for more than one listing. Next, within each product category, we identify unique combinations of the product name, flavor and product identification number (this number is provided by the registrant but is not required in the product listing). We use the count of unique product name-flavor-identification number combinations as the upper-bound estimate of product-package-label combinations. Our lower-bound estimate of product-package-label combinations is the count of unique product name-flavor observations in the data. We identify duplicates based on exact matches of product name-flavor-identification number or product name-flavor. Although this matching process removes many of the duplicates, some may remain because of slight misspellings.

The registrant who lists the tobacco product selects the tobacco product category for the product listing. We don't know if registrants select the correct tobacco product category for their listed products. Misclassification could occur for any product, and we have identified what appears to be several e-liquids that may be misclassified as other product categories. However, we assume that e-liquids would not go through the SE pathway because we do not know of any grandfathered e-liquid products. We identify product names that contain words like "liquid," "mL," "bottle," and "%" and reclassify these observations as potential e-liquids. Our search of product names is not case sensitive (that is, we identify "liquid" as well as "LIQUID"). In our upper bound, we assume that the registrant has selected the correct tobacco product category

[11] We use the following product types in the product listing data for each deemed tobacco product: for cigars we use 'Cigar' and 'Other-Cigar'; for pipe tobacco we use 'Pipe tobacco'; for pipes we use a variety of 'Other' categories ('Other- a pipe,' 'Other-Woodpipe,' 'Other-Tobacco Pipe,' 'Other-Smoking Pipe,' 'Other-Pipe,' 'Other-Ordinary Tobacco Pipe,' and 'Other-pipe'); for waterpipe tobacco we use 'Waterpipe tobacco,' 'Other-HOOKAH TOBACCO' and 'Other-Shisha'; for waterpipes we use a variety of 'Other' categories ('Other-Waterpipe,' 'Other-Water Pipe,' 'Other-Hookah,' 'Other-Complete Waterpipe,' 'Other-Complete Hookah,' 'Other-WATERPIPE COMPLETE HOOKAH,' 'Other-Mini Hookah,' 'Other-Waterpipeset' and 'Other-Waterpipe Set'); and for ENDS delivery systems we use the sum of 'Advanced personal vaporizer,' 'E-cigar,' 'E-cigarette,' 'E-hookah,' 'E-pipe,' and 'Vape pen' categories.

[12] As of August 8, 2016, all deemed, new tobacco products were subject to the requirements of premarket review; however, for new products that were on the market as of August 8, 2016, FDA does not intend to enforce the requirements of premarket review until August 8, 2021 (combustible deemed products) or August 8, 2022 (non-combustible deemed products). We removed products identified in their respective listings as introduced to the market after August 8, 2016 for multiple reasons. For example, the listing may identify a product that has been on the market as of August 8, 2016 but with different labels and/or different non-container closure system packaging; may identify a grandfathered product being reintroduced onto the market; or may be in error.

when listing the product. In our lower bound, we assume that these products are e-liquids and remove them from our product counts.

Finally, we note that given the data available at the time of this analysis we are unable to create adjustments factors or weights to make the estimates from our convenience sample representative of the total product listing data. We recognize this raises issues of external validity. We solicit comment on the data and the appropriate range of estimates considering the caveats discussed above, including potential issues of overcounting, undercounting, co-packaging, misclassification, and the representativeness of the data.

Table 3 summarizes the raw counts in the tobacco registration and listing module (TRLM). The table also summarizes our estimated range of product-package-label combinations by tobacco product category after cleaning the data and removing the duplicate listings as discussed above.

Table 3. Counts of Deemed Tobacco Products from the Tobacco Registration and Listing Module Database by Tobacco Product Category

Product Type	Raw Counts [1]	Upper Bound Baseline Count of Product-Package-Label Combinations (after dropping duplicates) [2]	Lower Bound Baseline Count of Product-Package-Label Combinations (after dropping duplicates and potential e-liquids) [3]
Cigars	64,570	61,130	52,934
Pipe Tobacco	8,984	8,809	8,701
Pipes	323	323	323
Waterpipe tobacco	6,734	6,546	6,019
Waterpipes	406	406	363
ENDS Delivery Systems	52,258	50,461	12,242
Total	133,275	127,675	80,582

[1] From TRLM database as pulled by the contractor on December 15, 2017.

[2] Removed duplicates from the TRLM database. We excluded products that are not finished tobacco products (identified in the listing as for further manufacturing use), products that were identified in the listing as introduced to the market after August 8, 2016, products that were canceled or discontinued, and co-packaging kits. The upper-bound keeps unique product name-flavor-identification number combinations.

[3] Removes duplicates from the TRLM database. We excluded products that are not finished tobacco products (identified in the listing as for further manufacturing use), products that were identified in the listing as introduced to the market after August 8, 2016, products that were canceled or discontinued, and co-packaging kits. The lower-bound keeps unique product name-flavor combinations and excludes products that may be e-liquids.

In addition, because manufacturers need not receive premarket authorization for label changes of existing products, we can exclude products that have the same product-package combinations but different labels from our estimate of baseline product counts of SE Reports for deemed tobacco products. We use the number of unique product-package combinations in Table 3 as our baseline product count. We calculate the proportion of product-package combinations to

product-package-label combinations from the information in Table 6 of the Deeming final RIA[13] and multiply the number of product-package-label combinations at baseline by our calculated proportion. We use this estimate as our baseline product count for estimating the number of SE Reports we expect to be submitted for some deemed tobacco product categories. Table 4 contains our estimates of product-package combinations by tobacco product category. We request comment on the proportion of product-package combinations to product-package-label combinations, as well as our resulting estimate of product-package combinations of deemed tobacco products.

Table 4. Estimated Number of Product-Package Combinations of Deemed Tobacco Products by Tobacco Product Category

Product Type	Estimate of product-package-label combinations at baseline	Estimated proportion product-package combinations to product-package-label combinations	Estimate of product-package combinations[1]
Cigars	52,934 to 61,130	67%	35,289 to 40,753
Pipe Tobacco	8,701 to 8,809	82%	7,119 to 7,207
Pipes	323	100%	323
Waterpipe tobacco	6,019 to 6,546	80%	4,814 to 5,235
Waterpipes	363 to 406	100%	363 to 406
ENDS Delivery Systems	12,242 to 50461	80%	9,764 to 40,369
Total	80,582 to 127,675		57,702 to 94,294

1 Estimated by multiplying the number of product-package-label combinations at baseline by the estimated proportion of product-packages combinations to product-package-labels combinations that we calculated using the number of product formulations and product-package combinations from Table 6 of the Deeming final RIA.

(3) Expected Number of SE Reports by Product Category for Deemed Tobacco Products

To estimate the number of SE Reports we expect to receive initially and in subsequent years, CTP's 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 likely to be grandfathered. Note that, as explained above, our use of initial registration and product listing submission data for deemed products may lead to an over or under estimate of the number of products and SE Reports. We request comment on these estimates.

(a) Cigars

[13] The terminology we used in the Deeming final RIA differed from the terminology we have used in this analysis. In the Deeming final RIA, we used the terms 'product formulation' and 'product-package.'

We assume that the majority of cigar products on the market as of the effective date for the Final Deeming Rule would potentially be grandfathered (i.e. on the market as of February 15, 2007). Grandfathered products may be referenced as a predicate product in an SE Report. Firms may choose to request a standalone grandfathered determination from us, or may choose to file an SE Report referencing a predicate product that the applicant identified as grandfathered. Requesting a standalone grandfathered determination from us provides a means of establishing, in advance, a predicate product for reference in future SE Reports. Not every standalone grandfathered submission may lead to an SE Report and certain standalone grandfathered submissions may be referenced in multiple SE Reports. Along with other information, standalone requests for grandfathered determination for cigar products may serve as a predictor of the number of SE Reports expected.

To estimate the number of initial SE Reports for cigars, 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 grandfathered products established through requests for standalone grandfathered determination (1,492 originally regulated products have been established as grandfathered through this process as of August 31, 2018).[14] We use this relationship, in addition to FDA's past experience with SE Reports for originally regulated products and subject matter expertise on cigar manufacturing and the amount of variation in cigar products, and estimate that the number of SE Reports received for cigar products during the initial submission period will be an average of two to five times the number of cigar products that have been established as grandfathered through a standalone grandfather submission.

From requests for standalone grandfathered determination that have been voluntarily submitted to FDA for cigar products, 1,042 such products have been established as grandfathered as of August 31, 2018. As a lower bound estimate, we use these 1,042 grandfathered cigar products and the assumption of an average of 2 SE Reports per each such established grandfathered cigar product to estimate that roughly 2,100 initial SE reports will be submitted.[15] As an upper bound estimate, we use the number of cigar products determined to be grandfathered from a standalone submission and the assumption of an average of 5 SE reports per grandfathered cigar product to estimate that roughly 5,200 initial SE Reports will be submitted.[16] This creates a range of 2,100 to 5,200 initial SE Reports for cigars.[17]

As stated in the preamble to the Final Deeming Rule, FDA does not intend to enforce premarket review requirements for manufacturers that make tobacco blending changes to address the natural variation of tobacco (e.g., tobacco blending changes due to variation in growing conditions) to maintain a consistent product. Assuming the estimate of 2,100 to 5,200 initial SE Reports represents changes that have been made to cigar products in the eleven years since February 15, 2007, we assume a linear trend and estimate that 189 to 474 SE reports will be

[14] Standalone grandfathered determinations for tobacco products can be accessed at https://www.accessdata.fda.gov/scripts/ctpGnd/.

[15] 1,042 grandfathered cigar products x 2 SE reports per grandfathered cigar product = 2,084 initial SE reports for cigar products, or roughly 2,100.

[16] 1,042 grandfathered cigar products x 5 SE reports per grandfathered cigar product = 5,210 initial SE reports for cigar products, or roughly 5,200.

[17] This estimate does not include cigar products that would be grandfathered (with or without a request for determination) and, thus, would not be expected to apply for marketing authorization.

submitted for cigar products in each subsequent year after the initial period. We request comment on these assumptions and estimates.

(b) Electronic Nicotine Delivery Systems (ENDS) Devices

We have no new information to suggest additional predicate or grandfathered ENDS devices and, to date, there have not been any ENDS devices that have applied to FDA for grandfather determination. Therefore, we retain the assumption from the Final Deeming Rule of eight to ten potentially grandfathered ENDS devices available for reference as predicate products in SE Reports, and use this as our starting point for the estimates below.

To estimate the number of initial SE Reports for ENDs devices, we assume a high average of 25-50 SE Reports referencing each potential grandfathered ENDS device as a predicate and estimates that as many as 200-500 ENDS devices may submit SE reports initially (8 x 25 = 200, 10 x 50 = 500).

We use this estimate of 200-500 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 an average of roughly 20-100 SE Reports will be submitted for ENDS Devices annually after the initial period. We request comment on these estimates.

(c) Pipe Tobacco, Pipes, Waterpipe Tobacco and Waterpipes

For all other deemed tobacco products – including pipes, pipe tobacco, waterpipes, and waterpipe tobacco – we estimate the number of SE Reports from the range of product-package combinations in Table 4. For each tobacco product category, our subject matter experts had previously estimated 1) the percentage of products projected to submit applications for premarket review, and 2) the percentage of applications for premarket review submitted as SE Reports. We retain these assumptions. To estimate the number of initial SE Reports, we apply the estimates from our subject matter experts to the estimate of the number of product-package combinations. Table 5 summarizes the number of initial pipe, pipe tobacco, waterpipe, and waterpipe tobacco products projected to submit SE Reports.

Table 5. Number of Initial SE Reports for Pipe Tobacco, Pipes, Waterpipe Tobacco and Waterpipes

Product Type	Estimate of product-package combinations	Percent of Products to Submit Applications	Percent of Applications Submitted as SE Reports	Number of Initial SE Reports (Lower Bound)	Number of Initial SE Reports (Upper Bound)
Pipe Tobacco	7,119 to 7,207	35%	57%	1,424	1,441

Pipes	323	4%	75%	10	10
Waterpipe tobacco	4,814 to 5,235	35%	57%	965	1,049
Waterpipes	363 to 406	4%	75%	11	12
Total	12,619 to 13,172			2,409	2,513

Our subject matter experts had also previously estimated 1) the percentage of products projected to remain on the market after the initial period, 2) the percentage of annual applications for marketing authorizations submitted as SE Reports, and 3) that the number of new products seeking premarket authorization in subsequent years would be equivalent to 5 to 10 percent of the products that remain on the market. We retain these assumptions and use them to estimate the number of annual SE Reports submitted after the initial period for pipe, pipe tobacco, waterpipe, and waterpipe tobacco products. For example, we calculate the lower-bound estimated number of annual SE Reports as

= (estimate of product-package combinations x proportion that stay on the market x 5% x proportion of submissions that are SE Reports).

Table 6 summarizes the annual number of pipe, pipe tobacco, waterpipe, and waterpipe tobacco products projected to submit SE Reports.

Table 6. Number of Annual SE Reports for Pipe Tobacco, Pipes, Waterpipe Tobacco and Waterpipes After the Initial Period

Product Type	Estimate of product-package combinations	Percent of Products Projected to Remain on the Market	Percent of Applications Submitted as SE Reports	Estimated Number of Annual SE Reports (Lower Bound) [1]	Estimated Number of Annual SE Reports (Upper Bound) [2]
Pipe Tobacco	7,119 to 7,207	95%	69%	233	473
Pipes	323	95%	71%	11	22
Waterpipe tobacco	4,814 to 5,235	95%	69%	157	341
Waterpipes	363 to 406	95%	72%	12	28
Total	12,619 to 13,172			414	864

1 Calculated assuming that the number of products seeking premarket authorization annually is equivalent to 5% of products that remain on the market.
2 Calculated assuming that the number of products seeking premarket authorization annually is equivalent to 10% of products that remain on the market.

We request detailed comments on these assumptions and on our estimates for the number of SE Reports for these deemed tobacco products.

(d) Summary of Deemed Tobacco Product SE Reports

Table 7 summarizes our estimate of the number of initial and annual SE Reports by product category for deemed tobacco products.

Table 7. Estimated Number of SE Reports by Product Category for Deemed Tobacco Products

Product Type	Number of Initial SE Reports (Lower Bound)	Number of Initial SE Reports (Upper Bound)	Number of Annual SE Reports (Lower Bound)	Number of Annual SE Reports (Upper Bound)
Cigars	2,084	5,210	189	474
Pipe Tobacco	1,424	1,441	233	473
Pipes	10	10	11	22
Waterpipe tobacco	965	1,049	157	341
Waterpipes	11	12	12	28
ENDS Delivery Systems	200	500	20	100
Total	4,693	8,223	623	1,437

For the purposes of this analysis, we assume that this proposed rule would be finalized in 2019 and call this Year 1. For simplicity, we assume that we will not receive SE Reports for deemed tobacco products until the calendar year of the premarket review compliance date. Therefore, we assume that we would begin receiving initial SE Reports for combustible deemed products in 2021 (Year 3) and for noncombustible deemed products in 2022 (Year 4). [18] In 2021, we estimate the number of SE Reports as the initial SE Reports for cigars, pipe tobacco, pipes, waterpipe tobacco and waterpipes. For 2022, we estimate the number of SE Reports as the initial SE Reports for ENDS devices, plus the annual SE Reports for cigars, pipe tobacco, pipes, waterpipe tobacco and waterpipes. Estimates of SE Reports for the year 2023 onward equal the sum of annual SE Reports for all deemed tobacco product categories. Table 8 summarizes our estimates of the number of SE Reports we expect to receive each year over the time horizon of this analysis for deemed products.

Table 8. Number of SE Reports for deemed tobacco products expected each year

Calendar Year	Analysis Year	Deeming SE Reports - Low	Deeming SE Reports – High
2019	1	0	0
2020	2	0	0

[18] We classify cigars, pipe tobacco, waterpipe tobacco, pipes and waterpipes as combustible tobacco products. ENDS devices are classified as noncombustible tobacco products.

2021[1]	3	4,493	7,723
2022[2]	4	803	1,837
2023	5	623	1,437
2024	6	623	1,437
2025	7	623	1,437
2026	8	623	1,437
2027	9	623	1,437
2028	10	623	1,437

[1] Initial SE Reports except for ENDS Devices
[2] Initial ENDS Devices SE Reports plus annual SE Reports for all other deemed product categories

We request comment on the estimated number of SE reports that will be submitted. We also seek comments and any relevant new data that would assist us in more accurately modeling a firm's decision regarding whether to submit initial and subsequent annual SE Reports for a particular product.

2. Number of Findings Related to Substantial Equivalence Reports

As of June 2017, we have issued around 600 SE orders and issued around 200 NSE orders for new tobacco products.[19] We have also issued 299 refuse to accept letters for SE Reports. As of June 2017, over 1,400 substantial equivalence reports have been withdrawn by manufacturers.

3. Review cycles

In the proposed 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 Center for Tobacco Products estimates that it takes, on average, around 349 calendar days to review SE Reports in the absence of the proposed rule.[20] We convert calendar days into business days to capture the number of working days spent on a report.[21] Without the rule, we estimate that our average review time for SE Reports equals around 249 business days.

[19] Tobacco Product Marketing Orders, http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm.
[20] 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.
[21] Business days are calculated by multiplying calendar days by 5/7.

4. Time to prepare and submit substantial equivalence reports

Based on originally regulated products and in the absence of the proposed rule, our Center for Tobacco Products estimates that it would 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).[22] 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. [1]).

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 9 below.

Table 9. 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
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 proposed rule would 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 proposed rule would apply 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

[22] This estimate is based on the Paperwork Reduction Act (PRA) burden estimates published with our SE FAQ guidance on March 5, 2015. 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.

counts of importers of tobacco products as a proxy for the number of foreign firms that would submit SE reports under this proposed rule.

Based on aggregate information from the Alcohol and Tobacco Tax and Trade Bureau (TTB)[23], in 2015 there were 39 domestic manufacturers of cigarettes, 23 manufacturers of roll-your-own tobacco, 17 manufacturers of smokeless tobacco products, 100 manufacturers of cigars, and 68 manufacturers of pipe (including waterpipe) tobacco. In addition, there were 28 importers of cigarettes, 23 importers of roll-your-own tobacco, 25 importers of smokeless tobacco products, 139 importers of cigars, and 38 importers of pipe (including waterpipe) tobacco. 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.[24] In general, we expect that few ENDS products would 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, for simplicity, we do not include estimates of ENDS-only manufacturers subject to this rule. We request comment on this assumption and on the number of ENDS-only entities that would be affected by this proposed rule.

Summing TTB's counts of entities would over-estimate the number of affected establishments because an establishment could be counted more than once. TTB estimates that there are 171 domestic manufacturers and 223 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 10 summarizes information about the current number of manufacturers and importers potentially affected by this proposed rule. However, we do not know if every manufacturer would attempt to market a new tobacco product through the substantial equivalence pathway.

Table 10. Number of Manufacturers and Importers Potentially Affected

Domestic Manufacturing Entities	Count
Cigarettes	39
Roll-Your-Own Tobacco	23
Smokeless Tobacco Products	17
Cigars	100
Pipe and Waterpipe Tobacco	68
ENDS	0
Total manufacturing entities	**247**
Total accounting for dual manufacturing	**171**

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

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

Importers	
Cigarettes	28
Roll-Your-Own Tobacco	23
Smokeless Tobacco Products	25
Cigars	139
Pipe and Waterpipe Tobacco	38
ENDS	0
Total importers	**253**
Total accounting for dual importing	**223**

2. Affected Substantial Equivalence Reports

The proposed rule, if finalized, would cover SE Reports received on or after the effective date of the rule. Based on past SE Report submissions, we estimate that 100 to 400 SE Reports would be submitted each year for new cigarette, roll-your-own tobacco, and smokeless tobacco products. We use our registration and listing data along with CTP's expert judgment and other internal data sources to estimate the number of SE Report submissions for new deemed tobacco products. We estimate between 4,000 to 7,500 SE Reports for new deemed tobacco products in Year 3 of our analysis, 750 to 1,800 SE Reports in Year 4, and 580 to 1,400 in Years 5 through 10. However, this proposed rule would not cover any pending SE Reports received before the effective date of any final rule. In addition, provisional SE Reports would not be covered by this proposed rule.

E. Costs of the Proposed Rule

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

1. Administrative One-Time Costs

The one-time compliance activities associated with this proposed 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 proposed rule would need to devote time to reading and understanding this rule. To understand this rule, affected entities would read the current preamble, codified regulatory text and instructions for filling out an electronic form required with each report which together contain around 50,000 words. Consistent with HHS guidance, we assume that industry reviewers read at the average adult reading speed of approximately 200 words to 250 words per minute, so the time to read the regulation would be 3.3 hours to 4.2

hours per person. We assume that one to four people read the rule at each entity manufacturing or importing affected products. We request comment on these estimates.

To value the time for complying with these provisions, we use composite wages calculated from the Bureau of Labor Statistics' national industry-specific occupational employment and wage estimates for the tobacco manufacturing industry (Ref. [2]).[25,26] 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 $65.91.[27] We double this to account for benefits and overhead, yielding an hourly labor cost of $131.82.

We estimate the cost for one reviewer to read the rule ranges from $439 to $549. For each affected entity, these costs range from $439 to $2,197. As previously discussed in section II.D.1, we estimate that the proposed rule would affect 394 entities manufacturing or importing tobacco products. The total costs for reading and understanding the rule range from around $0.2 million to around $0.9 million. Table 11 includes a summary of these costs.

Table 11. One-time costs for reading and understanding the rule

	Low	High
Reading time (Hours)	3.3	4.2
Wage ($ per hour)	$131.82	$131.82
Affected entities	394	394
Number of people reading per entity	1	4
Total Cost ($ million)	**$0.2**	**$0.9**

Affected entities may respond to the proposed rule by establishing or revising procedures related to substantial equivalence reports, even though this is not required by the rule. This would be a one-time cost. We estimate that this activity would take 4 hours for small entities and 8 hours for large entities. We request comment on these estimates. The Small Business Administration defines a small tobacco manufacturer as a firm with fewer than 1,500 employees (Ref. [3], SBA 2016). We use detailed firm size information from the U.S. Census Bureau 2012 Statistics of U.S. Businesses to estimate that around 96 percent of tobacco entities are small (Ref. [4], SUSB 2012 detailed).[28] The latest year for which this detailed information is available is 2012. Based on this data, we estimate that 377 affected entities would fall below the threshold.

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

[25] May 2016 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200 – Tobacco Manufacturing. <http://www.bls.gov/oes/>

[26] The BLS did not publish wage estimates for legal occupations within the tobacco manufacturing industry in 2016. We use instead, the legal occupation wage reported for the manufacturing industry (NAICS Sectors 31, 32 and 33).

[27] The calculation is 0.5*($59.40) + 0.5*($72.42) = $65.91.

[28] See III.A for a discussion of why this is only an approximation of the percent that are small.

management occupations (occupation code 11-1021), and 10 percent administrative occupations (occupation code 43-0000). This mix yields a composite wage of $69.42.[29] We double this to account for benefits and overhead, yielding an hourly labor cost of $138.85.

We estimate that each small entity could incur costs of $555.38 and that each large entity could incur costs of $1,110.77. The total cost for affected entities to establish or revise procedures related to preparing SE reports is around $0.23 million.

Table 12 shows the estimated costs for these affected entities to establish or revise submission procedures.

Table 12. One-time costs for establishing or revising procedures

	Small	Large
Total hours	4	8
Wage ($ per hour)	$138.85	$138.85
Number of entities	377	17
Total cost ($ million)	**$0.21**	**$0.02**

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

2. Recordkeeping costs

The proposed rule would require applicants to maintain records related to their SE Reports. Applicants would have to keep records for four years after an SE order is issued. 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 would keep electronic records.

We estimate that each applicant would spend between 0 (zero) hours to 5 hours each year maintaining these records and deleting records that no longer need to be kept. Our lower-bound estimate accounts for entities that do not have any SE records to keep because they have not submitted an SE Report or have not received an order for a new tobacco product. We request comment on these estimates.

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 occupations (occupation code 17-0000); 30 percent office and administrative support

[29] The calculation is 0.2*($77.50) + 0.7*($74.28) + 0.1*($19.27) = $69.42.

occupations (occupation code 43-0000); and 20 percent legal occupations (occupation code 23-0000). This mix yields a composite wage of $38.08.[30] We double this to account for benefits and overhead, yielding and hourly labor cost of $76.16.

We estimate that each applicant would incur between $0 and $380.82 for annual recordkeeping costs. Total annual recordkeeping costs range from $0.0 million to $0.15 million. Table 13 summarizes estimated annual recordkeeping costs for SE Reports.

Table 13. Annual Recordkeeping Costs

	Low	Medium	High
Recordkeeping time (Hours)	0	2.5	5
Labor cost ($ per hour)	$76.16	$76.16	$76.16
Affected entities	394	394	394
Annual cost for affected entities ($ million)	**$0.00**	**$0.08**	**$0.15**

3. Electronic form

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

Applicants would fill out this form each time they submit a new SE Report, although applicants may bundle SE Reports for certain new tobacco products. Our Center for Tobacco Products estimates that it would initially take about 30 minutes per product to fill out the form. However, subsequent reports may only take between 5 minutes and 10 minutes because applicants would be able to cut and paste from old forms. We convert these estimates into hours and estimate that it would take 0.5 hours (= 30/60) for each product in the first year and between 0.08 hours (= 5/60) and 0.17 hours (= 10/60) for each product in subsequent years. We request comment on these estimates.

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 would 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 would 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

[30] The calculation is 0.3*($28.79) + 0.2*($45.90) + 0.3*($19.27) + 0.2*($72.42) = $38.08.

compile and submit the report. In valuing the time to comply with this provision, 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 $38.08.[31] We double this to account for benefits and overhead, yielding and hourly labor cost of $76.16.

Table 14 summarizes the annual incremental costs for filling out the required electronic form for each SE Report.

Table 14. Annual costs for the electronic form

	Low	Medium	High
SE Reports for originally regulated tobacco products - Year 1	100	250	400
SE Reports for originally regulated tobacco products - Subsequent years	100	250	400
SE Reports for deemed tobacco products - Year 3	4,493	6,108	7,723
SE Reports for deemed tobacco products - Year 4	803	1,320	1,837
SE Reports for deemed tobacco products - Subsequent years	623	1,030	1,437
Electronic form - first year (hours)	0.50	0.50	0.50
Electronic form - Subsequent years (hours)	0.08	0.13	0.17
Labor cost ($ per hour)	$76.16	$76.16	$76.16
Cost for reports for originally regulated tobacco products - Year 1 ($ million)	$0.004	$0.010	$0.015
Cost for reports for originally regulated tobacco products - Subsequent years ($ million)	$0.001	$0.002	$0.005
Cost for deemed tobacco products - Year 3 ($ million)	$0.171	$0.233	$0.294
Cost for deemed tobacco products - Year 4 ($ million)	$0.031	$0.050	$0.070
Cost for deemed tobacco products - Subsequent years ($ million)	$0.004	$0.010	$0.018

Note: Numbers may not sum or multiply due to rounding.

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 proposed rule, if finalized, than in the absence of rulemaking. We request comment on how to estimate these potential costs to industry.

[31] The calculation is 0.3*($28.79) + 0.2*($45.90) + 0.3*($19.27) + 0.2*($72.42) = $38.08.

We request comment on all cost estimates contained in this document as well as comment on additional costs we may have excluded from our analysis.

F. Benefits of the Proposed Rule

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 proposed 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 proposed rule would 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 would 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 $76.16, the maximum amount saved for including certifications equals about $14,000 (= 185 hours x $76.16 per hour) per SE Report. Applicants may also save time in preparing the environmental assessment (EA) that accompanies the SE Report. We request comment on these potential time-savings and the estimated hours saved per SE Report.

We do not have enough information to estimate the number of SE Reports that may include certifications as a result of this proposed rule, if finalized. We request comment on the number of SE Reports that may include certifications in the future and on the time saved per SE Report.

b) Cost Savings for FDA

The quantified benefits of this proposed rule, if finalized, are cost-savings to government. Our Center for Tobacco Products estimates that this proposed rule, if finalized, would lead to cost-savings for us to review SE Reports. These cost-savings would be realized due to both fewer review cycles, as well as fewer staff per SE review.

We expect that applicants would submit more complete SE Reports, meaning that we would 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 proposed rule, we intend to shorten review times as measured by fewer review cycles for SE Reports. In addition, we believe that more complete and clearer SE Reports would 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 would 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 Center for Tobacco Products provided estimates on the number of staff that would be involved with SE reviews without and with the rule. In addition, this proposed rule explains that we intend to shorten review times as measured by the number of review cycles. The Center for Tobacco Products estimates that with the rule we intend to review SE Reports in one to three review cycles. In the proposed rule, we explain that we intend for FDA's review to be 90 calendar days per cycle (i.e., each review cycle would be 90 calendar days). We convert calendar days into business days to capture the average number of working days spent on a report.[32] Table 15 summarizes the number of staff and review times for SE Reports both with and without the rule.

Table 15. 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).

The Center for Tobacco Products 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 would take 0.02 (=1/50) of an FTE, and at the high end one SE Report would 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 16 summarizes our review times in labor hours.

Table 16. 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).

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

In valuing our time, we use a wage based on full-time equivalent (FTE) employees. We use a fully-loaded cost per FTE of $120 per hour. We assume that there are 100 to 400 SE Reports to review each year. Thus, we estimate cost-savings of around $1.7 million to $23.2 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 proposed rule. The cost-savings per report range from about $17,000 to about $58,000, with our best estimate at $29,000. Table 17 summarizes these cost-savings.

Table 17. Annual FDA Review Costs

	Low	Medium	High
Annual SE reports	100	250	400
Labor hours saved per SE Report	145	241	483
Review time cost-savings ($ millions)	$1.7	$7.2	$23.2

We would 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 proposed rule, if finalized.

We note, however, that these cost-savings would 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.[33]

2. Qualitative benefits

This proposed rule would provide additional clarity to industry about the requirements for the content and format of SE Reports. The proposed rule would also establish the general procedures we intend to follow in reviewing and communicating with applicants. In addition, this proposed rule would 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 pre-market tobacco application, (2) submit a substantial equivalence report, or (3) submit a request for an exemption from a substantial equivalence 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 proposed rule does not change what we would require to include in a premarket tobacco product application or an SE exemption request.

[33] 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.

We do not estimate any health benefits due to this proposed rule. The FD&C Act, and not this proposed rule, provides the requirements to show that a new tobacco product is substantially equivalent to the predicate tobacco product. 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.

3. Other benefits

We request comment on all cost-savings estimates contained in this document as well as comment on additional cost-savings we may have excluded from our analysis. We also request comment on any health impacts of this proposed rule, if finalized.

G. Summary of Benefits and Costs

This proposed rule would 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 $0.60 million to $2.64 million, with a primary estimate of $1.61 million at a 3 percent discount rate and from $0.56 million to $2.32 million, with a primary estimate of $1.43 million at a 7 percent discount rate over 10 years. The annualized costs to industry over 10 years range from $0.07 million to $0.31 million, with a primary estimate of $0.19 million at a 3 percent discount rate and from $0.08 million to $0.33 million, with a primary estimate of $0.20 million at a 7 percent discount rate.

The benefits of this proposed 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 $14.8 million to $197.8 million, with a primary estimate of $61.8 million at a 3 percent discount rate and from $12.2 million to $162.8 million, with a primary estimate of $50.9 million at a 7 percent discount rate over 10 years. The annualized cost-savings ranges from $1.7 million to $23.2 million at both 3 and 7 percent discount rates. The primary estimate of annualized cost-savings is $7.2 million at both 3 and 7 percent discount rates.

Overall, this proposed rule would lead to a present discounted value of net social benefits ranging from $14.2 million to $195.1 million, with a primary estimate of $60.2 million at a 3 percent discount rate and from $11.7 million to $160.5 million, with a primary estimate of $49.5 million at a 7 percent discount rate. Table 18 summarizes the present discounted value of the incremental costs and benefits of this proposed rule.

Table 18. 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	$0.8	$0.2	$0.5	$0.8

Establish or revise procedures	$0.2	$0.2	$0.2	$0.2	$0.2	$0.2
Recordkeeping	$0.0	$0.6	$1.1	$0.0	$0.4	$0.9
Electronic form	$0.2	$0.3	$0.5	$0.2	$0.3	$0.4
Total costs	**$0.6**	**$1.6**	**$2.6**	**$0.6**	**$1.4**	**$2.3**
Total benefits	**$14.8**	**$61.8**	**$197.8**	**$12.2**	**$50.9**	**$162.8**
Net Benefits	**$14.2**	**$60.2**	**$195.1**	**$11.7**	**$49.5**	**$160.5**

Overall, this proposed rule would lead to an annualized net social benefits in the form of cost savings over 10 years ranging from $1.7 million to $22.9 million at both 3 and 7 percent discount rates. The primary estimate of annualized net social benefits is $7.1 million at a 3 percent discount rate and $7.0 million at a 7 percent discount rate. Table 19 summarizes the annualized incremental costs and benefits of this proposed rule.

Table 19. 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	$0.10	$0.02	$0.07	$0.12
Establish or revise procedures	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03
Recordkeeping	$0.00	$0.06	$0.13	$0.00	$0.06	$0.13
Electronic form	$0.02	$0.04	$0.06	$0.03	$0.04	$0.06
Total costs	**$0.07**	**$0.19**	**$0.31**	**$0.08**	**$0.20**	**$0.33**
Total benefits	**$1.7**	**$7.2**	**$23.2**	**$1.7**	**$7.2**	**$23.2**
Net Benefits	**$1.7**	**$7.1**	**$22.9**	**$1.7**	**$7.0**	**$22.9**

The qualitative benefits associated with this proposed 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 proposed 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

We analyze several alternatives to the proposed 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 proposed rule. We use primary estimates for the annualized costs over 10 years. Table 20 summarizes the proposed rule and alternatives in order from least costly to most costly.

Table 20. Annualized costs and benefits for the proposed rule and alternatives

Description	Annualized costs (3%)	Annualized benefits (3%)	Annualized net benefits (3%)	Change in annualized net benefits from proposed rule (3%)	Annualized costs (7%)	Annualized benefits (7%)	Annualized net benefits (7%)	Change in annualized net benefits from proposed rule (7%)
One review cycle for all SE Reports	$0.2	$8.6	$8.5	$1.4	$0.2	$8.6	$8.4	$1.4
Proposed Rule	$0.2	$7.2	$7.1	NA	$0.2	$7.2	$7.0	NA
Extend the effective date of the rule	$0.2	$6.4	$6.2	($0.8)	$0.2	$6.3	$6.1	($1.0)
Allow more review cycles	$0.2	$0.9	$0.7	($6.4)	$0.2	$0.9	$0.7	($6.4)

Note: Values in parentheses are negative values (i.e. less net benefits than the proposed 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 Center for Tobacco Products would review all SE Reports in one review cycle and issue a not substantially equivalent (NSE) order for deficient reports. This would differ from the proposed rule, in which we intend to issue a deficiency letter for incomplete SE Reports and allow the applicant to submit additional information as amendments. Initially, this would result in more NSE orders and reduced use of our resources per report. Over time, we expect that industry would submit complete reports. We do not have estimates for costs to industry of this alternative. 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 would be reviewing SE Reports as under the proposed rule. However, we now only account for one review cycle for all SE Reports instead of up to three review cycles estimated for the proposed rule. Table 21 summarizes the staff and review times at baseline, under the proposed rule, and under this alternative.

Table 21. FDA staff and review time for reviewing all SE Reports in one review cycle

	With Rule	Alternative - 1 review cycle	Net change from proposed 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 21 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 proposed rule are between $0.3 million and $4.5 million, with a primary estimate of $1.4 million. Table 22 summarizes our review costs under this alternative.

Table 22. FDA review costs when reviewing all SE Reports in one review cycle

	Low	Medium	High
Number of SE Reports	100	250	400
Labor hours saved per SE Report	27.9	46.5	93.0

Review time cost-savings ($ millions)	$0.3	$1.4	$4.5

When we compare to our review times without the rule, our annualized review cost-savings increase from around $7.2 million under the proposed rule to around $8.6 million with this alternative at both 3 and 7 percent discount rates.

2. Extend the effective date of the rule

Extending the effective date of the proposed rule, if finalized, would 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 would 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 would experience no cost-savings prior to the effective date of the rule, and then would experience the same annual cost-savings as estimated for the proposed rule in each year after the effective date.

The annualized costs to industry under this alternative would be around $0.19 million at a 3 percent discount rate and around $0.20 million at a 7 percent discount rate using the primary estimates over 10 years. The annualized cost-savings to government falls from around $7.2 million to around $6.4 million at a 3 percent discount rate and to around $6.3 million at a 7 percent discount rate. Overall, this alternative would be associated with less benefits (measured as government cost-savings) than the proposed rule. This alternative reduced net benefits by around $0.8 million at a 3 percent discount rate and $1.0 million at a 7 percent discount rate.

3. Provide more than three review cycles and deficiency notifications for some 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 would 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 would 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 proposed rule. We assume that the number of staff reviewing each SE Report would not change under this alternative. Table 23 summarizes the staff and review times at baseline, under the proposed rule, and under this alternative.

Table 23. 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 proposed 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 23 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 proposed rule. The estimated annualized costs to government of this alternative are between $1.5 million and $20.3 million, with a primary estimate of $6.4 million compared to the proposed rule. Table 24 summarizes our review costs under this alternative.

Table 24. FDA review costs when reviewing SE Reports with more review cycles and deficiency letters

	Low	Medium	High
Number of SE Reports	100	250	400
Labor hours per SE Report	127.1	211.9	423.8
Review time cost-savings ($ millions)	($1.5)	($6.4)	($20.3)

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

When we compare to our review times without the rule, our primary annualized review cost-savings decrease from around $7.2 million under the proposed rule to around $0.9 million under this alternative at both 3 and 7 percent discount rates.

I. Uncertainty

In the final Deeming Rule, we announced a compliance policy for certain small-scale tobacco product manufacturers that may need additional time to comply with some requirements.[34] Specifically, we explained that we generally intend to grant small-scale tobacco product manufacturers additional time to respond to SE deficiency letters. We are uncertain how many small-scale tobacco product manufacturers there are, how many SE Reports they may submit, and how many SE Reports would be subject to an extension.

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

[34] FDA considers a "small-scale tobacco product manufacturer" to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less."

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. We request comment on any costs or cost-savings to industry we may have omitted.

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. 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.

This proposed rule would require applicants to choose a single predicate tobacco product that is in the same tobacco product category (e.g. smokeless) and sub-category (e.g. loose moist snuff) as the new tobacco product. We currently accept reports relying on a predicate tobacco product that is in a different tobacco product category and sub-category than the proposed new tobacco product. However, based on our experience reviewing these reports, it is unlikely that we would find a new tobacco product substantially equivalent to a predicate tobacco product in a different tobacco product category and sub-category. In addition, reports using multiple predicates or predicates in other tobacco categories take longer to review.

We are uncertain how many reports would have contained multiple predicates or predicate products in different categories or sub-categories in the absence of this rule. However, it is expected that using a single predicate from the same tobacco product category and sub-category will further reduce the time and resources needed to review SE Reports.

J. International Effects

The requirements of the proposed 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 foreign tobacco product firms who would submit SE Reports. We request comment on the number of foreign manufacturers of tobacco product who would submit SE Reports.

III. Small Entity Effects

We have examined the economic implications of this proposed rule for small entities as required by the Regulatory Flexibility Act. If a proposed rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this proposed rule would 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 proposed rule, serves as the Initial 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 proposed 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 proposed rule would 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 would 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 proposed rule would be designated under the North American Industry Classification System (NAICS) as "tobacco product manufacturers." Importers may be designated as wholesalers or retailers. Most tobacco product-importing wholesalers would be classified as "tobacco and tobacco product merchant wholesalers." Table 25 shows the Small Business Administration (SBA) size thresholds for small businesses in each of these categories, as well as the most comparable size categories available from the U.S. Census (Ref. [3] [SBA, 2016]; Ref. [4][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.

[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 Small Business Administration's definition of small is applicable to the small entity analysis required under the Regulatory Flexibility Act.

Table 25. 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

Table 26 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 "tobacco manufacturing" businesses with employees are small (Ref. [4]).[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 be definition be small, the Census understates the percentage of manufacturing firms that are small.

Table 26. 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 Tobacco Tax and Trade Bureau (TTB) data that are small is

[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 don't know for sure that this is the case.

the same as the percentage of tobacco manufacturing firms that are small; thus 164 (=171 x 0.96) small manufacturing establishments would be affected by this proposed 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 would greatly affect our estimates. We request comment on this assumption.

Based on Table 26 we also expect that most of the importers affected by this rule would be small. Using the proportion of tobacco and tobacco product merchant wholesalers that are small, 214 (=0.96 x 223) small importers would be affected by this rule.

B. Description of the Potential Impacts of the Proposed 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 proposed rule on small entities (Ref. [4]). This detailed data allows us to more closely match the SBA size standards to the Census employment categories.

The upper-bound estimate of annualized compliance costs for industry is around $329,818 at a 7 percent discount rate over 10 years. We divide these compliance costs among manufacturers and importers based on their frequency in the TTB entity data. Around $143,000 of the estimated annualized compliance costs are assigned to domestic manufacturers, and the other $187,000 of the estimated annualized costs are assigned to importers (= $329,818 x 171/(171+223) and = $329,818 x 223/(171+223)). Next, we distribute these compliance costs among firm size categories based on the detailed 2012 SUSB data. Finally, we compare these compliance costs to the estimated revenues from the 2012 SUSB data. Table 27 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 would have much lower costs.

Table 27. 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%	86	$190.4	$72,342	0.04%
	20 to 99	27	29.0%	50	$1,351.1	$41,558	0.003%
	100 to 499	9	9.7%	17	$838.7	$13,853	0.002%
	500 to 1,000	3	3.2%	6	N.A.	$4,618	N.A.
	1,000 to 1,500	3	3.2%	6	$2,294.3	$4,618	0.0002%
	0 to 1,500	89	95.7%	164	$4,674.5	$136,988	0.003%
	Total	93	100.0%	171	$41,049.5	$143,145	
424940	0 to 19	890	76.9%	171	$6,420.4	$143,471	0.002%
	20 to 99	178	15.4%	34	$10,569.3	$28,694	0.0003%
	100 to 199	42	3.6%	8	$6,585.0	$6,771	0.0001%
	200 to 499	23	2.0%	4	$7,565.9	$3,708	0.0000%
	500+	25	2.2%	5	$89,060.0	$4,030	0.00000%
	0 to 200	1110	95.9%	214	$23,574.8	$178,936	0.001%

	Total	1158	100.0%	223	$120,200.7	$186,674	

As shown in Table 27, the estimated annualized costs of the proposed rule for small entities fall below 0.1 percent of their annual revenues. Therefore, we propose to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities. We request detailed comment on this finding and on any significant impacts on small entities.

IV. References

The following references have been placed on display in the Division of Dockets Management (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] FDA, Center for Tobacco Products, Office of Regulations, *SE Burden Captured Under Deeming Rule [Memorandum]*, 2016.

[2] U.S. Bureau of Labor Statistics, "May 2016 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200 - Tobacco Manufacturing," May 2016. [Online]. Available: http://www.bls.gov/oes/. [Accessed October 2017].

[3] U.S. Small Business Administration, "Table of Size Standards," 2016. [Online]. Available: https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf. [Accessed March 2016].

[4] 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 describes the data sources and calculations for the impacts relating to the SE pathway for originally regulated tobacco products attributable to the statutory SE provisions as currently interpreted by FDA. We request comment on the estimates we provide in this Appendix.

A. Benefits

Prior to the enactment of the TCA, manufacturers of tobacco products could introduce new products onto the market without any review by FDA. After the enactment of the TCA, 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 TCA. 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 200 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 don't 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.

B. Costs

Number of originally regulated tobacco product SE Reports

As of December 2017, 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 around 3,500 provisional SE Reports and 2,500 regular SE Reports, as reflected in our tracking system.[38]

[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

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. Table 28 summarizes the number of SE Reports we received from 2010 to March 2015, and Table 29 summarizes the number of SE Reports we received from April 2015 to December 2017.

Table 28. Number of SE Reports submitted from 2010 to 2015

Year	Provisional SE	Regular SE
2010	26	
2011	3,491	265
2012	0	495
2013	0	131
2014	0	71
2015	0	89

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.
https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-product-submissions-received&fy=All

Table 29. Number of SE Reports submitted from 2015 to 2017

Year	Full SE	Streamlined SE
2015	73	867
2016	371	104
2017	98	20

Note: The 2015 data only covers April through December. CTP divided Regular SE Reports into two categories (full SE and streamlined SE) and began tracking them separately in April 2015.
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 in 2016 and 2017 to create a range. We use 2016 and 2017 because the reports submitted in these years reflect the types of SE Reports we expect to receive in the future. The average number of SE Reports submitted each month in 2017 is around 10; the number of full SE Reports submitted each month in 2016 is around 30.[39] Therefore, between 120 (= 10 x 12) and 360 (= 30 x 12) SE Reports have been submitted each year. We use a range from 100 to 400 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

[39] We recognize that basing the future estimates on the number of full SE Reports submitted in 2016 would yield an underestimate since at least some of the streamlined SE Reports were for product quantity changes.

Based on originally regulated products and in the absence of the proposed rule, our Center for Tobacco Products estimates that it would 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).[40] 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 data (Ref. [1]).

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 30 below.

Table 30. 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 proposed rule would 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 proposed rule.[41] We convert calendar days into business days to capture the number of working days spent on a report.[42] Without the rule, we estimate that our average review time for SE Reports equals around 249 business days.

[40] 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.
[41] 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.
[42] Business days are calculated by multiplying calendar days by 5/7.

Our Center for Tobacco Products also provided estimates on the number of staff that would be involved with SE reviews without the rule. We estimate that without the rule, an average of 5.6 staff would review each SE Report. Our Center for Tobacco Products 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 would take 0.02 (=1/50) of an FTE, and at the high end one SE Report would 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 Reports x 249 business days x 8 hours per day = 224 hours). Table 31 summarizes our review times in labor hours.

Table 31. 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 2010.

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 30.[43] 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 28 and Table 29. 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.[44] 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.

[43] 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/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM472328.pdf] 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.

[44] 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.

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 $38.08.[45] We double this to account for benefits and overhead, yielding and hourly labor cost of $76.16. Table 32 summarizes costs to industry to prepare SE Reports in each year.

Table 32. Industry costs for preparing SE Reports

Year	Low	Medium	High
2010	$69,309	$252,484	$435,658
2011	$10,012,519	$36,474,178	$62,935,836
2012	$1,319,541	$4,806,900	$8,294,260
2013	$349,212	$1,272,129	$2,195,046
2014	$189,268	$689,475	$1,189,682
2015	$5,025,682	$5,025,682	$5,025,682
2016	$6,493,743	$6,493,743	$6,493,743
2017	$1,695,411	$1,695,411	$1,695,411
2018	$266,574	$3,484,503	$6,702,432
2019	$266,574	$3,484,503	$6,702,432
2020	$266,574	$3,484,503	$6,702,432
2021	$266,574	$3,484,503	$6,702,432
2022	$266,574	$3,484,503	$6,702,432
2023	$266,574	$3,484,503	$6,702,432
2024	$266,574	$3,484,503	$6,702,432
2025	$266,574	$3,484,503	$6,702,432
2026	$266,574	$3,484,503	$6,702,432
2027	$266,574	$3,484,503	$6,702,432
2028	$266,574	$3,484,503	$6,702,432

To estimate FDA costs to review SE Reports, we use the range of hours for review in Table 31. In valuing FDA time, we use a wage based on full-time equivalent (FTE) employees. We use a fully-loaded cost per FTE of $120 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.

[45] The calculation is 0.3*($28.79) + 0.2*($45.90) + 0.3*($19.27) + 0.2*($72.42) = $38.08.

As of December 2017, we have taken final actions on around 1,050 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 final action occurs. Some FDA costs may be incurred earlier than the calendar year in which final 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.[46] 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. 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 1,000 provisional SE Reports from 2018 to 2028.[47] These are simplifying assumptions. Table 33 summarizes the number of actual and estimated provisional SE Report final actions by year.

Table 33. Number of provisional SE Report final actions by year

Year	Provisional SE Report final actions
2010	0
2011	0
2012	0
2013	0
2014	399[1]
2015	194
2016	297
2017	157
2018	91
2019	91
2020	91
2021	91
2022	91
2023	91
2024	91
2025	91
2026	91
2027	91
2028	91

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

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

[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.

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 34.

Table 34. FDA costs for reviewing SE Reports for Originally Regulated Products

Year	Low	Medium	High
2010	$0	$0	$0
2011	$7,138,646	$15,467,066	$23,795,486
2012	$13,334,451	$28,891,311	$44,448,171
2013	$3,528,915	$7,645,983	$11,763,051
2014	$12,660,994	$27,432,154	$42,203,314
2015	$48,650,544	$51,986,402	$55,322,259
2016	$44,115,933	$53,450,049	$62,784,165
2017	$13,567,917	$18,502,113	$23,436,309
2018	$5,142,764	$24,611,797	$44,080,831
2019	$5,142,764	$24,611,797	$44,080,831
2020	$5,142,764	$24,611,797	$44,080,831
2021	$5,142,764	$24,611,797	$44,080,831
2022	$5,142,764	$24,611,797	$44,080,831
2023	$5,142,764	$24,611,797	$44,080,831
2024	$5,142,764	$24,611,797	$44,080,831
2025	$5,142,764	$24,611,797	$44,080,831
2026	$5,142,764	$24,611,797	$44,080,831
2027	$5,142,764	$24,611,797	$44,080,831
2028	$5,142,764	$24,611,797	$44,080,831

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 2019 as Year 1 to match our main analysis of this proposed rule. Therefore, 2010 is Year -8 and 2028 is Year 10. We estimate the costs of preparing and reviewing SE

Reports for the 19 years from 2010 to 2028. The present discounted value of costs of SE Reports for originally regulated products ranges from around $231 million to $885 million, with a primary estimate of $558 million at a 3 percent discount rate, and from around $249 million to $883 million, with a primary estimate of $566 million at a 7 percent discount rate. The annualized cost over this period ranges from around $16 million to $62 million, with a primary estimate of $39 million at a 3 percent discount rate, and from around $24 million to $85 million, with a primary estimate of $55 million at a 7 percent discount rate.