DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Certain Tobacco Products

Docket No. FDA-2024-N-1111

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

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## Executive Summary

This proposed rule, if finalized, would require an ACE filer to submit the STN for tobacco products submitted for any entry containing ENDS tobacco product(s) at the time of entry in the ACE or any other EDI system authorized by Customs and Border Protection (CBP). Benefits of the rule would be cost savings for the federal government and industry from reducing FDA's time spent on obtaining the STN of each ENDS product contained in the entry. We discuss these benefits qualitatively. We quantify costs to ACE filers of import entries containing ENDS products from reading and understanding the rule as well as obtaining and submitting the STN for these ENDS product(s). We estimate that the present value of costs of the rule over 10 years would range from $0.021 million to $0.061 million at a 2 percent discount rate, with a primary estimate of $0.041 million. The annualized costs would range from $0.002 million to $0.007 million, with a primary estimate of $0.005 million.

Table of Contents

## I. Introduction and Summary

### A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, 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, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of OIRA [the Office of Information and Regulatory Affairs] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this proposed rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Small businesses would be affected by the rule in the same way as non-small businesses. Small businesses would bear the costs of the rule, if finalized, but would also enjoy most of the benefits. Because small entities would face minor one-time costs relative to their firm revenue to read the rule and to submit the required data, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $183 million, using the most current (2023) 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 of Costs and Benefits

This proposed rule, if finalized, would require an ACE filer[1] to submit the Submission Tracking Number (STN) for tobacco products submitted for any entry

1 An ACE filer is defined in 21 CFR 1.71 to mean the person who is authorized to submit an electronic import entry for an FDA-regulated product in the Automated Commercial Environment or any other CBP-authorized EDI system.

containing Electronic Nicotine Delivery System (ENDS) tobacco product(s) at the time of entry in the Automated Commercial Environment (ACE) or any other electronic data interchange (EDI) system authorized by U.S. Customs and Border Protection (CBP). This information is important data for FDA to efficiently verify premarket authorization for the ENDS product in the entry.

If the STN is not voluntarily submitted in ACE at the time of entry, FDA needs to conduct a manual review, which includes contacting the ACE filer or importer to obtain the STN of each ENDS product contained in the entry. The manual admissibility review slows FDA import admissibility decisions. Thus, by reducing FDA's time spent on obtaining the STN of each ENDS product contained in the entry, we expect this rule to generate benefits in the form of cost savings for the federal government and industry. The proposed rule, if finalized, would result in a more effective and efficient admissibility review by FDA of those entry lines containing an ENDS product. Industry may also benefit from the reduced time spent by FDA in making admissibility determinations on ENDS products contained in an entry.

ACE filers of import entries containing ENDS products would face costs to read and understand the rule as well as to obtain and submit the STN for the ENDS product(s) imported or offered for import. These costs would occur only once for each unique entity and ENDS product combination as a requirement upon initial submission of the STN, as explained later in this document.

Table 1 summarizes the estimated benefits and costs of this proposed rule, if finalized. Because we lack information to quantify expected benefits of the rule, Table 1 presents them qualitatively. We expect that the rule would result in cost savings to both industry and FDA from more efficient and effective import admissibility review. We estimate that the present value of costs of the rule over 10 years would range from $0.021 million to $0.061 million at a 2 percent discount rate, with a primary estimate of $0.041 million. The estimated annualized costs of this rule over a 10-year period would range from $0.002 million to $0.007 million at a 2 percent discount rate, with a primary estimate of $0.005 million.

**Table 1. Summary of Benefits, Costs and Distributional Effects of Proposed Rule (Millions of 2022 Dollars)**

| *Category* | *Primary Estimate* | *Low Estimate* | *High Estimate* | *Dollar Year* | *Discount Rate* | *Time Horizon* | *Notes (e.g., Risk Assumptions; Source Citations; Whether Inclusion of Capital Effects Differs Across Low, Primary, High Estimates; etc.)* |
|---|---|---|---|---|---|---|---|

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| *BENEFITS* | | | | | | | |
| Annualized monetized benefits | | | | | 2% | | |
| Annualized quantified, but non-monetized, benefits | | | | | | | |
| | | | | | | | |
| Unquantified benefits | Cost savings to federal government and industry from more efficient and effective import review. | | | | | | |
| *COSTS* | | | | | | | |
| Annualized monetized costs | $0.005 | $0.002 | $0.007 | 2022 | 2% | 10 | |
| Annualized quantified, but non-monetized, costs | | | | | | | |
| Unquantified costs | | | | | | | |
| *TRANSFERS* | | | | | | | |
| Annualized monetized Federal budgetary transfers | | | | | 2% | | |
| *Bearers of transfer gain and loss?* | | | | | | | |
| Other annualized monetized transfers | | | | | 2% | | |
| *Bearers of transfer gain and loss?* | | | | | | | |
| *NET BENEFITS* | | | | | | | |
| Annualized monetized net benefits | | | | | 2% | | |

| *Category* | *Effects* | *Notes* |
|---|---|---|
| Effects on State, local, or Tribal governments | None | |
| Effects on small businesses | None | |
| Effects on wages | None | |
| Effects on growth | None | |

## C. Terminology

In Table 2, we provide definitions for several terms we use in this document. We note that these definitions only apply to this document.

**Table 2. Terms used in the Regulatory Impact Analysis**

| Term | Description |
|---|---|
| ABI | Automated Broker Interface. |
| ACE | Automated Commercial Environment or any other CBP-authorized EDI system. |
| ACE Filer | The person who is authorized by CBP to submit an electronic import entry for an FDA-regulated product in ACE, as defined in 21 CFR 1.71. |
| CBP | U.S. Customs and Border Protection |
| Deeming Rule | We use this term to refer to the 2016 final rule titled "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." The Deeming Rule deemed products meeting the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the tobacco product provisions of Chapter IX of the FD&C Act, including ENDS. |
| EDI | Electronic Data Interchange |
| ENDS | FDA generally considers "ENDS" to be electronic nicotine delivery systems that deliver aerosolized e-liquid when inhaled, including components and/or parts of ENDS (e.g., e-liquids, cartridges/pods, tanks). |
| EX REQ | A request for exemption from demonstrating a tobacco product is substantially equivalent under 21 CFR 1107.1. |
| FDA | U.S. Food and Drug Administration |
| FD&C Act | Federal Food, Drug and Cosmetic Act |
| MGO | A marketing granted order is the order described in section 910(c)(1)(A)(i) of the FD&C Act stating that the new tobacco product may be introduced or delivered for introduction into interstate commerce. |
| PREDICT | FDA's Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting system. |

| | |
|---|---|
| PMTA | A Premarket Tobacco Product Application means the application described in section 910(b) of the FD&C Act. This term includes the initial premarket tobacco product application and all subsequent amendments. |
| SE Report | Substantial Equivalence Report means a submission under section 905(j)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act that includes the basis for the applicant's determination that a new tobacco product is substantially equivalent to a predicate tobacco product. This term includes the initial substantial equivalence report and all subsequent amendments. |
| STN | Submission Tracking Number for ENDS tobacco products (the application number that FDA assigns to submissions such as a PMTA, supplemental PMTA, Substantial Equivalence (SE) report, or Exemption from Substantial Equivalence Request (EX REQ) for ENDS tobacco products), as defined in 21 CFR 1114.3. |
| TST | Affirmation of Compliance Code in ACE for the Submission Tracking Number for tobacco products. |
| Unique ENDS product | A particular combination of manufacturer, product code, and ACE filer for an ENDS product. |

## II. Preliminary Economic Analysis of Impacts

### A. Background

The Federal Food, Drug and Cosmetic Act (FD&C Act) generally requires that manufacturers of a new tobacco product, including ENDS products,[2] apply for premarket review and receive premarket authorization of their product through one of three pathways – SE, exemption from SE (EX REQ), or a PMTA before entering the U.S. market. The premarket authorization requirements of Chapter IX of the FD&C Act apply to all new tobacco products, including ENDS products (including electronic cigarettes and e-liquids).

Tobacco products imported or offered for import into the U.S., including ENDS products, must comply with all applicable statutory and regulatory requirements, including the premarket authorization requirements of Chapter IX of the FD&C Act. A

[2] Section 910(a)(1) of the Tobacco Control Act of 2009 states, "For purposes of this section the term 'new tobacco product' means— (A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007."

new tobacco product that does not have an FDA Marketing Granted Order (MGO) in effect under section 910(c)(1)(A)(i) of the FD&C Act and is not otherwise exempt from the premarket review requirement is adulterated pursuant to section 902(6)(A) of the Act. In addition, a new tobacco product is misbranded under section 903(a)(6) of the FD&C Act if a notice or other information respecting the product was not provided as required by section 905(j) of the FD&C Act. Tobacco products offered for import into the U.S. that appear to be adulterated and/or misbranded are subject to refusal under section 801(a)(3) of the FD&C Act.

In 2016, FDA issued a final rule[3] to establish requirements for the electronic filing of entries of FDA-regulated products in ACE or any other EDI system authorized by CBP, in order for the entry to be processed by CBP and to help FDA in determining admissibility of that product. ACE is a commercial trade processing system operated by CBP that is designed to implement the International Trade Data System, automate import and export processing, enhance border security, and foster U.S. economic security through lawful international trade and policy.

The 2016 ACE final rule required the submission of certain data elements in ACE. This entry data would be transmitted by ACE to FDA's import systems in order to facilitate FDA's process of making an admissibility decision on certain FDA-regulated commodities imported or offered for import into the United States. In addition to mandatory data elements, some data elements are optional for an ACE filer to submit in ACE at the time of entry. Currently, the Affirmation of Compliance for an STN assigned by the Agency to the application for premarket review for an ENDS product under section 910 of the FD&C Act is optional.[4] Submission of the complete and accurate STN allows FDA to efficiently make admissibility decisions for the ENDS products.

## B. Need for Federal Regulatory Action

As part of admissibility review, FDA reviews the marketing status for any ENDS product contained in the entry. While importers of ENDS products have private incentives to comply with all applicable FDA laws and regulations, private incentives may not be sufficient for firms to provide the optimal amount of information to FDA about their imports.

As described above, the submission of the STN for tobacco products in ACE at the time of entry, is currently optional. If an accurate STN is not submitted in ACE, FDA cannot use an automated look up to verify the status of the ENDS product. In this case,

[3] Submission of Food and Drug Administration Import Data in the Automated Commercial Environment, 81 FR 85854 (Nov. 29, 2016).

[4] The following three pathways are available to apply to FDA for authorization to legally market a tobacco product in the U.S.: Premarket Tobacco Product Application (PMTA), Substantial Equivalence (SE), and Exemption from Substantial Equivalence (EX REQ). To date, premarket applications for ENDS products have mostly been submitted through the PMTA pathway.

FDA needs to conduct a manual review to determine admissibility of such ENDS products, which slows FDA import decisions.

ACE filers who do not submit an STN in ACE at the time of entry also face delays in receiving an FDA admissibility decision and may require additional time and resources to provide this information to FDA. Despite these delays, we have found that, currently, ACE filers have generally not voluntarily submitted this information in ACE for an ENDS product at the time of entry. As long as the STN is an optional submission in ACE, a reliance on private incentives alone is therefore unlikely to result in the socially optimal level of information necessary for efficient FDA admissibility review. Federal regulatory action would fill this information gap, supporting FDA's ability to protect public health through more efficient admissibility determinations and reduce delays for ENDS importers. This rule, therefore, would improve government operations and service delivery.

## C. Purpose of the Proposed Rule

If finalized, this proposed rule would require that the ACE filer submit in ACE, at the time of entry, the Tobacco Submission Tracking Number (the Affirmation of Compliance code "TST") for ENDS product(s) that are imported or offered for import into the U.S. Specifically, "TST" requires the STN for the premarket application for an entry containing an ENDS product to be submitted in ACE at the time of entry. The STN is assigned by the Agency to the application for premarket review for an ENDS product under section 910 of the FD&C Act and is currently an optional submission in ACE.

The purpose of the rule is to assist the FDA in making decisions on admissibility for ENDS products by facilitating FDA's automated review process. The proposed rule, if finalized, would result in more effective and efficient admissibility review by FDA of those entry lines containing an ENDS product.

## D. Baseline Conditions

### 1. Description of the Baseline

This proposed rule aims to help facilitate FDA's import review and increase the likelihood of an entry receiving an automated "May Proceed." An automated "May Proceed" does not constitute a determination by FDA about the article's compliance status, and it does not preclude FDA action at a later time.

Submitting the STN for tobacco products in ACE at the time of entry is currently optional for ACE filers offering finished ENDS products, including ENDS components or parts, for import. Without regulatory action, the baseline for this analysis assumes that this data element would continue to be optional for these products. Our analysis therefore

accounts for the incremental costs related to requiring the submission of the STN in ACE and the cost savings related to more efficient import admissibility review by FDA.

2. The Cost of Labor

Following guidelines from the U.S. Department of Health and Human Services [1], we estimate the cost of labor as the fully-loaded wage. The fully-loaded wage is the hourly wage including benefits and overhead, which is assumed to be 100 percent of the mean wage. For industry wages, we use 2022 Bureau of Labor Statistics (BLS) national industry-specific occupational employment and mean wage estimates for the wholesale trade industry [2].[5] Table 3 presents the mean wages and fully-loaded wages used in this analysis.

**Table 3. Wages Used to Evaluate the Cost of Labor**

| Occupation Type | Dollar Year | Wage ($) | Fully-Loaded Wage ($) |
|---|---|---|---|
| Management | 2022 | $66.94 | $133.88 |
| Legal | 2022 | $79.76 | $159.52 |
| Office and Administrative Support | 2022 | $22.56 | $45.12 |

3. Baseline and Projected Estimates of Covered Entities

CBP determines who is authorized to file an entry in ACE. ACE Filers can be an importer of record (an owner, purchaser, or consignee) or a customs broker licensed by CBP, who is hired by the importer to file the entry. If importers find that it would more cost effective to delegate some of the tasks borne by this rule to customs brokers in exchange for a fee, they may choose to delegate this burden to brokers instead of completing these tasks by themselves.

Covered entities are ACE filers that import finished ENDS products including ENDS components or parts of ENDS products, sealed in final packaging or in the final form in which they are intended to be sold to consumers.[6] ACE filers are persons who are authorized to submit an electronic import entry for an FDA-regulated product in ACE, as defined in 21 CFR 1.71. We expect that the STN information would need to be entered in ACE only once for each particular ACE filer-manufacturer-product combination, which we define as a Unique ENDS product for the purposes of in this document. Table 4 summarizes the number of import lines, ACE filers, and Unique ENDS products expected

[5] We use the mean hourly wage for legal occupations (code 23-0000), management occupations (code 11-0000), and office and administrative support staff occupations (code 43-0000).
[6] We identify these products through the Process Indicator Code (PIC) and Class. Data for finished (PIC A) ENDS (Class L) products or finished (PIC A) ENDS component or part (Class M) products were pulled for use in this analysis. For more information, see https://www.fda.gov/industry/import-program-tools/product-codes-and-product-code-builder.

to be affected by the rule. We request comment on alternative approaches for identifying the number of Unique ENDS products.

We use FDA import data from 2018-2021[7] to project future trends in imported products over a 10-year time horizon but note that import trends before 2020 may not be a good predictor of future trends due to changes in the ENDS market during this time period. On August 8, 2016, all deemed tobacco products, including ENDS, became subject to FDA's tobacco authorities, including premarket authorization requirements.

We estimate that from 2018-2021, the number of import lines that would have been subject to the proposed regulation decreased by an average of 19 percent per year.[8] Due to the large variation in year-to-year changes, we use low and high estimates for ACE filers and Unique ENDS products. The number of ACE filers for ENDS imports increased by an average of 9 percent per year between 2018 and 2021. The largest one-time increase occurred from 2018 to 2019 (23 percent), with a smaller increase from 2019 to 2020 (6 percent) and a decrease from 2020 to 2021 (-1 percent). For ACE filers, we therefore use 9 percent as our upper bound estimate, and a lower bound where the number of ACE filers is constant over time. The number of Unique ENDS products decreased by 20 percent on average from 2018 to 2021, with a decrease of 7 percent from 2018 to 2019, a decrease of 17 percent from 2019 to 2020, and a decrease of 36 percent between 2020 and 2021. We use the minimum decrease of 7 percent as our upper bound. Because the maximum decrease of 36 percent could be driven by the September 9, 2020, court-ordered deadline[9] for PMTAs, we use the average decrease over the full time period (20 percent) as our lower bound. Based on historical review of premarket applications for ENDS products, FDA expects the vast majority of premarket applications for ENDS products to be submitted through the PMTA pathway.

We request comment on these projections and other shocks or trends, such as past and potential future changes in the market and consumption, that may influence the expected number of covered entities and unique ENDS products over time.

[7] Prepared by the U.S. FDA, Office of Regulatory Affairs, Division of Import Operations, Import Operations Branch on March 30, 2022.

[8] It is unclear to what extent the effects of Coronavirus disease 2019 (SARS-CoV-2, or COVID-19) and related mask mandates and stay-at-home orders affected the number of ENDS import lines, ENDS industry, use, and prevalence. For example, while we see a small spike in the number of ENDS import lines in 2020, the overall trend is decreasing. We did not adjust the projected number of ENDS import lines, ACE filers, and Unique ENDS products to account for COVID-19 impacts.

[9] On July 11, 2019, the United States District Court for the District of Maryland ordered the FDA to require manufacturers of e-cigarettes and other deemed new tobacco products that were on the market as of August 8, 2016, to submit applications for premarket review by May 12, 2020. Due to the COVID-19 pandemic, FDA requested the deadline be extended to September 9, 2020, and the court granted the request.

**Table 4. The Projected Number of ENDS Import Lines, ACE Filers, and Unique ENDS Products Covered by the Rule over a 10-year period.**

| Year | Number of import lines | Number of ACE filers | | Number of Unique ENDS products | |
|---|---|---|---|---|---|
| | | Low | High | Low | High |
| **1** | 55,337 | 177 | 177 | 10,766 | 10,766 |
| **2** | 44,823 | 177 | 193 | 8,613 | 9,996 |
| **3** | 36,307 | 177 | 210 | 6,890 | 9,282 |
| **4** | 29,408 | 177 | 229 | 5,512 | 8,618 |
| **5** | 23,821 | 177 | 250 | 4,410 | 8,002 |
| **6** | 19,295 | 177 | 272 | 3,528 | 7,430 |
| **7** | 15,629 | 177 | 297 | 2,822 | 6,899 |
| **8** | 12,659 | 177 | 324 | 2,258 | 6,405 |
| **9** | 10,254 | 177 | 353 | 1,806 | 5,947 |
| **10** | 8,306 | 177 | 384 | 1,445 | 5,522 |

4. Baseline ACE Submissions and Import Admissibility Review

Currently, ACE filers have the option to input the STN in ACE, at the time of entry, when offering an ENDS product for import. As described above, the STN is assigned to the application for premarket review for an ENDS product under section 910 of the FD&C Act. Importers may delegate this task to customs brokers in exchange for a fee. ACE filers submit import entry data in ACE using software that is connected to the Automated Broker Interface (ABI) for the ACE system. Submitting import entry information to ACE requires the importer and/or customs broker to locate the source of the data, prepare it for entry into ACE, and enter it using the ACE filer's software program for ACE. Once entry information has been entered for a Unique ENDS product, this information can be automatically applied to future import entries associated with that specific product.

ACE electronically transmits the data submitted by an ACE filer at the time of entry to FDA's import systems. The entry data is initially screened using FDA's Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT), a risk-based electronic screening tool, to determine if manual review of the entry is needed. If the PREDICT review indicates that manual review is necessary, FDA personnel will review the entry information submitted by the ACE filer and may request additional information to make an admissibility determination and/or may seek to examine or sample the FDA-regulated product(s) in the entry before making an admissibility decision. As discussed previously, if manual review is not needed, FDA can use an automated admissibility review process to issue a "May Proceed" to CBP in the ACE system.

Entries containing ENDS products without submission of the STN trigger a manual review process. Entries that contain the STN may facilitate use of an automated

admissibility review that compares the entry information submitted by the ACE filer in ACE to the information in FDA's internal database.

According to our internal records, there were no STNs submitted by ACE filers for ENDS products from January1, 2021 to June 30, 2023. We assume that at baseline, ACE filers would continue not to voluntarily submit the STN for each imported ENDS product in ACE at the time of entry.

## E. Benefits of the Proposed Rule

The proposed rule, if finalized, would result in a more effective and efficient admissibility review by FDA of those import entry lines containing an ENDS product. Because we lack information to quantify expected benefits of the proposed rule, we discuss them qualitatively.

We expect that this rule would result in cost savings to both industry and FDA. FDA would benefit from a decrease in the amount of time and resources spent on manual admissibility review by gaining the ability to use an automated admissibility process for ENDS products. Currently, because the STN is not being voluntarily submitted in ACE at the time of entry, FDA needs to conduct a manual review, which slows FDA import decisions and introduces inefficiencies into the import admissibility process for ENDS products. Automated review made possible by the STN data element submitted by ACE filers into ACE would also allow for more efficient identification of ENDS products. By reducing FDA's time and resources spent on manual admissibility review for ENDS products imported or offered for import, this rule would result in cost savings. Industry may also benefit from reduced verification time and delays for admissibility determinations. By accurately providing FDA with the STN information in ACE, most ENDS importers may potentially be able to receive an automated 'May Proceed' from FDA, which is faster because of more efficient import entry processing by FDA, and potentially reduce the probability of having to submit additional information to FDA after the initial submission in ACE at the time of entry. These benefits to industry would also be in the form of cost savings.

## F. Costs of the Proposed Rule

Covered entities would face costs to read and understand the rule as well as to prepare and enter the required information for each Unique ENDS product imported or offered for import into the U.S. These costs would occur only once for each entity and product. In the first year following the rule's effective date, all covered entities importing affected products would incur these costs for new shipments. In subsequent years, importers would only incur the costs of submitting an STN for a unique ENDS product for the first time.

In Table 4, we presented the expected number of covered entities and products over time. Though the number of Unique ENDS products is projected to decrease over

time, we assume that there will be some turnover of entities and products in this market that results in the both the exit and re-entry of entities/products covered at baseline as well as the potential entry of new entities/ENDS products over time. Of the projections in Table 4 that shows a steady increase of new ACE filers, we also assume 5.2 percent increase in newly imported ENDS products after the first year of the rule. We base this estimate on the average annual percent change in total U.S. real Gross Domestic Product for imported goods during the period between 2011 and 2021[10], which we use as a proxy for how the market for imported goods is growing over time [2]. Table 5 presents the number of ACE filers and unique ACE filer-manufacturer-products that would face costs each year. We request comment on this methodology and how the expected number of covered entities and products may change over time.

We also note that the low columns of Table 5 assume that, even if the number of ACE filers is stagnant, those existing filers could import new Unique ENDS products over time, which might result in a non-zero number of future products affected by the rule. However, if the number of ACE filers is decreasing and/or existing ACE filers introduce no new Unique ENDS products in the future, the lower bound estimate of those products would be overestimated.

**Table 5. ENDS Import Lines, ACE filers, and Unique ENDS Products Expected to Incur Costs over a 10-year Period.**

| Year | Number of ENDS import lines | Number of ACE filers | | Number of Unique ENDS products | |
|---|---|---|---|---|---|
| | | Low | High | Low | High |
| **1** | 55,337 | 177 | 177 | 10,766 | 10,766 |
| **2** | 2,878 | 0 | 16 | 448 | 520 |
| **3** | 2,331 | 0 | 17 | 358 | 483 |
| **4** | 1,888 | 0 | 19 | 287 | 448 |
| **5** | 1,529 | 0 | 21 | 229 | 416 |
| **6** | 1,239 | 0 | 22 | 183 | 386 |
| **7** | 1,003 | 0 | 25 | 147 | 359 |
| **8** | 813 | 0 | 27 | 117 | 333 |
| **9** | 658 | 0 | 29 | 94 | 309 |
| **10** | 533 | 0 | 32 | 75 | 287 |

1. One-Time Costs to Read and Understand the Rule

[10] Because the future growth rate of new ACE filers and newly imported ENDS products is unknown, we use a distribution to set a range. For the period between 2011 and 2021, we estimate an average growth rate of 5.2 percent per year as a mean of the Pert distribution with the following parameters: minimum growth rate of 0.6 percent per year (from 2019), most likely growth rate of 3.8 percent per year (the average from 2011-2021), and maximum growth rate of 14.6 percent per year (from 2021). We exclude 2020, in which the percent change was -5.9 percent, due to the impact of the COVID-19 pandemic on imported goods.

All entities affected by this proposed rule, if finalized, would spend time to read and understand the final rule, resulting in a one-time cost. The proposed preamble and codified together contain approximately 7,000 words, which we use to approximate the length of the final rule. Consistent with HHS guidance, we assume that industry reviewers read at the average adult reading speed of approximately 250 words to 200 words per minute, so the time to read and understand the regulation would range from 0.47 hours to 0.58 hours per person [1]. We assume that one to two reviewers would read the final rule per ACE filer. We request comment on this assumption.

To value the time associated with reading and understanding the rule if finalized, we use composite wages drawn from Table 3. We use a blend of 50 percent management occupations and 50 percent legal occupations. We average the fully-loaded wages to account for benefits and other indirect costs, yielding a composite wage of $146.70.[11]

In Table 6, we estimate the cost for one reviewer to read the rule, if finalized, to range from $68.95 to $85.09. Depending on the number of reviewers, these costs would range from $68.95 to $170.17 for each affected entity.

**Table 6. One-Time Costs for Reading and Understanding the Rule (2022 Dollars)**

| | **Low** | **High** |
|---|---:|---:|
| Word count | 7,000 | 7,000 |
| Average reading speed (words per minute) | 250 | 200 |
| Reading time (hours) | 0.47 | 0.58 |
| Composite wage (per hour) | $146.70 | $146.70 |
| Cost per industry reviewer | $68.95 | $85.09 |
| Number of reviewers per entity | 1 | 2 |
| Cost per entity | $68.95 | $170.17 |
| Number of entities | 177 | 177 |
| **Total cost** | $12,204 | $30,120 |

In Table 6 we multiply our lower and upper bound costs by the lower and upper bound estimates of covered entities in Table 5. We assume these costs will occur in year one, the year the final rule becomes effective. These costs range from a total of $12,204 to $30,120, with a midpoint of $21,162. For the high estimate, we assume that after the first year new entrants into the ENDS import market would primarily rely on the already knowledgeable customs brokers to communicate to them the requirements to submit STN in ACE. We attribute these costs to new entrants as a usual and customary start-up business cost and do not include them in this analysis. We request comment on this assumption.

[11] The management occupation fully-loaded wage is $133.88 per hour, and the legal occupation fully-loaded wage is $159.52 per hour. The calculation is 0.5 x ($133.88) + 0.5 x ($159.52) = $146.70.

2. One-Time Costs to Enter Mandatory Import Data

If finalized, importers of ENDS products will face one-time costs to retrieve and submit the STN for tobacco products for an imported ENDS product submitted in ACE at the time of entry. The importer is responsible for complying with this regulation, though importers may delegate this task to a customs broker in exchange for a fee.

In the first year, for a Unique ENDS product, an importer will need to identify the information mandated by this rule and prepare this information for submission into ACE or provide the STN to its customs broker for submission in ACE at the time of entry. Importers will need an administrative worker to prepare the additional information required for each new Unique ENDS product and complete the entry declarations using software that is connected to the ABI for the ACE system.[12] We assume that once this information has been entered for a Unique ENDS product, it will automatically apply to all import lines associated with that product in future entries submitted to ACE.

For each import line containing a Unique ENDS product covered by this proposed rule, we assume time would be spent by an administrative worker on obtaining the STN, including reaching out to the ENDS manufacturer(s) if necessary; logging into their software for the ACE system; submitting the STN to ACE; and, if applicable, sending the updated STN to its customs broker for submission in ACE at the time of entry. Once the STN is gathered and entered into the filer's and/or custom broker's ACE software, we assume that it does not need to be gathered again by the filer and/or customs broker for any subsequent entry containing the same Unique ENDS product. We expect these data retrieval and entry costs to occur in the year that the proposed rule, if finalized, becomes effective for all ENDS products imported or offered for import at baseline. In each subsequent year, any additional time spent preparing the required information would depend on the number of new unique ENDS product combinations imported or offered for import.

The 2016 ACE final rule assumed that preparing data elements for the first time could range from a few seconds to several minutes, depending on the complexity and location of the information. We assume that importers have the complete and accurate STN readily available and that they will not need to contact manufacturers or other entities to obtain this data element. We request comment on this assumption. Likewise, we assume that importers would provide a complete and accurate STN to any customs brokers they hire to submit an entry containing a covered ENDS product in ACE. Finally, we assume that this time includes quality checks to ensure the accuracy of the STN submitted in ACE at the time of entry. Some of this verification may be manual verification by importer staff or messaging from FDA reviewers that an incorrect STN was submitted in ACE at the time of entry.

[12] ACE filers use certain privately-issued software that interfaces with the ABI to submit data for entries in ACE at the time of entry.

Based on the 2016 ACE final rule, we assume the time needed to locate, prepare, enter, and quality check the STN for the ENDS product offered for import would range from one to three minutes per Unique ENDS product. Using the fully-loaded hourly wage of an administrative worker from Table 3 ($45.12), the cost per each Unique ENDS product would range from $0.75 (=1 minute x ($45.12/60)) to $2.26 (=3 minutes x ($45.12/60)). As presented in Table 7, we multiply these low and high estimates by the low and high estimates of Unique ACE ENDS products in Table 5. The resulting estimates show how the total costs for all affected ENDS products change over a 10-year period, ranging from a total of $9,528 to $32,334, where the midpoint of this range is $20.931. The majority of these costs occur in the first year the final rule becomes effective, as ACE filers input the STN in their software for ACE in preparation for submission into ACE at the time of entry. In subsequent years, importers incur these costs only for new Unique ENDS products.

**Table 7. Costs Over a 10-year Period for Retrieving, Updating, and Entering Information in Internal Databases for Use with ACE (2022 Dollars)**

| Year | Total costs for all affected products | |
|---|---|---|
| | Low | High |
| 1 | $8,075 | $24,331 |
| 2 | $336 | $1,175 |
| 3 | $269 | $1,092 |
| 4 | $215 | $1,012 |
| 5 | $172 | $940 |
| 6 | $137 | $872 |
| 7 | $110 | $811 |
| 8 | $88 | $753 |
| 9 | $71 | $698 |
| 10 | $56 | $649 |
| **Total cost** | **$9,528** | **$32,334** |

4. Total Quantified Costs

Table 8 summarizes the undiscounted costs of the rule over a 10-year period. We expect affected entities to incur costs starting in year one, which is the year the rule becomes effective. Total estimated undiscounted costs range from $21,732 to $62,454, with a midpoint of $42,093.

**Table 8. Streams of Undiscounted Costs Due to the Proposed Rule over a 10-year Period (2022 Dollars)**

| Year | Reading and understanding the rule | Retrieving, updating, and entering import data into internal software for ACE | Total costs |
|---|---|---|---|

| | Low | High | Low | High | Low | High |
|---|---|---|---|---|---|---|
| 1 | $12,204 | $30,120 | $8,075 | $24,331 | $20,278 | $54,452 |
| 2 | $0 | $0 | $336 | $1,175 | $336 | $1,175 |
| 3 | $0 | $0 | $269 | $1,092 | $269 | $1,092 |
| 4 | $0 | $0 | $215 | $1,012 | $215 | $1,012 |
| 5 | $0 | $0 | $172 | $940 | $172 | $940 |
| 6 | $0 | $0 | $137 | $872 | $137 | $872 |
| 7 | $0 | $0 | $110 | $811 | $110 | $811 |
| 8 | $0 | $0 | $88 | $753 | $88 | $753 |
| 9 | $0 | $0 | $71 | $698 | $71 | $698 |
| 10 | $0 | $0 | $56 | $649 | $56 | $649 |
| **Total** | **$12,204** | **$30,120** | **$9,528** | **$32,334** | **$21,732** | **$62,454** |

Table 9 shows the presented discounted and annualized value of quantified costs over a 10-year period. We calculate the primary estimate from the midpoint of the low and high estimates. At a 2 percent discount rate, the present discounted costs range from approximately $21 thousand to $61 thousand, with a primary estimate of $41 thousand. The annualized costs range from approximately $2 thousand to $7 thousand, with a primary estimate of $5 thousand.

**Table 9. Present Discounted Value and Annualized Value of Quantified Costs Due to the Proposed Rule over a 10-year Period (2022 Dollars)**

| Costs | Discount Rate | Low | Primary | High |
|---|---|---|---|---|
| Present Discounted Value | 2% | $21,209 | $40,889 | $60,569 |
| Annualized Value | 2% | $2,361 | $4,552 | $6,743 |

## H. International Effects

In 2021, ENDS and ENDS components and parts were imported from roughly 40 countries of origin.[13] Because ACE filers of ENDS products are not currently voluntarily submitting the STN, we expect compliance costs to be spread across all importers regardless of country of origin of the ENDS product.

[13] Prepared by the U.S. FDA, Office of Regulatory Affairs, Division of Import Operations, Import Operations Branch on January 20, 2022.

## I. Uncertainty and Sensitivity Analysis

The largest source of uncertainty in this analysis is how the number of covered new importers and new Unique ENDS products may change over time. Though the number of Unique ENDS products has been declining over time, it is difficult to project future trends due to uncertainty in this market. It is also difficult to anticipate the number of new importers or new Unique ENDS products that may be introduced as consumer demand for ENDS changes. Additionally, recently FDA has proposed two rulemakings on tobacco product standards: one that would prohibit menthol in cigarettes and another that would prohibit characterizing flavors in cigars as well as a tobacco product manufacturing practices rule.[14] If finalized, these rules may influence future importation trends of ENDS products due to changes in tobacco product consumption. This analysis does not contemplate potential importation changes resulting from these proposed rules.

However, we note that even if we doubled our assumption about the expected growth rate of new importers, import lines, and ENDS products (from 5.2 percent per year to 10.4 percent per year), estimated costs remain similar to our main estimates in Table 9. With this higher growth rate, the present discounted value of costs over a 10-year period at a 2 percent discount rate ranges from $23 thousand to $68 thousand, with a primary estimate of $45 thousand. The annualized costs at a 2 percent discount rate range from $3 thousand to $8 thousand, with a primary estimate of $5 thousand.

## J. Analysis of Regulatory Alternatives to the Proposed Rule

FDA has identified and assessed a regulatory alternative to the proposed rule. If the effective date were to be delayed six months following the final rule's publication date, industry's compliance costs would also be delayed. This delay would result in a small decrease in total estimated costs. During the time it takes for the rule to go into effect, FDA would continue to conduct manual review of affected products and experience no benefits from increased efficiency.

# III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. To assess the proposed rule's economic impact on small entities, we estimate the number of affected small entities and compare their revenues with rule-related costs. Small businesses would be affected by the rule in the same way as non-small businesses. They would bear the costs of the rule, if finalized, but would also enjoy most of the benefits in a form of cost savings from potentially receiving an import admissibility decision faster. Because small entities would face minor one-time costs relative to firm revenue to read the rule and to submit the required data, we propose to certify that the proposed rule will not have a

[14] https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria

significant economic impact on a substantial number of small entities. We therefore do not provide additional regulatory options that would minimize the impact of the rule on small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

We use the wholesale trade agents and brokers industry[15] to identify entities that would be impacted by the rule. For this industry, the U.S. Small Business Administration defines small businesses as those with fewer than 100 employees.[16]

From the U.S. Census Bureau's 2017 Statistics of U.S. Businesses [4], approximately 99 percent of all wholesale trade and broker firms employ fewer than 125 employees. These small firms represent approximately 57-58 percent of total revenue in the wholesale trade agents and brokers industry. Table 10 presents the number of firms, total annual receipts, and average annual receipts per firm according to employment size categories. Values have been adjusted for inflation from 2017 to 2022 dollars. Because about 0.5 percent of all import lines are tobacco products[17], we expect only a small proportion of all small entities in the wholesale trade and brokers industry would be affected by the rule, as discussed in other sections of this document.

**Table 10. Employment Size and Revenue of Small Entities: Wholesale Trade and Brokers (2022 Dollars)**

| Employment Size | Number of Firms | Total Annual Receipts ($1,000) | Average Annual Receipts per Firm ($1,000) |
|---|---|---|---|
| <5 | 29,679 | $125,547,151 | $4,230 |
| 5-9 | 3,840 | $88,480,352 | $23,042 |
| 10-14 | 1,264 | $52,983,524 | $41,917 |
| 15-19 | 633 | $42,711,376 | $67,475 |
| 20-24 | 390 | $45,718,864 | $117,228 |
| 25-29 | 288 | $22,525,820 | $78,215 |
| 30-34 | 186 | $14,852,191 | $79,850 |
| 35-39 | 119 | $12,733,584 | $107,005 |
| 40-49 | 168 | $19,725,017 | $117,411 |
| 50-74 | 207 | $29,561,892 | $142,811 |

[15] North American Industry Classification System (NAICS) code 425120.
[16] The most recent size standards for "Wholesale Trade Agents and Brokers" are available in the U.S. Small Business Administration's Table of Small Business Size Standards Matched to North American Industry Classification System Codes, 25 (March 17, 2023), https://www.sba.gov/document/support-table-size-standards.
[17] Tobacco products represented 263,845 of 48,114,975 total import lines in 2021 and 229,477 of 51,241,458 total import lines in 2022. Yearly FDA import data is available here: https://datadashboard.fda.gov/ora/cd/impsummary.htm.

| | | | |
|---|---|---|---|
| 75-99 | 109 | $15,885,648 | $145,740 |
| 100-149 | 96 | $15,197,654 | $158,309 |

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

Small entities would face costs to read and understand the rule and to obtain the STN and submit it in ACE at the time of entry. To assess the magnitude of these costs relative to revenue, we use the smallest category of firms with less than five employees. As shown in Table 10, firms with less than 5 employees represent 80 percent of all small entities but only about 26 percent of total annual receipts.

Estimated one-time costs of reading the rule range from $68.95 to $170.17 for each affected entity. Using the upper bound of $170.17, one-time costs represent 0.004 percent of average annual revenues for firms with under five employees.

The estimated cost of data entry for each new Unique ENDS product would range from $0.75 to $2.26. We lack information on the likely number of these products requiring data entry per small entity. However, for these costs to exceed 1 percent of these firms' average annual receipts, a firm would need to enter data for about 19,000 unique combinations each year. Comparing this number to the estimated number of Unique ENDS products in Table 4 and in Table 5 (where the per year maximum is 10,766 for all affected entities), we conclude that the actual data entry of each small entity must fall well below 19,000. Though we might expect small firms with more than five employees to import a comparatively larger number of products, these firms have significantly greater annual receipts on average. We request comment on the average number of Unique ENDS products imported by small entities.

Because the costs of the rule are small compared to small entities' annual revenue, we propose to certify that the proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

## IV. References


[1] U.S Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Guidelines for Regulatory Impact Analysis," 2016.

[2] U.S. Department of Labor, Bureau of Labor Statistics, "May 2022 National Industry-Specific Occupational Employment and Wage Estimates," [Online]. Available: https://www.bls.gov/oes/current/naics2_42.htm. [Accessed 18 September 2023].

[3] U.S. Department of Commerce, Bureau of Economic Analysis, "Table 1.1.1. Percent Change From Preceding Period in Real Gross Domestic Product," 29 November 2023. [Online]. Available:

https://apps.bea.gov/iTable/?reqid=19&step=2&isuri=1&categories=survey. [Accessed 30 November 2023].

[4] U.S. Census Bureau, "2017 SUSB Annual Data Tables by Establishment Industry," May 2021. [Online]. Available: https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html. [Accessed 14 September 2023].