

removal of a country from the IASA category list.

In addition, the FAA proposes to reduce the time for removal from the IASA list from four years to two years. The removal criteria published in 2013 no longer meet the need for timeliness and accuracy of information on the IASA Category Rating list. The 2013 criteria leave Category 1 countries on the list for an extended period of time and may give the U.S. traveling public a false sense of safety. Also, leaving Category 2 countries on the list for an extended period of time can be perceived as unfairly penalizing those countries when there has been no activity since the Category 2 rating was issued. As a result, the FAA proposes to reduce the removal benchmark from four years to two years absent the interaction described above. The FAA seeks comment on the proposed change from four years to two years, or whether any other timeframe would be appropriate.

Clarification as to When an IASA Will Be Performed in a Country With No IASA Category Rating

The FAA will perform an IASA of a country with no IASA Category rating after an operator from that country files an application with OST for economic authority to conduct (1) services to/from the United States with its own aircraft/crews, and/or (2) code-share operations that involve the foreign air carrier displaying the code of a U.S. air carrier on any services operated by the foreign air carrier. This would ensure that an initial IASA is used to assess whether the CAA and its operator(s) have each taken the necessary measures to manage and oversee operations in accordance with ICAO standards.

Clarification of FAA and CAA Development of a Corrective Action Plan Upon Notification of an IASA Category 2 Rating

If the FAA finds, as a result of an assessment, that a foreign CAA is not overseeing aviation safety in accordance with ICAO standards, the FAA will, prior to the conclusion of an assessment, state its findings in an oral briefing to that foreign CAA. The FAA will also deliver to the foreign CAA a written record of FAA findings and will schedule a follow-up final discussion with the foreign CAA. The final discussion shall take place no earlier than 15 calendar days following the delivery of the written record of findings. In any case in which the assessment finds an instance of non-compliance, the FAA will notify the foreign CAA that is the subject of such

finding. Within 90 days after the transmission of such notification, the FAA will request and initiate final discussions with the foreign country to recommend actions by which the foreign country can mitigate the noncompliance. If the FAA determines that the foreign CAA has not corrected its oversight deficiencies after the conclusion of the final discussion, the country will, upon formal communication from the United States Government, receive an official determination of Category 2 status, and be subject to restrictions on the operations of its air carriers to the United States and on the placement of U.S. carrier codes on flights operated by its carriers.

For additional communication and support for a country assigned an IASA Category 2 rating, the FAA may conduct a virtual meeting with the CAA to discuss the IASA findings. The FAA proposes to provide the CAA with a Corrective Action Plan outline for the CAA to use to document the actions needed to resolve safety deficiencies and the timelines for resolution. This would allow the CAA to begin work to address its safety oversight findings from the IASA in a timely manner.

Upon CAA request, the FAA may, under a technical assistance agreement, assist the CAA in developing a Corrective Action Plan to address its safety oversight deficiencies and timelines for completion.

FAA Actions To Address Safety Concerns Outside of the IASA Process

The FAA retains its authority to take action to address a known safety concern to prevent further non-compliance or unsafe operation of an aircraft by an air carrier, including limiting operations to/from the United States by foreign air carriers with their own aircraft/crews; placing limits on code share arrangements involving the display of a U.S. air carrier code by foreign air carriers from countries for which the FAA has identified safety oversight concerns and initiating immediate IASA category changes when justified based on available safety information. The FAA may also communicate with a CAA about safety concerns the FAA may be aware of so that the CAA can immediately take its own mitigating action. The FAA believes that immediate action that results in the resolution of a safety concern or provides the avenue for clarifying information from the CAA is in the best interest of public safety.

Comments Invited

The FAA invites public comments on the proposed IASA policy modifications and clarifications. The FAA will consider the public comments submitted during this comment period in finalizing the IASA policy.

Issued in Washington, DC.

Jodi L. Baker,

Deputy Administrator for Aviation Safety.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2024–N–1111]

RIN 0910–AI64

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration, with the Department of the Treasury's concurrence, proposes amending its regulations to require that the Submission Tracking Number for Electronic Nicotine Delivery System tobacco products that are being imported or offered for import be submitted in the Automated Commercial Environment or any other electronic data interchange system authorized by U.S. Customs and Border Protection, at the time of entry.

DATES: Either electronic or written comments on the proposed rule must be submitted by October 15, 2024. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by October 15, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 15, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2024-N-1111 for "Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Certain Tobacco Products." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two

copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents, the plain language summary of the proposed rule of not more than 100 words as required by the "Providing Accountability Through Transparency Act," or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

Submit comments on information collection under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently Under Review—Open for Public Comments" or by using the search function. The title of this proposed collection is "Importer's Entry Notice—OMB Control Number 0910-0046—Revision."

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule: Ann M. Metayer, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4375, Silver Spring, MD 20993-0002, 301-796-3324.

With regard to the information collection: JonnaLynn Capezzuto, Office of Operations, Food and Drug

Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
A. Purpose of the Proposed Rule
B. Summary of the Major Provisions of the Proposed Rule
C. Legal Authority
D. Costs and Benefits
II. Table of Abbreviations/Commonly Used Acronyms in This Document
III. Background
A. Introduction/History of This Rulemaking
B. Need for the Regulation
C. FDA's Current Regulatory Framework
IV. Legal Authority
V. Description of the Proposed Rule
VI. Proposed Effective Date
VII. Preliminary Economic Analysis of Impacts
VIII. Analysis of Environmental Impact
IX. Paperwork Reduction Act of 1995
X. Federalism
XI. Consultation and Coordination With Indian Tribal Governments
XII. Reference

I. Executive Summary

A. Purpose of the Proposed Rule

The proposed rule would require that the Submission Tracking Number (STN) for tobacco products, as defined in 21 CFR 1114.3, be submitted for any entry containing an 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). The purpose of the rulemaking is to assist the Food and Drug Administration (FDA, the Agency, or we) in making decisions on admissibility for ENDS products by facilitating FDA's automated review process. The proposed rule, if finalized, would result in a more effective and efficient import admissibility review process by lowering instances of manual review by FDA of entries containing ENDS products, which will protect the public health by conserving Agency resources and more quickly identifying ENDS products that do not have marketing authorization and which may be associated with a greater public health risk. The automated review compares the STN submitted by the ACE filer, as defined in 21 CFR 1.71, to information in FDA's internal databases to determine if a "May Proceed" is appropriate. 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.

B. Summary of the Major Provisions of the Proposed Rule

FDA proposes to revise part 1, subpart D of 21 CFR chapter I (21 CFR part 1, subpart D), added by a final rule issued by the Agency on November 29, 2016 (81 FR 85854), which established requirements for the electronic filing of certain data elements for FDA-regulated products in ACE, or any other EDI system authorized by CBP, at the time of entry. That final rule took effect on December 29, 2016.

The proposed rule would require an ACE filer to submit in ACE at the time of entry the Affirmation of Compliance for Tobacco Submission Tracking (code TST) for ENDS products. 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 Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 387j). Currently, the submission of the STN in ACE is optional. Requiring submission of the STN in ACE at the time of entry would help FDA to more effectively and efficiently make admissibility decisions for ENDS products being imported or offered for import into the United States by increasing the opportunity for automated admissibility review of these entries by FDA’s import systems.

C. Legal Authority

The legal authority for this proposed rule includes sections 301, 701, 801, and 910 of the FD&C Act (21 U.S.C. 331, 371, 381 and 387j), respectively).

D. Costs and Benefits

This proposed rule, if finalized, would require an ACE filer to submit the STN for tobacco products for any entry containing ENDS tobacco

product(s) at the time of entry in ACE or any other EDI system authorized by 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.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
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.
APPH	Appropriate for the protection of the public health.
CBP	U.S. Customs and Border Protection.
EDI	Electronic Data Interchange.
ENDS	Electronic Nicotine Delivery System. 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).
FDA	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug and Cosmetic Act.
ITDS	International Trade Data System.
MGO	A <i>marketing granted order</i> 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.
PMTA	Premarket Tobacco Product Application.
PRIA	Preliminary Regulatory Impact Analysis.
PRA	Paperwork Reduction Act of 1995.
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	Tobacco Submission Tracking. 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.

III. Background

A. Introduction/History of This Rulemaking

ACE is a commercial trade processing system operated by CBP that is designed to implement the International Trade Data System (ITDS), automate import and export processing, eliminate redundant information requirements, and allow the effective enforcement of laws and regulations related to international trade. FDA is a Partner Government Agency for purposes of import data submitted in ACE. As of July 23, 2016, ACE became the sole EDI system authorized by CBP for entry of

FDA-regulated products into the United States (see 81 FR 32339).

FDA issued a final rule effective December 29, 2016, entitled “Submission of Food and Drug Administration Import Data in the Automated Commercial Environment” which added subpart D to part 1 of 21 CFR chapter I to require that certain data elements important to our import admissibility review be submitted in ACE at the time of entry. This proposed rule would add a requirement to submit in ACE, at the time of entry, the STN for an ENDS product to § 1.79.

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control

Act) (Pub. L. 111–31) enacted on June 22, 2009, provided FDA with the authority to regulate tobacco products by recognizing the Agency as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. Section 201(rr)(1) of the FD&C Act (21 U.S.C. 321(rr)(1)), defines “tobacco product” as “any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption,

including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).” The term “tobacco product” does not mean an article that is: a drug (section 201(g)(1)), a device (section 201(h)), a combination product (section 503(g) of the FD&C Act (21 U.S.C. 353(g))). It also does not mean an article that is a food (section 201(f)), if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

Component or part means any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product’s performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product (21 CFR parts 1100, 1140, and 1143).

The FD&C Act requires manufacturers of new tobacco products to receive marketing authorization before entering the market. Section 910(a) of the FD&C Act defines a “new tobacco product” as any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

The Deeming rule (81 FR 28973), which published in the **Federal Register** on May 10, 2016, and took effect on August 8, 2016, extended FDA’s authority to regulate products that meet the statutory definition of “tobacco product” in the FD&C Act (including components and parts but excluding accessories of such newly deemed tobacco products). Deemed products include ENDS, and their components and parts, but not their accessories. Examples of ENDS products that were deemed include vapes or vape pens, e-liquids, e-cigarettes, cigalikes, e-pens, e-hookahs, e-cigars, and e-pipes.

The Consolidated Appropriations Act of 2022 (the Appropriations Act) (Pub. L. 117–103), enacted on March 15, 2022, expanded the definition of the term “tobacco product” in section 201(rr) of the FD&C Act to include products that contain nicotine from any source. The Appropriations Act also amended section 901(b) of the FD&C Act to apply

chapter IX of the FD&C Act to any tobacco product containing nicotine that is not made or derived from tobacco. As a result, ENDS products that contain non-tobacco nicotine, including synthetic nicotine, are now subject to the provisions in chapter IX of the FD&C Act (21 U.S.C. 387 to 387t).

To legally market and distribute a new tobacco product in the United States, an applicant may seek authorization under the following three pathways: Premarket Tobacco Product Application (PMTA), Substantial Equivalence (SE), and Exemption from Substantial Equivalence (EX REQ). Generally, for a new tobacco product, a marketing granted order (MGO) under section 910(c)(1)(A)(i) of the FD&C Act is required unless: (1) the manufacturer of the product submits a report under section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) and FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act) or (2) the manufacturer submits a report under section 905(j)(1)(A)(ii) of the FD&C Act and all modifications are covered by exemptions from the requirements of substantial equivalence granted by FDA under section 905(j)(3) of the FD&C Act. A tobacco product manufacturer includes any person, including any repacker or relabeler, who imports a finished tobacco product for sale or distribution in the United States. See section 900(20) (21 U.S.C. 387(20)) of the FD&C Act. We expect the vast majority of premarket applications for ENDS products to be submitted through the PMTA pathway.

A new tobacco product that does not have an 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 FD&C Act (21 U.S.C. 387b(6)(A)). In addition, a new tobacco product is misbranded under section 903(a)(6) of the FD&C Act (21 U.S.C. 387c(a)(6)) if a notice or other information respecting the product was not provided as required by section 905(j) of the FD&C Act. The premarket review requirements of chapter IX of the FD&C Act apply to all new tobacco products, including ENDS products (e.g., electronic cigarettes and e-liquids).

B. Need for the Regulation

Manufacturers, importers, retailers, and distributors of ENDS products are responsible for ensuring that these tobacco products are compliant with the FD&C Act requirements and

implementing regulations, including premarket authorization requirements.

Any tobacco product imported or offered for import into the United States that appears to be adulterated and/or misbranded is subject to refusal under section 801(a)(3) of the FD&C Act. We have determined that the STN for an ENDS product contained in an entry is a data element that is important for our import admissibility review of that ENDS product. Currently, this information is an optional submission in ACE for ENDS products and is not currently being submitted by ACE filers at the time of entry. Submission of a complete and accurate STN in ACE at the time of entry will facilitate FDA’s review process by electronically comparing the STN to information in FDA’s internal databases. This will help to expedite FDA’s import review process and increase the likelihood of an entry of an ENDS product with a currently effective marketing authorization receiving an automated “May Proceed.” Facilitating the use of automated review for admissibility of ENDS products would allow the Agency to conserve our resources by reducing the instances of manual admissibility review and to more effectively and efficiently make admissibility decisions.

FDA generally considers ENDS to be electronic nicotine delivery systems that deliver aerosolized e-liquid when inhaled, to include components, and/or parts (e.g., e-liquids, cartridges/pods, tanks) of ENDS. FDA conducts a science-based evaluation to determine whether a new tobacco product meets the applicable statutory standard for marketing authorization—such as, whether the product would be appropriate for the protection of the public health (APPH) with respect to the risks and benefits to the population as a whole, including both users and nonusers, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using them.

Public health risks can include, for example, ENDS batteries that overheat, cause fires, or explode; ENDS packaging that allows for young children to be accidentally exposed to the product and poisoned; and youth initiation and use of ENDS products. In making the APPH assessment for a tobacco product such as an ENDS product, for example, FDA weighs, among other things, the negative public health impact stemming from youth initiation and use of the product against the potential positive public health impact stemming from

adult cigarette smokers transitioning away from combusted cigarettes to the ENDS product.

C. FDA's Current Regulatory Framework

ACE electronically transmits the entry data submitted by an ACE filer at the time of entry to FDA via an electronic interface. The Affirmation of Compliance for STN in ACE for tobacco products is currently an optional submission. When FDA's import systems receive entry data from ACE, the 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 required. A manual review means that 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 direct that the FDA-regulated product be examined or sampled by FDA before admissibility is determined.

By requiring the STN to be submitted in ACE at the time of entry for ENDS products being imported or offered for import into the United States, FDA would be able to more effectively and efficiently determine the marketing authorization status of these products. Accurate and complete information submitted by an ACE filer increases the likelihood that an entry line containing an ENDS product that has a currently effective MGO will be given an automated "May Proceed" by FDA. We have found that ACE filers are not submitting the STN for an ENDS product in ACE at the time of entry. The proposed rule would preserve Agency resources by decreasing the amount of manual reviews, which may involve document requests and communication with ACE filers or importers because the STN and marketing status of the ENDS product will be able to be verified electronically using FDA's internal databases. A "May Proceed" does not constitute a determination by FDA that the product complies with all provisions of the FD&C Act and FDA regulations, and it does not preclude FDA action later. We believe that submission of the STN for all entries containing ENDS products would increase the opportunity for issuing a "May Proceed" without manual review of ENDS products that have a currently effective MGO. This would result in a much faster and effective admissibility review process for both FDA and trade than a manual review.

IV. Legal Authority

FDA has the legal authority under the FD&C Act to regulate the importation of ENDS products into the United States (sections 701 and 801 of the FD&C Act). Section 701(a) of the FD&C Act authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act, while section 701(b) of the FD&C Act authorizes FDA and the Department of the Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the FD&C Act. This proposed rule is being jointly prescribed by FDA and the Department of the Treasury.

Section 801(a) of the FD&C Act provides authority for FDA to refuse admission to a tobacco product being imported or offered for import if such product appears adulterated or misbranded. A new tobacco product that does not have an FDA marketing order in effect pursuant to section 910(c)(1)(A) is adulterated pursuant to section 902(6)(A) of the FD&C 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. Under section 301(a) of the FD&C Act, it is a prohibited act to introduce or deliver for introduction into interstate commerce a tobacco product that is adulterated or misbranded.

V. Description of the Proposed Rule

We propose to revise to part 1 of 21 CFR chapter I to require submission of the STN in ACE or any other CBP-authorized EDI system, at the time the electronic entry is filed. The STN is currently an optional submission in ACE for ENDS products. This information is important data for FDA to efficiently verify premarket authorization for the ENDS product in the entry. Under this proposed rule, if finalized, if an ACE filer fails to submit the STN as required in proposed § 1.79(b), the ACE system would not process the entry. If the complete STN is submitted in ACE in the correct syntax and the provided entry information matches the information in FDA's databases for that STN, the entry of that ENDS product may be eligible for a "May Proceed" using an automated admissibility review by FDA. If the STN submitted in ACE does not correspond with the information in FDA's data systems for that ENDS product, FDA would need to conduct a manual review to verify the STN. Conducting a manual review slows FDA's review by creating inefficiencies in the review process and

could create delays for the importer and other parties to the shipment.

As discussed earlier, FDA could issue an automated "May Proceed" if the ACE filer submits a complete STN, in the correct syntax, in ACE at the time of entry and the provided entry information matches the information in FDA's databases for that STN.

Currently, due to FDA's import program's limited resources, the automated look up validation process (the part of FDA's import systems that matches the STN with information in our databases) is only programmed for STNs for ENDS products. Thus, this proposed rule is limited to ENDS products because, at this time, the FDA automated look up validation process can only perform electronic verification of the STN for ENDS products.

VI. Proposed Effective Date

We propose that any final rule based on this proposal become effective 30 days after the date of publication of the final rule in the **Federal Register**.

VII. Preliminary Economic Analysis of Impacts

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 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.

This proposed rule, if finalized, would require an ACE filer to submit

the STN for tobacco products submitted for any import entry containing ENDS tobacco product(s) at the time of entry in ACE or any other EDI system authorized by 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 rulemaking 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 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 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 in the Preliminary Regulatory Impact Analysis (PRIA).

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 rulemaking 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.			Cost savings.
Costs:							
Annualized monetized costs.	\$0.005	\$0.002	\$0.007	2022	2%	10	
Annualized quantified, but non-monetized, costs.	
Unquantified costs.	
Transfers:							

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE—Continued
[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.)
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.						

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis economic of impacts is available in the docket for this proposed rule (Ref. 1) and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of

these provisions is given in the *Description of the Proposed Rule* section of this document. Included in our estimate of the annual reporting and recordkeeping burden is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Title: Importer’s Entry Notice—OMB Control Number 0910–0046—Revision.

Description: This proposed rule would require the submission of the STN for tobacco products for ENDS products being imported or offered for import into the United States via ACE or any other electronic data interchange system authorized by CBP. The purpose of the rule is to facilitate FDA’s review of imported ENDS products. This will allow the Agency to focus our resources on those FDA-regulated products that may be associated with a greater public health risk.

Description of Respondents: Respondents to the information collection provisions of the proposed rule are importers, and licensed customs brokers hired by an importer to file the entry in ACE, who offer products for importation that are finished ENDS products, including components and parts of ENDS products, sealed in final packaging or in the final form in which

they are intended to be sold to consumers.

The proposed rule would add the STN, assigned to the premarket application for an ENDS product under section 910 of the FD&C Act, to the data elements required for entries containing FDA-regulated tobacco products in § 1.79 that must be submitted in ACE at the time of entry. Currently, this is an optional submission. Requiring the STN to be submitted in ACE at the time of entry for finished ENDS products would help facilitate FDA’s import review.

FDA’s burden estimates are based on data discussed in the PRIA. For the analysis of the information collection, we calculate the submission of the STN in the ACE system as an initial first-year burden and subsequent recurring years. We anticipate these data retrieval and entry times to occur in the first year the rule becomes effective for all ENDS

products imported or offered for import as a requirement upon initial submission of import information for unique entities and ENDS products combinations. In each subsequent year, any additional time spent on obtaining and submitting the required information would depend on the number of new Unique ENDS products imported or offered for import. As discussed in the PRIA, we assessed the baseline procedure for verifying marketing status. Currently, entries received without the optional STN data element trigger a manual admissibility review process by FDA to determine their premarket review status. From January 1, 2021, through June 27, 2023, there were no entries containing ENDS products where a filer voluntarily submitted a STN in ACE at the time of entry. We therefore assume that no ACE filers are submitting this information at

baseline. For each Unique ENDS product, we assume time would be spent by an administrative worker on locating the sources of the data; obtaining the required information for submission to ACE, including reaching out to manufacturers if necessary; logging into the system; entering the required information or updating the already existing information in that firm’s internal database(s). Once this information is gathered and entered into a firm’s internal database(s), we foresee that it does not need to be gathered again for a subsequent shipment of the same Unique ENDS product.

As part of this proposed rulemaking, we are revising the currently approved collection of information for the ACE system under OMB control number 0910–0046.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED FIRST-YEAR REPORTING BURDEN ¹

21 CFR 1.79(b); Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Gathering and Entering STN into an ACE Filer’s internal database(s).	177	60.825	10,766	0.033 (2 minutes)	355

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 displays the estimated first year reporting burden associated with gathering and entering the required STN for ENDS products into the ACE filer’s software program. Our burden estimates are consistent with estimates from table 5 in the PRIA, which summarizes the number of import lines, ACE filers, and unique ENDS products expected to be affected by the rule. As we stated previously, we identify Unique ENDS products through a particular combination of manufacturer, product code, and ACE filer. Table 5 in the PRIA presents low and high estimates. For PRA purposes, we have utilized the midpoint of these low and high values. We estimate that 177 respondents

(number of ACE filers) will submit 10,766 annual responses (number of unique ENDS products) in the first year that the proposed rule is finalized.

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 ACE filers have the required information readily available and that they will not need to contact manufacturers or other entities to obtain this data element. Likewise, we assume that importers would provide the necessary information to any licensed customs brokers they hire to complete these tasks. Finally, we

assume that this time includes quality checks to ensure the accuracy of the information submitted in ACE. Some of this verification may be manual verification by staff or messaging from ACE or FDA that identifies incorrect information. To calculate the average burden per response we utilized assumptions in the 2016 ACE final rule, and we assume the time needed to locate, prepare, enter, and quality check the required information would range from 1 to 3 minutes per Unique ENDS product. For PRA estimates we have used the midpoint of 2 minutes (0.033 hours) per response. Our total first year burden is estimated to be 355 hours.

TABLE 3—ESTIMATED SUBSEQUENT YEARS REPORTING BURDEN ¹

21 CFR 1.79(b); Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Gathering and Entering the Submission Tracking Number into Filer’s Internal Database.	8	56.5	452	0.033 (2 minutes)	15

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3 displays the estimated subsequent years burden associated with gathering and entering the required STN for ENDS products into the ACE filer’s internal database. In each

subsequent year after year one, any additional time spent preparing the required information would depend on the number of new Unique ENDS products imported or offered for import.

As with the estimate for first year burden, our estimates for subsequent year burden are based on the midpoint of low and high estimates from table 5 in the PRIA. We estimate recurring

burden by averaging years 2–3 based on a 3-year OMB approval timeframe, which equaled to 8.25 respondents (number of ACE filers) and rounded to 8. For the number of annual responses, we used the average of years 2–3 which equaled to 452 annual responses (number of Unique ENDS products). We estimate the same estimate of 2 minutes (0.033 hours) per response as in table 2, and our total recurring burden is estimated to be a rounded 15 hours.

If this proposed rule is finalized, we estimate that ENDS tobacco product importers submitting the required STN will increase the burden under OMB control number 0910–0046 by 370 hours (355 first year burden hours + 15 subsequent (years 2–3) recurring hours).

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through <https://www.regulations.gov> (see **ADDRESSES**).

All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that this proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the proposed rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on

the distribution of power and responsibilities between the Federal Government and Indian Tribes.

XII. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA, Submission of Food and Drug Administration Import Data in the Automated Commercial Environment (Proposed Rule) Preliminary Regulatory Impact Analysis. Economic Impact Analyses of FDA Regulations.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR part 1 as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393, and 2223; 42 U.S.C. 216, 241, 243, 262, 264, 271.

■ 2. In § 1.79, add paragraph (b) to read as follows:

§ 1.79 Tobacco products.

* * * * *

(b) *Submission tracking number* assigned to an application for market authorization submitted for an electronic nicotine delivery system product, such as a premarket tobacco product application (PMTA) or a supplemental PMTA.

Dated: August 12, 2024.

Robert M. Califf,

Commissioner of Food and Drugs. In concurrence with FDA.

Dated: August 12, 2024.

Aviva R. Aron-Dine, Acting Assistant Secretary of the Treasury for Tax Policy.

[FR Doc. 2024–18343 Filed 8–15–24; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 1000

[245A2100DD/AAKC001030/AOA501010.999900]

Self-Governance PROGRESS Act Negotiated Rulemaking Committee; Notice of Meeting

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule; public meetings.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Self-Governance PROGRESS Act Negotiated Rulemaking Committee (Committee), will hold public meetings to negotiate and advise the Secretary of the Interior (Secretary) on a proposed rule to implement the Practical Reforms and Other Goals To Reinforce the Effectiveness of Self-Governance and Self-Determination for Indian Tribes Act of 2019 (PROGRESS Act).

DATES: The meetings are open to the public and will be held:

- Thursday, September 12, 2024, and
- Thursday, September 19, 2024.

ADDRESSES: The meeting will be held in the John Muir Room of the Department of the Interior Building, 1849 C Street NW, Washington, DC. Members of the public may attend the meeting in-person or participate virtually. Send your comments, within 30 days following the meeting, to the Designated Federal Officer, Vickie Hanvey, using the following methods:

- *Preferred method:* Email to comments@bia.gov with “PROGRESS Act” in subject line.
- *Alternate methods:* Mail, hand-carry or use an overnight courier service to the Designated Federal Officer, Ms. Vickie Hanvey, Office of Self-Governance, Office of the Assistant Secretary—Indian Affairs, 1849 C Street NW, Mail Stop 3624, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT:

Vickie Hanvey, Designated Federal Officer, comments@bia.gov, (918) 931–0745. Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

Please make requests in advance for sign language interpreter services,