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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1108

[Docket No. FDA-2025-N-7130]

RIN 0910-AH59

Establishment Registration and Product Listing for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing regulations to prescribe the format, content, and procedures for establishment registration and tobacco product listing. Complete and accurate establishment registration and product listing information is important to accomplish statutory, regulatory, and public health objectives. Currently, only domestic owners and operators are required to register their establishments and list their tobacco products with FDA while foreign owners and operators are not subject to these requirements, creating significant gaps in Agency information. This action, if finalized, would extend registration and listing requirements to include owners and operators of foreign establishments.

DATES: Either electronic or written comments on the proposed rule must be submitted by **[INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 **[INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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-2025-N-7130 for "Establishment Registration and Product Listing for 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.

FOR FURTHER INFORMATION CONTACT: With regard to the proposed rule: James Anthony, Office of Regulations, or Anthony Villa, Office of Compliance and Enforcement, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov. With regard to the information collection: Amber Barrett, Office of Operations, Food and Drug

Administration, Three White Flint North 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act) added section 905 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387e), requiring the owners and operators of domestic tobacco product manufacturing establishments to register their establishments with FDA and submit product listings. Currently, domestic establishments are required to submit registration and product listing information and FDA has issued guidance to help tobacco establishments implement this provision. Under section 905 of the FD&C Act (21 U.S.C. 387e), every person who owns or operates any domestic establishment engaged in the "manufacture, preparation, compounding, or processing" of a tobacco product, including repackagers/relabelers, is required to register and list. For the purposes of the proposed rule, the term "manufacture" would include assembling, processing, homogenizing, mixing, formulating, labeling, or packaging. This proposed rule clarifies that persons who engage in the manufacture of a tobacco product include specification developers, third-party manufacturers, and bulk tobacco product manufacturers. For the purposes of this proposed rule, references to manufacturers or manufacturing hereinafter are inclusive of this definition and the requirements of the proposed rule would apply to owners and operators of establishments that perform manufacturing, preparation, compounding, or processing functions.

FDA is also proposing corresponding changes to the forms currently used by domestic establishments, which would be used by all registrants to submit registration and listing information, and proposing that all registration and listing information be submitted electronically, unless a waiver has been granted by FDA for the registrant. Under sections 905 and 909 of the FD&C Act, FDA is also proposing recordkeeping requirements for a historical file of consumer information, labeling and advertisements for all tobacco products listed, as well as recordkeeping requirements for information about the distribution of free samples of smokeless tobacco products.

Section 905 also applies to owners or operators of foreign establishments engaged in such functions, but section 905(h), specific to foreign establishments, requires the Secretary of Health and Human Services to promulgate regulations to implement the provision. This creates significant gaps in Agency information. This proposed rule would extend registration and listing requirements to foreign establishments that engage in the "manufacture, preparation, compounding, or processing" of a tobacco product. Registered foreign establishments would be subject to inspection under section 905(g) and 905(h) of the FD&C Act (21 U.S.C. 387e(g) and 387e(h)).

Consequently, this rule would allow FDA to better protect the public health by helping to ensure that owners and operators of domestic and foreign establishments that manufacture tobacco products sold in, distributed in, and/or imported into the United States, are complying with Federal law, including FDA's premarket authorization requirements. Information that would be required by the rule would enable FDA to better pursue enforcement actions against non-compliant tobacco products that have entered commercial distribution or await entry into commercial distribution, at the border or

otherwise, and in doing so better protect the public health. For example, registration and listing information would enable FDA to more efficiently identify adulterated or misbranded tobacco products, including unauthorized electronic nicotine delivery system (ENDS) products, which would be subject to refusal when imported or offered for import into the United States. In addition, since registered establishments are subject to FDA inspections by statute, this rule will extend FDA's inspections of establishments to foreign establishments. FDA currently inspects foreign establishments only to support premarket tobacco product application (PMTA) review per 21 CFR 1114.27.

On February 13, 2025, the President signed Executive Order (E.O.) 14212 titled "Establishing the President's Make America Healthy Again Commission." The E.O. sets forth that "[i]t shall be the policy of the Federal Government to aggressively combat the critical health challenges facing our citizens, including the rising rates of mental health disorders, obesity, diabetes, and other chronic diseases. To do so, executive departments and agencies (agencies) that address health or healthcare must focus on reversing chronic disease." On September 9, 2025, the Make America Healthy Again Commission released the Strategy Report titled "Make Our Children Healthy Again," which outlines a strategy of increased enforcement against illegal ENDS products.

Tobacco use is the leading preventable cause of death and disease in the United States, including preventable chronic disease. Accordingly, this rule would support FDA's efforts to advance Administration priorities by helping FDA identify tobacco products sold, distributed, and/or imported into the United States, and the establishments that manufacture them, that do not comply with Federal law, and by enabling FDA to better pursue enforcement actions against non-compliant tobacco products.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would prescribe the format, content, and procedures for establishment registration and tobacco product listing for domestic and foreign manufacturers of tobacco products. The proposed rule would extend registration and listing requirements to foreign establishments that engage in the "manufacture, preparation, compounding, or processing" of a tobacco product. Registered foreign establishments would be subject to inspection under section 905(g) and 905(h) of the FD&C Act (21 U.S.C. 387e(g) and 387e(h)). Proposed 21 CFR 1108 describes criteria for who would be required to register and list, when and how they would be required to register and list, and the type of information they would be required to submit to FDA. For both domestic and foreign establishments, this includes clarifying that the term "manufacture" includes persons who engage in this activity, such as specification developers, third-party manufacturers, and bulk manufacturers. Proposed 21 CFR 1108 would streamline the registration and listing process by enabling registrants to confirm that there are no changes and thereby complete their updates more efficiently, specifying the establishment information and uniquely identifying information for each listed product, and designating which establishment and unique product information is required or voluntary. Proposed 21 CFR 1108 generally would require the electronic submission of the registration and listing information. FDA is also proposing to require owners or operators of such establishments to maintain a historical file of consumer information, labeling and advertisements for all tobacco products listed in accordance with this part, as well as information related to the distribution of free samples of smokeless tobacco products.

C. Legal Authority

FDA is issuing this proposed rule under its authority delegated under sections 301, 701(a), 801(p), 902, 903, 905, 907, 909, 910, and 911 of the FD&C Act. Section 301 of the FD&C Act describes the acts that are prohibited by the FD&C Act (21 U.S.C. 331). Section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act (21 U.S.C. 371(a)). Section 801(p) of the FD&C Act requires FDA to report to Congress on exports of tobacco products that do not conform to tobacco product standards established pursuant to the FD&C Act (21 U.S.C. 381(p)). Sections 902 (21 U.S.C. 387b) and 903 (21 U.S.C. 387c) of the FD&C Act describe the scenarios in which a tobacco product will be deemed adulterated and misbranded, respectively. Section 905 of the FD&C Act sets forth establishment registration and product listing requirements for owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products. In addition, section 905 permits FDA, by regulation, to require any foreign establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products to register and list (21 U.S.C. 387e). Under section 907 of the FD&C Act, FDA can adopt a tobacco product standard if it finds that the standard is appropriate for the protection of the public health (21 U.S.C. 387g). Section 909 of the FD&C Act permits FDA, by regulation, to require manufacturers and importers of tobacco products to establish and maintain records, make reports, and provide information to ensure that such tobacco products are not adulterated or misbranded, and to otherwise protect the public health (21 U.S.C. 387i). Section 910 of the FD&C Act sets forth requirements for the premarket submission of applications

and authorization of certain tobacco products (21 U.S.C. 387j). Moreover, under section 910(g) of the FD&C Act, FDA has the authority to exempt by regulation tobacco products intended for investigational use from the provisions of Chapter IX of the FD&C Act (21 U.S.C. 387j(g)). Section 911 of the FD&C Act sets forth requirements for modified risk tobacco products, including product authorization and marketing (21 U.S.C. 387k).

D. Costs and Benefits

This proposed rule prescribes the format, content, and procedures for establishment registration and tobacco product listing. If finalized, this proposed rule would also extend registration and listing requirements to owners and operators of foreign establishments where, currently, only domestic owners and operators are required to register and list their tobacco products. In addition, since registered establishments are subject to FDA inspections by statute, this rule will extend FDA's inspections of establishments to foreign establishments. While the specific benefits are difficult to quantify, having complete and accurate tobacco product establishment registration and product listing information for both domestic and foreign establishments can help FDA accomplish several important statutory, regulatory, and public health objectives, such as identifying establishments operating in violation of the FD&C Act, facilitating the recall of non-compliant tobacco products that have entered commercial distribution, or refusing adulterated or misbranded tobacco products imported or offered for import.

We quantify costs to be incurred by both domestic and foreign establishments from the time used to enter and submit their registration and product listing information and also from the time it takes for their managers to accompany FDA inspections. The

20-year annualized total costs to domestic and foreign establishments and FDA would range from $6.80 million to $26.55 million at a 7 percent discount rate, with a primary estimate of $15.57 million. Costs incurred by domestic establishments would be $0.013 million (primary estimate at 7% discount rate), representing 0.1% of total costs. Costs incurred by foreign establishments are $0.37 million (primary estimate at 7% discount rate), representing 2.4% of total costs; FDA costs would account for the remaining 97.5% of total costs. This proposed rule would not affect the total amount of user fees set by statute nor the size of the federal budget.

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

Abbreviation/Acronym	What It Means
CFR	Code of Federal Regulations
CTP	Center for Tobacco Products
DUNS	Data Universal Numbering System
ENDS	Electronic Nicotine Delivery Systems
E.O.	Executive Order
EX REQ	Substantial Equivalence Exemption Request
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FEI	FDA Establishment Identifier
FR	Federal Register
FTZ	Foreign Trade Zone
FURLS	FDA Unified Registration and Listing System
HTP	Heated Tobacco Products
MRTPA	Modified Risk Tobacco Product Application
PD #	FDA-assigned Product Identification Number
PMTA	Premarket Tobacco Product Application
PRIA	Preliminary Regulatory Impact Analysis
RGID #	FDA-assigned Registration Identification Number
SE	Substantial Equivalence
SKU	Stock Keeping Unit

STN	FDA-assigned Submission Tracking Number
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act
TP #	FDA-assigned Tobacco Product Number
TRLM	Tobacco Registration and Listing Module
TRLM NG	Tobacco Registration and Listing Module Next Generation
UPC	Universal Product Code
U.S.	United States
U.S.C.	United States Code

III. Background and Purpose

FDA is proposing regulations that would prescribe the form and content for (1) registration by owners or operators of domestic and foreign establishments that manufacture, prepare, compound, or process tobacco products, and (2) listing of finished tobacco products manufactured, prepared, compounded, or processed by such persons. FDA is issuing this proposed rule under its authority delegated under sections 301, 701(a), 801(p), 902, 903, 905, 907, 909, and 910 of the FD&C Act. Complete and accurate establishment registration and product listing information is important to accomplish statutory, regulatory, and public health objectives. For example, we may use establishment registration and listing information to:

- Identify, conduct surveillance on, and catalog marketed tobacco products;
- Identify persons or establishments producing a specific tobacco product;
- Schedule and plan inspections of registered establishments pursuant to section 905(g) and 905(h) of the FD&C Act (21 U.S.C. 387e(g) and 387e(h));

- Facilitate the recall of tobacco products commercially distributed by owners or operators of tobacco product establishments;
- Identify tobacco products marketed in violation of the law;
- Identify and surveil tobacco products imported or offered for import into the United States from foreign establishments;
- Identify tobacco products manufactured in the United States that are intended for export;
- Identify establishments operating in violation of the FD&C Act and its implementing regulations;
- Facilitate communication between the Agency and the tobacco product industry; and
- Provide public access to up-to-date information regarding registered establishments and listed products through FDA's Establishment Registration & Tobacco Product Listing page.[1]

Additionally, we rely on up-to-date registration and listing information to help us carry out several other statutory provisions. For instance, we use this information to generate accurate estimates of the number of businesses that are affected by our rulemaking activities. These estimates help us assess the impact of our regulations on regulated industry as required under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) and E.O. 12866.

[1] The FDA Center for Tobacco Product's Establishment Registration and Tobacco Product Listing Page can be found at https://trlm-ng-rlsite.fda.gov/home.

In proposing the requirements, we considered: (1) FDA's ongoing experience since 2009 with tobacco product establishment registration and product listing for domestic establishments, including FDA's experience implementing its electronic tobacco product registration and listing system for domestic establishments; (2) Public comments on a draft guidance on the topic of registration and listing[2]; and (3) FDA's need for information about the types and number of manufactured tobacco products. If finalized, the rule would explain the detailed requirements of the registration and listing processes.

FDA based many of the requirements in this proposed rule on the recommendations and interpretations originally outlined in an FDA guidance for industry entitled "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments" (R&L Guidance)[3] (finalized and first issued on November 12, 2009 (74 FR 58298) and subsequently revised in 2014, 2016, 2017, and most recently in 2023). This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA under the requirements of section 905 of the FD&C Act (21 U.S.C. 387e). While several of the requirements in this proposed regulation are the same as or similar to the R&L Guidance recommendations, FDA has further refined the proposed requirements to implement the statutory requirements set forth by section 905 of the FD&C Act (21 U.S.C. 387e). Taking into account the Agency's and industry's experience with registration and listing of domestic establishments, this proposed rule would provide additional clarity and

[2] FDA announced the availability of the draft guidance on October 21, 2009 (74 FR 54052). Public comments on the draft guidance are available at https://www.regulations.gov/docket/FDA-2009-D-0508.
[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/registration-and-product-listing-owners-and-operators-domestic-tobacco-product-establishments.

efficiency for the format, content, and procedures for establishment registration and tobacco product listing for domestic and foreign owners and operators.

Section 905 of the FD&C Act (21 U.S.C. 387e) requires the owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product to register their establishments with FDA and submit product listings. Currently, domestic establishments are required to submit registration and product listing information and FDA has issued guidance to help tobacco product establishments implement this provision. In this proposed rule, FDA is clarifying that persons who engage in the manufacture of a tobacco product include specification developers, third-party manufacturers, and bulk tobacco product manufacturers. FDA is proposing corresponding changes to the forms currently used by domestic establishments, which would be used by all registrants to submit registration and listing information and proposing that all registration and listing information be submitted electronically, unless a waiver has been granted by FDA for the registrant. Under sections 905 and 909 of the FD&C Act, FDA is also proposing recordkeeping requirements for a historical file of consumer information, labeling and advertisements for all tobacco products listed, as well as recordkeeping requirements for information about the distribution of free samples of smokeless tobacco products.

Section 905(h) of the FD&C Act provides FDA with the authority to issue regulations requiring foreign manufacturers to register their establishments and list their products. Section 905(h) states, "[a]ny establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by

[FDA]." Because FDA has not issued such regulations, foreign owners or operators are not currently required to register their establishments or list their tobacco products that are imported or offered for import into the United States, unlike domestic owners or operators who are subject to the already effective, self-implementing registration and listing requirements of section 905 of the FD&C Act (21 U.S.C. 387e). This discrepancy creates gaps in information for FDA to perform its public health mission. This proposed rule would therefore extend registration and listing requirements to foreign establishments that engage in the manufacture, preparation, compounding, or processing of a tobacco product. Registered foreign establishments would be subject to inspection under section 905(g) and 905(h) of the FD&C Act (21 U.S.C. 387e(g) and 387e(h)). FDA believes that issuing this regulation to apply these requirements to foreign owners and operators would bring parity between foreign and domestic owners and operators and in doing so improve FDA's understanding of the types of tobacco products being manufactured, the tobacco products sold in the United States, and the location of all establishments engaged in manufacturing them. For example, FDA does not have registration and listing information from establishments that manufacture ENDS outside of the United States that are imported or offered for import into the United States; having that information would help FDA more efficiently identify commercially marketed tobacco products in the United States that do not comply with the law and keep abreast of the marketplace. Accordingly, FDA is proposing registration and listing requirements for foreign tobacco product establishments.

In addition to providing FDA with important information to protect public health, registration and listing information allows FDA to generate estimates of the number of

businesses that are affected by rulemaking activities. These estimates help us assess the impact of FDA regulations on regulated industry, which is required under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601-612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996; the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 et seq.); the PRA; and E.O. 12866 (September 30, 1993). Additionally, establishment registration and product listing information provides FDA with the data for the annual export report to Congress required under section 801(p)(1) of the FD&C Act. In addition to lessening the burden on FDA and tobacco product establishments, electronic submission of registration and listing information furthers the purpose of the Government Paperwork Elimination Act of 1998 (GPEA) (44 U.S.C. 3504(a)(1)(B)(vi)). GPEA requires Federal agencies to give persons who are required to maintain, submit, or disclose information, the option of doing so electronically when practicable as a substitute for paper, and to use electronic authentication (electronic signature) methods to verify the identity of the sender and the integrity of the electronic content.

IV. Legal Authority

The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act by, among other things, adding a new chapter (chapter IX) granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health. The Tobacco Control Act added section 905 to the FD&C Act (21 U.S.C. 387e), requiring the owners and operators of domestic manufacturing establishments engaged in manufacturing tobacco products to register with FDA and submit product listings.

Section 905(b) of the FD&C Act requires "every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products" to register with FDA the name, places of business, and all such establishments owned or operated by that person (21 U.S.C. 387e(b)). Under section 905(b) of the FD&C Act, every owner and operator must register by December 31st of each year.

Section 905(c) of the FD&C Act requires that every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product(s) in any such establishment immediately register its establishment (21 U.S.C. 387e(c)). Section 905(d) of the FD&C Act requires that every person required to register under section 905(b) or (c) immediately register any additional establishment which that person owns or operates in any State and in which that person begins to engage in such activities (21 U.S.C. 387e(d)). Section 905(f) of the FD&C Act provides that, upon request, FDA must make any registration filed under section 905 of the FD&C Act available to the requestor for inspection (21 U.S.C. 387e(f)). Additionally, section 905(h) of the FD&C Act gives FDA authority to require foreign establishments that are engaged in the manufacture, preparation, compounding, or processing of a tobacco product(s) to register their establishments and to list their products in accordance with regulations published by FDA (21 U.S.C. 387e(h)). Such regulations shall require foreign establishments to provide the information required by section 905(i) and shall include provisions for registration of foreign establishments upon the condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products

manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a). (21 U.S.C. 381(a)).

Section 905(i)(1) of the FD&C Act requires that all registrants "shall, at the time of registration … file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution," along with certain accompanying information, including a copy of all consumer information and other labeling (21 U.S.C. 387e(i)(1)). In addition, section 905(i)(3) of the FD&C Act requires that certain changes to previously submitted product listing information be reported to FDA biannually (21 U.S.C. 387e(i)(3)).

Information provided pursuant to section 905 of the FD&C Act directly implicates, or has the ability to implicate, several prohibited acts under section 301 of the FD&C Act. For example, the failure to register in accordance with section 905 of the FD&C Act, the failure to provide any information required by section 905(i) of the FD&C Act, and the failure to provide a notice required by section 905(i)(3) of the FD&C Act constitute prohibited acts under section 301(p) of the FD&C Act (21 U.S.C. 331(p)). Additionally, prohibited acts under the FD&C Act also include: the introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded (section 301(a)), the adulteration or misbranding of any tobacco product in interstate commerce (section 301(b)), and the receipt in interstate commerce of any tobacco product that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise (section 301(c)) (21 U.S.C. 331(a)-(c)). A tobacco product is deemed adulterated under section 902 of the FD&C Act when, for

example, it is a tobacco product subject to a tobacco product standard under section 907 and it is not in conformity with such standard (section 902(6)) or it is required by section 910(a) to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i) (section 902(6)) (21 U.S.C. 387b(5)-(6)). A tobacco product is misbranded under section 903 of the FD&C Act when, for example, it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h) or if it was not included in a product list required by section 905(i) (section 903(a)(6)) (21 U.S.C. 387c(a)(6)). Violations relating to establishment registration and product listing are subject to regulatory action, including, but not limited to, civil money penalties, seizure, and injunction.

Section 801(p)(1) of the FD&C Act requires FDA to provide an annual report to the Senate Committee on Health, Education, Labor and Pensions and to the House of Representatives Committee on Energy and Commerce (21 U.S.C. 381(p)(1)). This report must contain: (1) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to the FD&C Act; (2) the public health implications of such exports, including any evidence of a negative public health impact; and (3) recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.

Under section 907 of the FD&C Act, FDA can adopt a tobacco product standard if it finds that the standard is appropriate for the protection of the public health (21 U.S.C. 387g). Section 909 of the FD&C Act permits FDA, by regulation, to require manufacturers and importers of tobacco products to establish and maintain records, make

reports, and provide information to ensure that such tobacco products are not adulterated or misbranded, and to otherwise protect the public health (21 U.S.C. 387i). Section 910 of the FD&C Act sets forth requirements for the premarket submission of applications and authorization of certain tobacco products (21 U.S.C. 387j). Moreover, under section 910(g) of the FD&C Act, FDA has the authority to exempt by regulation tobacco products intended for investigational use from the provisions of Chapter IX of the FD&C Act (21 U.S.C. 387j(g)). Section 911 of the FD&C Act sets forth requirements for modified risk tobacco products, including product authorization and marketing (21 U.S.C. 387k). In addition, under section 701(a) of the FD&C Act, FDA has the authority to issue regulations for the efficient enforcement of the FD&C Act (21 U.S.C. 371(a)).

V. Description of the Proposed Rule

A. Scope (Proposed § 1108.1)

Proposed § 1108.1 sets forth that the requirements of this part apply to domestic and foreign establishments that manufacture, prepare, compound, or process tobacco products that are subject to chapter IX of the FD&C Act.[4] Tobacco product manufacturers would include specification developers, third-party manufacturers, bulk tobacco product manufacturers, and repackagers/relabelers.[5] The proposed scope is

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[4] The proposed rule would thus not apply to "premium cigars" that are not subject to chapter IX of the FD&C Act. By rulemaking, FDA has deemed all cigars, among other products, subject to chapter IX of the FD&C Act. On August 9, 2023, the U.S. District Court for the District of Columbia issued an order vacating that rule (generally referred to as the Deeming Rule) "insofar as it applies to premium cigars." *Cigar Ass'n of Am. v. FDA*, No. 16-cv-01460, Dkt. No. 277 (D.D.C. Aug. 9, 2023). The court gave a definition that specified what constituted a premium cigar for the purposes of its ruling. On January 24, 2025, the U.S. Court of Appeals for the District of Columbia Circuit affirmed the district court's order, in part, and reversed and remanded the case back to the district court "so that the district court can invite briefing on the appropriate definition of 'premium cigars.'" *Cigar Ass'n of Am. v. FDA*, No. 23-5220, Document #2096141 (D.C. Cir. Jan. 24, 2025.). That litigation is pending.

[5] Similar to the proposed rule entitled "Requirements for Tobacco Product Manufacturing Practice" (88 FR 15174, March 10, 2023), this proposed rule clarifies that persons who engage in the manufacture of a tobacco product include specification developers, third-party manufacturers, bulk tobacco product

discussed further in subsection *C. Who Must Register and Submit a Tobacco Product List* (Proposed § 1108.20) and subsection *J. Establishment Registration and Tobacco Product Listing for Foreign Establishments Importing or Offering for Import Tobacco Products into the United States* (Proposed § 1108.50).

B. Definitions (Proposed § 1108.3)

Proposed § 1108.3 sets forth several proposed definitions applicable to this part. The definitions follow.

The term "accessory" would be defined the same way it is in 21 CFR 1100.3. It would mean any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco or nicotine, and is not made or derived from tobacco or nicotine from any source; and meets either of the following: (a) is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or (b) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (1) solely controls moisture and/or temperature of a stored tobacco product; or (2) solely provides an external heat source to initiate but not maintain combustion of a tobacco product. This definition is consistent with FDA's "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, Guidance for Industry" (revised March 2023). Examples of accessories are ashtrays, spittoons, hookah tongs, cigar clips and stands, and pipe

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manufacturers, and repackagers/relabelers. For example, if a specification developer designs and establishes tobacco product specifications of a finished or bulk tobacco product and provides the specifications to a third-party manufacturer to physically manufacture the product, both the specification developer and the third-party manufacturer would be engaged in the manufacture of a tobacco product for purposes of this rule and would be required to comply with this proposed rule.

pouches, because they do not contain tobacco or nicotine or are not derived from tobacco or nicotine from any source, and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product. An electric heater or charcoal used for prolonged heating of waterpipe tobacco is not an accessory because it is used to maintain the combustion of the tobacco.

The term "brand" would be defined the same way it is in section 900(2) of the FD&C Act (21 U.S.C. 387(2)). It would mean a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes. For example, Company Q manufactures cigarettes under the following brand and subbrand names: "Acme Gold, Acme Blue, Bravo Red, and Bravo Green." Company Q uses 100 percent burley tobacco for its Acme products and 100 percent flue-cured tobacco for its Bravo products. Since Company Q selected the product names primarily to distinguish the type of tobacco used in each, the company has chosen to market its cigarettes under two separate brands ("Acme" and "Bravo") and indicates subbrands as Gold or Blue for Acme and Red or Green for Bravo.

The term "brand owner" would be defined as a person that owns a brand, through creation, acquisition, trademark, patent, copyright, or otherwise, and has directly or through license, the control and/or direction of the brand.

The term “bulk tobacco product” would be defined as a tobacco product not sealed in final packaging but otherwise suitable for consumer use as a tobacco product (e.g., bulk cigarettes, bulk roll-your-own (RYO) tobacco, bulk pipe tobacco). The proposed definition of bulk tobacco product also includes components or parts of tobacco products that are not sealed in final packaging but are otherwise suitable for consumer use as tobacco products (e.g., bulk filters, bulk e-liquids). Products that are suitable for consumer use as tobacco products are those products that do not require further processing by a tobacco product manufacturer, such as mixing, cutting, curing, blending, or adding components or parts, ingredients, additives and materials, before they can be used by a consumer. For example, an e-liquid not sealed in final packaging is suitable for consumer use as a tobacco product because it requires no additional processing by a tobacco product manufacturer before it can be used by a consumer in an ENDS device; it requires only final packaging and labeling to be a finished tobacco product. A product can be suitable for consumer use as a tobacco product even if it *could* undergo additional processing by a manufacturer, such as blending, as long as it does not *require* further processing by a manufacturer before use by a consumer. For example, coconut and pineapple flavored e-liquids not sealed in final packaging would be considered bulk tobacco products because they are suitable for consumer use as tobacco products, even if they might later be blended together by a manufacturer to make piña colada flavored e-liquid.

The term “commercial distribution” would be defined the same way it is in 21 CFR 1107.12. It would mean any distribution of a tobacco product, whether domestic or imported, to consumers or to any person, but does not include interplant transfers of a

tobacco product between establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for consumption or resale. This definition is consistent with FDA's "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, Guidance for Industry" (revised March 2023). This term would not include the handling or transfer of a tobacco product from one consumer to another for personal consumption. The term would have the same meaning for foreign establishments, but it would not include the distribution of any tobacco products that are neither imported nor offered for import into the United States. Finally, the definition would not include shipment of a tobacco product into a foreign trade zone if the product is then exported and not further distributed in the United States.

The term "component or part" would be defined as any software or assembly of materials intended or reasonably expected: (a) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (b) 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. This definition is consistent with FDA's "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, Guidance for Industry" (revised March 2023).

The term "domestic establishment" would be defined as an establishment in any State or Territory or possession of the United States.[6] This definition is consistent with FDA's "Registration and Product Listing for Owners and Operators of Domestic Tobacco

[6] As set forth by section 900(22) of the FD&C Act, the term 'United States' means "the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States."

Product Establishments, Guidance for Industry" (revised March 2023). We note that this definition includes establishments on Tribal land. FDA respects tribal sovereignty and understands the importance of collaboration and consultation, as appropriate, with federally-recognized tribal governments.

The term "establishment" would be defined as a place of business under one ownership at one general physical location, engaged in an operation described in § 1108.20(a). This definition is consistent with FDA's "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, Guidance for Industry" (revised March 2023). Establishment would refer to both domestic and foreign establishments unless otherwise noted. This definition is similar to the one included in the registration and listing guidance. If a general physical location, such as a campus, includes multiple buildings under the same management, then it would not be necessary to register each building as a separate establishment. However, buildings in the same general physical location that have different management would need to be registered as separate establishments.

The term "finished tobacco product" would be defined to mean a tobacco product, including all components and parts, sealed in final packaging intended for consumer use. This definition is consistent with FDA's "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, Guidance for Industry" (revised March 2023). Examples of finished tobacco products would include a pack of cigarettes, a can of moist snuff, and rolling papers, filters, filter tubes, or e-liquids sold to consumers.

The term “foreign establishment” would be defined to mean an establishment other than a domestic establishment.

The term “industry product identification number” would be defined to mean a unique, product-specific identifier or alphanumeric code, such as a universal product code (UPC), stock keeping unit (SKU), Item #, or Catalog #, that industry generates for internal record keeping and tracking. FDA intends to utilize an industry product identification number when corresponding with industry as a point of reference to help distinguish a specific product from other similar products made by the same manufacturer but with slight differences in product attributes (such as volume or quantity or packaging).

The term “labeling” would be defined in a similar way as in section 201(m) of the FD&C Act (21 U.S.C. 321(m)). It would mean: all labels and other written, printed, or graphic matter (a) upon any tobacco product or any of its containers or wrappers; or (b) accompanying such tobacco product. This definition is consistent with FDA’s “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, Guidance for Industry” (revised March 2023).

The term “manufacturer” would be defined as any person who manufactures, prepares, compounds, or processes a tobacco product, including repackaging or relabeling of any tobacco product. Examples of manufacturing include assembling, processing, homogenizing, mixing, formulating, labeling, or packaging. Manufacturers include specification developers, third-party manufacturers, bulk tobacco product manufacturers, and repackagers/relabelers. For a manufacturer that is a specification

developer, their establishment would be where the owner or operator develops the specifications.

The term "material change" would be defined to include: (a) any change in the tobacco product name (including brand or subbrand), warnings, or instructions for use; (b) any change in the owner or operator, or establishment; (c) any other significant change with respect to consumer information, to other labeling, or to the advertisements for the tobacco product, such as changes to the logo(s), identifiable patterns of color, or product descriptors; (d) any change in the marketing authorization or status for the marketing of such product; and (e) any change with respect to whether or not the product is subject to a tobacco product standard established under section 907 of the FD&C Act (21 U.S.C. 387g). With respect to changes in consumer information or other labeling of the tobacco product, changes that are not significant include changes to grammar, correction of typographical errors that do not change the content of the labeling, and changes in tax stamp or bar code. A change in marketing authorization or status that would create a material change under this definition includes: a change in any pre-existing tobacco product status determination, such as, for example if a pre-existing tobacco product is determined to not have been on the market as of February 15, 2007 (under 910(a)(1)); all authorizations to legally market a tobacco product including an order finding that a new tobacco product is exempt from the requirements of substantial equivalence (SE) (21 CFR 1107); an SE order; a PMTA marketing granted order; a modified risk tobacco product application (MRTPA) order which allows a product to include a modified risk or exposure statement or a non-renewal of a modified risk order; a not substantially equivalent order for provisional products under 910(a)(2)(B)(i); or an

order withdrawing or temporarily suspending authorization under 910(d) to legally market a product under 910(c)(1)(A)(i).

The term "operator" would be defined to mean a person, as defined in section 201(e) of the FD&C Act, who has management authority over an establishment. This definition is consistent with FDA's "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, Guidance for Industry" (revised March 2023).

The term "owner" would be defined to mean a person, as defined in section 201(e) of the FD&C Act, who has an ownership interest in an establishment. This definition is consistent with FDA's "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, Guidance for Industry" (revised March 2023).

The term "Product Identification Number (PD #)" would be defined to mean the number that FDA assigns to each product within a submission to distinguish among the products included in that submission. A PD # is only relevant within the context of a specific Submission Tracking Number (STN).

The term "Registration Identification Number (RGID #)" would be defined to mean the FDA-assigned unique identifier for a registered establishment's registration. The RGID # is assigned to each new electronic tobacco product registration and listing system submission and attaches to the establishment(s) and the product(s) in the initial submission. This information is important to ensure FDA and industry are referring to the same registered establishments and listed products. Updates to establishment

registration and product list information would reference the RGID # from the initial FDA submission.

The term "representative sampling of advertisements" would be defined to mean advertising material that gives a comprehensive picture of the promotional claims and campaigns in use for each tobacco product and which includes representative material from each medium being used to promote the product (e.g., advertisements that appear in or on magazines, newspapers, direct mail materials, retail or point-of-sale displays, posters, billboards, and via internet and mobile communications, such as web pages, banner advertisements, and text messages).

The term "specification developer" would be defined as a person who controls the design and development of a tobacco product or initiates or creates the specifications for the product.

The term "Submission Tracking Number (STN)" would be defined to mean the number that FDA assigns to submissions that are received from an applicant, such as a PMTA, supplemental PMTA, SE reports, SE exemption requests (EX REQ), MRTPA, and submissions related to investigational tobacco products.

The term "third-party manufacturer" would be defined as an entity, including a contract manufacturer, that physically manufactures a tobacco product on behalf of, or to specifications established by, another party, such as a brand owner or specification developer.

The term "tobacco product" would be defined the same way as in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)). It would mean 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 under the FD&C Act that is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g)). The term "tobacco product" 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. This definition is consistent with FDA's "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, Guidance for Industry" (revised March 2023).

The term "Tobacco Product Number (TP #)" would be a product-specific number that is generated by FDA for each product listed on an establishment's registration.

C. Who Must Register and Submit a Tobacco Product List (Proposed § 1108.20)

Proposed § 1108.20(a) and (b) specify those persons who would be required to register and to submit a tobacco product list to FDA. This paragraph would require an owner or operator of an establishment, except those listed in § 1108.20(c), engaged in the manufacture, preparation, compounding, or processing of a tobacco product to register in accordance with section 905 of the FD&C Act. This includes any owner or operator of any domestic establishment that manufactures a tobacco product for export, as well as any owner or operator of any establishment engaged in the manufacture of free smokeless tobacco samples. Manufacturers of tobacco products also include specification developers, third-party manufacturers, bulk tobacco product manufacturers, and repackagers/relabelers.

FDA is aware that some tobacco product manufacturers have established an organizational structure that places the specification development functions in an entity separate from the entity in charge of physically manufacturing the tobacco product; these entities develop and usually control changes to the specifications of the tobacco product. Such entities are specification developers under the proposed rule. If a specification developer designs, establishes, or provides the specifications of a tobacco product to another entity to physically manufacture the product, both the specification developer and the other entity would be engaged in the manufacture of tobacco products for purposes of this rule and would be required to comply with this proposed rule. Product design and the development of product specifications are integral parts of manufacturing.

Additionally, owners or operators are required to register every domestic establishment engaged in the manufacture, preparation, compounding, or processing of tobacco products, whether those establishments are distributing their tobacco product into domestic commerce or exporting them. FDA has the authority to inspect these establishments regardless of the destination of their shipments, and registration and listing information helps FDA ensure that products produced by export-only manufacturers comply with the FD&C Act and applicable regulations.

To avoid unnecessary duplicate registrations, proposed § 1108.20(a) would permit a parent, subsidiary, or affiliate company to submit registration information for all establishments when operations are conducted at more than one establishment and the establishments are under common or joint ownership or control, which is consistent with FDA's drug registration requirements for domestic and foreign establishments (see 21 CFR 207.17(a)). To reduce duplicative submissions, registration information for an

establishment should be submitted by only one entity - the owner or operator of that establishment, or the establishment's parent, subsidiary, or affiliate establishment. Duplicate submissions would create unnecessary burden for the Agency in its submission review and create unnecessary work for registrants. For example, if the parent company has a subsidiary and an affiliate, the parent company can submit the registration information on behalf of the parent, the subsidiary, and the affiliate. Additionally, an owner or operator may authorize a third-party agent to register the establishment(s) on its behalf.

Proposed § 1108.20(b) provides that every person who is required to register, as specified in § 1108.20(a), would also be required to submit a listing of all tobacco products that are being manufactured, prepared, compounded or processed by such person for commercial distribution, in accordance with section 905(i) of the FD&C Act and this proposed regulation. To reduce duplicative submissions, when operations are conducted at more than one establishment and the establishments are under common or joint ownership or control, this section would permit the parent, subsidiary, or affiliate company to submit listing information for all establishments.

Proposed § 1108.20(c) specifies persons who would not be required to register their establishments or submit a tobacco product list. Proposed § 1108.20(c)(1) states that persons engaged only in manufacturing investigational use tobacco products where the product is not available for sale or distribution other than as part of an investigation would not be required to register their establishments or list their products. However, if a manufacturer manufactures products for both investigational use and for commercial

distribution, that manufacturer would be required to register its establishment and would be required to list its tobacco products that are manufactured for commercial distribution.

Proposed § 1108.20(c)(2) states that manufacturers of only raw materials, other than tobacco, used in manufacturing a component or part of a tobacco product would not be required to register their establishments or list their products. Examples of such raw materials would be unprocessed acacia gum (taken from a tree and not processed) and minted titanium dioxide (used for whitening cigarette and tipping paper). For example, a manufacturer that only produces acetate tow used in the manufacturing of a filter for a cigarette would not be required to register its establishment or list its products. However, a manufacturer of both a tobacco product and raw material would have to register the establishment and list the tobacco product.

Proposed § 1108.20(c)(3) states that common carriers, in their receipt, carriage, holding, or delivery of a tobacco product in the usual course of business would not need to register their establishment or submit a tobacco product list. For example, a carrier for the United Parcel Service would typically be considered a common carrier under this proposed provision and, accordingly, would not be required to comply with the registration and listing requirements.

Proposed § 1108.20(d) states that registration and listing of a product does not constitute an admission, agreement, or determination by FDA that a product is a tobacco product within the meaning of section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)). In addition, registration and listing do not denote FDA authorization for the marketing of tobacco products in the United States within the meaning of sections 905 or 910 of the FD&C Act. Listed products that are subject to sections 905 and 910 of the FD&C Act

are not authorized for the legal sale and distribution in the United States unless they have an FDA marketing authorization order in effect.

D. When to Submit Establishment Registration and Tobacco Product Listing (Proposed § 1108.22)

Proposed § 1108.22 prescribes when an owner or operator of an establishment would have to submit its initial establishment registration and tobacco product listing as well as the continuing obligations of owners and operators to submit this information.

Proposed § 1108.22(a) provides that an owner or operator of a domestic establishment that has not previously engaged in an operation described in § 1108.20(a) would have to submit establishment registration and product listing information within five business days from first engaging in an operation described in § 1108.20(a). Section 905(c) requires domestic manufacturers to "immediately register" their establishments and list their products upon beginning any of these operations. We interpret "immediately" as used in section 905(c) to mean within five days from beginning the operation. This is the same interpretation of "immediately" that FDA has implemented for initial drug registration requirements for domestic establishments (see section 510(c) of the FD&C Act (21 U.S.C. 360(c)) and 21 CFR 207.21(a)).

Section 905(h) requires foreign manufacturers to register "under regulations promulgated by the Secretary." Proposed § 1108.22(a) provides that an owner or operator of a foreign establishment engaged in an operation described in proposed § 1108.20(a) would be required to submit establishment registration and tobacco product listing information before any tobacco product manufactured, prepared, compounded, or processed at the establishment is imported or offered for import into the United States,

which also comports with FDA's initial drug registration requirements for foreign establishments (see 21 CFR 207.21(b)).

Proposed § 1108.22(b) would require owners or operators to review, change as needed, or confirm there have been no changes to, their establishment registration and product listing information that is on file with FDA, documenting any changes that were not previously reported. Proposed § 1108.22(b) would also outline the submission timelines for these updates.

Proposed § 1108.22(b)(1) would require that, by December 31st of each year, each owner or operator of an establishment engaged in an operation described in § 1108.20(a) must register each of its establishments, and certify that all information associated with the registered establishments and its listed products is accurate and up to date. Each owner or operator of a registered establishment would need to review, change as needed, or confirm there have been no changes to, the registered establishment information and listed products. Annual registration would still be required even to confirm that there have been no changes.

Proposed § 1108.22(b)(2) would require each owner or operator of an establishment engaged in an operation described in § 1108.20(a) to review, change as needed, or confirm there have been no changes to their tobacco product listing information on file with FDA in June and December of every year. Owners or operators would be required to report any changes or deletions to listings previously reported, including any material changes to product listings previously reported, as described in § 1108.28, and list any new products not previously reported. For example, if the labeling for a product is changed in October, the product listing information would have to be

changed accordingly in December of the same year. This information would be used to help ensure the products marketed are in compliance with the FD&C Act and its implementing regulations.

E. Information Required for Tobacco Product Establishment Registration and Tobacco Product Listing (Proposed § 1108.24)

Proposed § 1108.24 would contain the requirements for an owner or operator to submit information about their establishment and tobacco products. The Tobacco Control Act and its implementing regulations establish a framework that enables FDA to request and receive information on establishment registration and tobacco product listing, and to set up systems through which FDA would have an integrated picture of the tobacco product distribution system. As a part of FDA's central information system, this proposed rule addresses the need for information on which domestic and foreign establishments manufacture a tobacco product or tobacco products distributed in the United States; which tobacco product each establishment handles; and how each establishment can be contacted. This information helps facilitate communication between the Agency and tobacco product establishments and is important for FDA to schedule and plan statutorily required inspections of registered establishments. This information would help FDA identify establishments operating in violation of the FD&C Act, such as those manufacturing products that are adulterated or misbranded under sections 902 and 903 of the FD&C Act or products that are non-compliant with FDA's premarket authorization requirements under section 910 of the FD&C Act, or to facilitate the recall of non-compliant tobacco products that have entered United States commercial distribution. For example, FDA has used registration and listing information from

domestic establishments that have initiated recalls to determine the depth of recall for the establishment's recall strategy and for FDA to verify the effectiveness of the recall depth specified by the strategy. This information would likewise facilitate the recall strategy and effectiveness checks for foreign establishments that initiate recalls.

Proposed § 1108.24(a) would contain the establishment registration information required, if applicable, to be submitted to FDA using FDA's electronic tobacco product registration and listing system, except as provided in § 1108.40(b). Proposed § 1108.24(a)(1) would require the full name, physical address, mailing address, and contact information for the establishment. Proposed § 1108.24(a)(2) would require the name, address, phone number, fax number, and email address of the owner and operator; if a partnership, the name of each partner; if a corporation, the place of incorporation and the name of each corporate officer and director; any trade names used by the owner and operator or other names under which the owner and operator conducts business or additional names by which the owner and operator is known. This information is important for FDA to efficiently coordinate inspections under section 905(g) of the FD&C Act, including by reducing duplication of registered establishments.

Proposed § 1108.24(a)(3) would require the name, address, phone number, fax number, and email address of the official correspondent designated by the owner or operator. This information is necessary in order for FDA to efficiently correspond on issues regarding the registration and listing submissions.

Proposed § 1108.24(a)(4) would require any trade names used by the establishment or other names under which the establishment conducts business or additional names by which the establishment is known. This information would allow

FDA to reduce duplication and properly identify establishments to determine whether they are properly registered and would eliminate confusion if an establishment is known by multiple names or if different establishments are known by similar names.

Proposed § 1108.24(a)(5) would require the establishment's website address(es) that concern tobacco products. This information is important to enable FDA to determine that tobacco products being manufactured for distribution are in compliance with the FD&C Act and applicable regulations. For example, FDA would be better able to determine whether such activities render a product misbranded under the FD&C Act or reflect the marketing of an unlisted or unauthorized product. Although this would only apply to manufacturers at this time, FDA would consider expanding this type of requirement to other entities that have websites that market tobacco products.

Proposed § 1108.24(a)(6) would require the RGID # of the establishment, if previously assigned by FDA. This information is important to ensure FDA and industry are referring to the same registered establishments and listed products and is needed as a point of reference when processing registration and product listing updates, including when a waiver has been obtained for paper submission.

Proposed § 1108.24(a)(7) would require the FDA Establishment Identifier (FEI) number if FDA previously assigned one to the establishment. FDA would provide an FEI number if the establishment has not been assigned one. Proposed § 1108.24(a)(7) would also allow optional submission of another unique identifier, such as a Data Universal Numbering System (DUNS) Number, for the place of business of the owner, the place of business of the operator, and the location of the establishment. If submitted, this information would help FDA determine whether an establishment has been duly

registered and to distinguish between registered establishments, especially if they have similar names.

Lastly, proposed § 1108.24(a)(8) would require the name of the Tribe if the establishment is located on Indian Country. The name of the Tribe for establishments located on Indian Country would help FDA coordinate compliance directly with the appropriate tribal government and respect statutory limits on contracting with third parties for inspections in Indian Country.

FDA is considering requiring establishments to provide additional contact information in their registration. The Agency requests comments on whether to also require the name, address, and contact information for the establishment's direct accounts, if applicable. Because tobacco products move through direct accounts, knowing those accounts would be helpful for FDA to verify compliance, facilitate the identification of adulterated or misbranded tobacco products that have entered commercial distribution, and take prompt compliance and enforcement actions when warranted.

FDA also requests comments on whether to require the name, address, phone number, fax number, email address, and contact information for the establishment's importers and consignees, if applicable. Section 905(h) of the FD&C Act requires registration of foreign establishments whose products are imported or offered for import into the United States. Importer and consignee information would help FDA determine whether imported tobacco products originate from registered establishments and would help FDA identify such products that may be in commercial distribution, including those that may be adulterated or misbranded under sections 902 and 903 of the FD&C Act.

FDA also requests comments on whether to require, for any tobacco product brand manufactured by the establishment that is not owned by the establishment, the name, address, phone number, fax number, email address, and contact information for the establishment's tobacco product brand owners. Requiring contact information for tobacco product brand owners would ensure that FDA can associate all manufacturers of finished and bulk tobacco products with brand owners. Section 905 of the FD&C Act requires owners or operators to register each establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product. Because brand owners may contract out these functions while retaining ultimate control over the product, the information that would be required would enable FDA to identify the brand owners on whose behalf manufacturers are producing a specific tobacco product. This information would help FDA identify the entity responsible for marketing or introducing such products into commercial distribution, including tobacco products that may be adulterated or misbranded under sections 902 and 903 of the FD&C Act.

FDA also requests comments on whether to require the name, address, phone number, fax number, email address, and contact information for the establishment's tobacco product specification developers, if any. As discussed in proposed § 1108.20(a), manufacturers of tobacco products include specification developers, so specification developers would be required to register their establishments and list their tobacco products. Because specification developers exercise functional control over product design and specifications, even if physical manufacturing is performed by another manufacturer, requiring the specification developer's contact information would help FDA associate manufacturers that physically manufacture finished and bulk tobacco

products with the manufacturers that develop their specifications. To this end, this information would help FDA efficiently identify establishments operating in violation of the FD&C Act, such as products that are adulterated or misbranded under sections 902 and 903 of the FD&C Act, or products that are non-compliant with FDA's premarket authorization requirements under section 910 of the FD&C Act, or to facilitate the recall of non-compliant tobacco products that have entered United States commercial distribution.

FDA requests comments on whether to require the brand owner, direct account, consignee, and importer information described above that the Agency is considering requiring, or any other information, and the reasons why.

Proposed § 1108.24(b) would provide that owners or operators of tobacco product establishments who have been granted a waiver under § 1108.40(b) from filing electronically through FDA's tobacco product registration and listing system must submit the information required by § 1108.24(a) in paper form using the procedures provided by FDA in accordance with § 1108.40(c).

Proposed § 1108.24(c) would require the owner or operator to designate an official correspondent for the registration to serve as their point of contact with FDA on issues relating to establishment registration and listing of tobacco products. Similar to what is recommended by the R&L Guidance, proposed § 1108.24(c)(1) and (c)(2) state that the official correspondent would be responsible for electronically transmitting to FDA all required registration and listing information unless a waiver from electronic submission has been granted in accordance with § 1108.40(b) as well as serving as a liaison for all correspondence with FDA concerning registration and listing.

FDA is proposing to require identification of an official correspondent for two reasons. First, an official correspondent is important to help FDA ensure adequate notice is provided to registrants through official Agency communications. As such, the designation of an official correspondent provides the agency with an official contact who can receive the information or documentation on behalf of the registrant. Second, identification of an official correspondent would assist FDA in communication with the registrant and help the Agency to efficiently process submissions and avoid delays. An official correspondent would act as a communications link between FDA and the registrant and would facilitate timely correspondence between FDA and the registrant, including responding to questions concerning registrations.

Proposed § 1108.24(d) would provide that the designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under section 301(p) of the FD&C Act or any other provision of the FD&C Act and its implementing regulations.

Proposed § 1108.24(e) would require owners or operators to submit listing information identified in paragraphs (e)(1) through (e)(10) for each tobacco product manufactured, prepared, compounded, or processed for commercial distribution. This information is important for FDA to identify the specific tobacco products that are being manufactured at each establishment. For example, FDA would be able to determine whether the same or similar products are being marketed under different brands or subbrands of tobacco products. The information must be submitted electronically through FDA's tobacco product registration and listing system unless FDA grants a waiver from electronic submission under § 1108.40(b).

Proposed § 1108.24(e)(1) would require each listing to include the current electronic tobacco product registration and listing system RGID # and the name of each establishment. The RGID # and name of each establishment would help FDA identify the products manufactured at that establishment, especially where multiple establishments have similar names. In the case of an owner or operator with multiple establishments, FDA would be able to use the manufacturing location to determine where to inspect to determine each tobacco product's compliance with the requirements of the FD&C Act. FDA would assign a RGID # to the initial establishment registration and product list submission. Any subsequent new establishment with the same owner and/or operator which begins performing a tobacco product manufacturing activity would be added by the registrant under that RGID #.

Proposed § 1108.24(e)(2) would require the name, including brand and subbrand name, or other commercial name(s) used in commercial distribution, for each tobacco product the registrant manufactures, prepares, compounds, or processes at a registered establishment.

Proposed § 1108.24(e)(3) would require the uniquely identifying information for each tobacco product the registrant manufactures, prepares, compounds, or processes, including product category, product subcategory, and product properties as provided in Table 1 below. If the product does not have a particular listed product property, such as filter ventilation percentage or characterizing flavor, the application would need to state "none" for that property. If a tobacco product listing did not include uniquely identifying information required under proposed § 1108.24(e)(3), the listing would not be complete.

FDA is proposing that uniquely identifying information would include the following:

- Product category (e.g., cigarette, smokeless tobacco product);
- Product subcategory (e.g., filtered cigarettes, loose moist snuff);
- Package type (e.g., hard pack or soft pack, plastic bag);
- Product quantity or count (e.g., 15 grams (g), 10 pouches);
- Portion size (e.g., 1.5 g/pouch);
- Length for cigarettes, cigarette tubes, rolling paper, paper tips, filters, and other tobacco products that contain this property;
- Width of rolling paper and other tobacco products that contain this property;
- Diameter of cigarettes, cigarette tubes, filters, and other tobacco products for which this property may be calculated;
- Filter ventilation percentage of cigarettes, filtered cigarette tubes, paper tips, filters, and other tobacco products that contain this property;
- E-liquid volume (e.g., 0.5 ml, 2.0 ml);
- Nicotine concentration (e.g., 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/e-cigarette);
- Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none)
- Propylene glycol (numeric value) and vegetable glycerin (numeric value) (e.g., N/A, 0/100, 50/50, 100/0);
- Wattage (e.g., 100 W, 200 W);

- Battery capacity (e.g., 100 mAh, 200 mAh);
- Characterizing flavor(s) (e.g., menthol, tobacco, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, unflavored), which is from the packaging or other labeling if applicable; and
- Additional properties needed to uniquely identify the tobacco product (if applicable).

The following table is not exhaustive and does not encompass all potential products and their uniquely identifying properties and is intended to serve as an example.

Table 1.--Elements of Uniquely Identifying Information by Tobacco Product Category and Subcategory

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
Cigarettes	• Filtered	• Package type (e.g., hard pack, soft pack, clam shell) • Product quantity (e.g., 20 cigarettes, 25 cigarettes) • Length (e.g., 89.1 mm, 100.0 mm) • Diameter (e.g., 6.0 mm, 8.1 mm) • Filter ventilation percentage (e.g., none, 10.0%, 25.0%) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Cigarettes	• Non-filtered	• Package type (e.g., hard pack, soft pack, clam shell) • Product quantity (e.g., 20 cigarettes, 25 cigarettes) • Length (e.g., 89.1 mm, 100.0 mm) • Diameter (e.g., 6.0 mm, 8.1 mm) • Filter ventilation percentage (e.g., none, 10.0%, 25.0%) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Cigarettes	• Other	• Package type (e.g., hard pack, soft pack, clam shell) • Product quantity (e.g., 20 cigarettes, 25 cigarettes) • Length (e.g., 89.1 mm, 100.0 mm) • Diameter (e.g., 6.0 mm, 8.125 mm) • Filter ventilation percentage (e.g., none, 10.0%, 25.0%)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
		• Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
RYO tobacco	• Roll-Your-Own Tobacco Filler	• Package type (e.g., bag, pouch) • Product quantity (e.g., 20.1 g, 16.0 oz) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
RYO tobacco	• Rolling Paper	• Package type (e.g., box, booklet) • Product quantity (e.g., 50 sheets, 200 papers) • Length (e.g., 79.1 mm, 100.0 mm, 110.2 mm) • Width (e.g., 28.1 mm, 33.0 mm, 45.2 mm) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
RYO tobacco	• Cigarette Tube, Filtered	• Package type (e.g., bag, box) • Product quantity (e.g., 100 tubes, 200 tubes) • Length (e.g., 89 mm, 100.0 mm) • Diameter (e.g., 6.0 mm, 8.1 mm) • Filter ventilation percentage (e.g., none, 10.0%, 25.0%) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
RYO tobacco	• Cigarette Tube, Non-filtered	• Package type (e.g., bag, box) • Product quantity (e.g., 100 tubes, 200 tubes) • Length (e.g., 89.1 mm, 100.0 mm) • Diameter (e.g., 6.0 mm, 8.1 mm) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
RYO tobacco	• Filter	• Package type (e.g., bag, box) • Product quantity (e.g., 100 filters, 200 filters) • Length (e.g., 8.0 mm, 12.1 mm) • Diameter (e.g., 6.0 mm, 8.1 mm)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
		• Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
RYO tobacco	• Paper Tip	• Package type (e.g., bag, box) • Product quantity (e.g., 200 tips, 275 tips) • Length (e.g., 12.0 mm, 15.1 mm) • Width (e.g., 27.1 mm) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
RYO tobacco	• Other	• Package type (e.g., bag, box) • Product quantity (e.g., 200 tips, 100 filters, 200 tubes) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Smokeless tobacco	• Moist Snuff, Loose	• Package type (e.g., plastic can with metal lid, plastic can with plastic lid) • Product quantity (e.g., 20.0 g, 2.1 oz) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Smokeless tobacco	• Moist Snuff, Portioned	• Package type (e.g., plastic can with metal lid, plastic can with plastic lid) • Product quantity (e.g., 22.5 g, 20.0g) • Portion count (e.g., 15 pouches, 20 pieces) • Portion mass (e.g., 1.5 g/pouch, 1.0 g/piece) • Portion length (e.g., 15.0 mm, 20.1 mm) • Portion width (e.g., 10.0 mm, 15.1 mm) • Portion thickness (e.g., 5.0 mm, 7.1 mm) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
Smokeless tobacco	• Snus, Loose	• Package type (e.g., plastic can with metal lid, plastic can with plastic lid) • Product quantity (e.g., 20.0 g, 2.1 oz) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Smokeless tobacco	• Snus, Portioned	• Package type (e.g., plastic can with metal lid, plastic can with plastic lid) • Product quantity (22.5 g, 20.0g) • Portion count (e.g., 15 pouches, 20 pieces) • Portion mass (e.g., 1.5 g/pouch, 1.0 g/piece) • Portion length (e.g., 15.0 mm, 20.1 mm) • Portion width (e.g., 10.0 mm, 15.1 mm) • Portion thickness (e.g., 5.0 mm, 7.1 mm) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Smokeless tobacco	• Dry Snuff, Loose	• Package type (e.g., plastic can with metal lid, plastic can with plastic lid) • Product quantity (e.g., 20.0 g, 2.1 oz.) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Smokeless tobacco	• Dissolvable	• Package type (e.g., plastic can with metal lid, plastic can with plastic lid) • Product quantity (e.g., 22.5 g, 20.0 g) • Portion count (e.g., 15 sticks, 20 pieces) • Portion mass (e.g., 1.5 g/strip, 1.0 g/piece) • Portion length (e.g., 10.0 mm, 15.1 mm) • Portion width (e.g., 5.0 mm, 8.1 mm) • Portion thickness (e.g., 3.0 mm, 4.1 mm) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
		• Additional properties needed to uniquely identify the tobacco product (if applicable)
Smokeless tobacco	• Chewing Tobacco, Loose	• Package type (e.g., bag, pouch, wrapped) • Product quantity (e.g., 20.0 g, 3.1 oz) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Smokeless tobacco	• Chewing Tobacco, Portioned	• Package type (e.g., plastic can with metal lid, plastic can with plastic lid) • Product quantity (22.5 g, 20.0g) • Portion count (e.g., 10 bits) • Portion mass (e.g., 2.1 g/bit) • Portion length (e.g., 8.0 mm, 10.1 mm) • Portion width (e.g., 6.0 mm, 8.1 mm) • Portion thickness (e.g., 5.1 mm, 7.0 mm) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Smokeless tobacco	• Other	• Package type (e.g., bag, box, can) • Product quantity (e.g., 20.1 g, 22.5 g, 3.0 oz.) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
ENDS	• E-Liquid, Open	• Package type (e.g., bottle, box, pod) • Product quantity (e.g., 1 bottle, 5 bottles) • E-liquid volume (e.g., 0.5 ml, 2.0 ml, 5.1 ml) • Nicotine concentration (e.g., 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/bottle) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Propylene glycol (PG)/vegetable glycerin (VG) ratio (e.g., not applicable [N/A], 0/100, 50/50, 100/0) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
ENDS	• E-Liquid, Closed	• Package type (e.g., cartridge, pod) • Product quantity (e.g., 1 cartridge, 5 cartridges) • E-liquid volume (e.g., 0.5 ml, 2.0 ml, 5.1 ml) • Nicotine concentration (e.g., 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 2.0 mg/bottle) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • PG/VG ratio (e.g., N/A, 0/100, 50/50, 100/0) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
ENDS	• E-Cigarette, Closed	• Package type (e.g., box, none, plastic clamshell) • Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes) • Length (e.g., 100.0 mm, 120.0 mm) • Diameter (e.g., 6.0 mm, 8.0 mm) • Wattage (e.g., 100 W, 200 W) • Battery capacity (e.g., 100 mAh, 200 mAh). • E-liquid volume (e.g., 0.5 ml, 2.0 ml, 5.1 ml) • Nicotine concentration (e.g., 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/e-cigarette) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • PG/VG ratio (e.g., N/A, 0/100, 50/50, 100/0) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
ENDS	• E-Cigarette, Open	• Package type (e.g., box, none, plastic clamshell) • Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes) • Length (e.g., 100.0 mm, 120.0 mm) • Diameter (e.g., 6.0 mm, 8.0 mm) • E-liquid volume (e.g., 0.5 ml, 2.0 ml, 5.1 ml) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Wattage (e.g., 100 W, 200 W) • Battery capacity (e.g., 100 mAh, 200 mAh) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
ENDS	• ENDS Component	• Package type (e.g., box, none, plastic clamshell) • Product quantity (e.g.,1 coil)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
		• Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry, wintergreen) • Additional properties needed to uniquely identify the tobacco product (if applicable)
ENDS	• ENDS Other	• Package type (e.g., box, none, plastic clamshell) • Product quantity (e.g., 1 e-cigarette, 5 bottles) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, cherry, wintergreen, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Cigars	• Cigar, Filtered Sheet-Wrapped	• Package type (e.g., hard pack, soft pack, clam shell) • Product quantity (e.g., 20 filtered cigars, 25 filtered cigars) • Length (e.g., 89.1 mm, 100.0 mm) • Diameter (e.g., 6.0 mm, 8.1 mm) • Filter ventilation percentage (e.g., none, 0%, 10.0%, 25.0%) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor (e.g., unflavored, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Cigars	• Cigar, Unfiltered Sheet-Wrapped	• Package type (e.g., box, film sleeve) • Product quantity (e.g., 1 cigar, 5 cigarillos) • Length (e.g., 100.1 mm, 140.0 mm) • Diameter (e.g., 8.0 mm, 10.1 mm) • Tip (e.g., none, wood tips, plastic tips) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor (e.g., unflavored, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Cigars	• Cigar, Unfiltered Leaf-Wrapped	• Package type (e.g., box, film, sleeve, none) • Product quantity (e.g., 1 cigar, 5 cigars) • Length (e.g., 150.1 mm, 200.0 mm) • Diameter (e.g., 8.0 mm, 10.1 mm) • Wrapper material (e.g., burley tobacco leaf, Connecticut shade grown tobacco leaf) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor (e.g., unflavored, whiskey) • Additional properties needed to uniquely identify the tobacco product (if applicable)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
Cigars	• Cigar Component	• Package type (e.g., box, booklet) • Product quantity (e.g., 10 wrappers, 20 leaves) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor (e.g., unflavored, menthol, cherry) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Cigars	• Cigar Tobacco Filler	• Package type (e.g., bag, pouch) • Product quantity (e.g., 20.0 g, 16.1 oz.) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor (e.g., unflavored, menthol, cherry) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Cigars	• Other	• Package type (e.g., box, booklet) • Product quantity (e.g., 1 cigar, 5 cigars, 20 leaves, 16 g) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, menthol, cherry) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Pipe Tobacco Products	• Pipe	• Package type (e.g., box, none) • Product quantity (e.g., 1 pipe) • Length (e.g., 200.0 mm, 300.1 mm) • Diameter (e.g., 25.1 mm) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, menthol, cavendish, cherry) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Pipe Tobacco Products	• Pipe Tobacco Filler	• Package type (e.g., bag, none) • Product quantity (e.g., 20.0 g, 16.1 oz) • Tobacco cut style (e.g., standard cut, such as shag cut, bugler cut, loose cut, etc., or a pressed cut, such as flake, cube cut, roll cake, etc., or a mixture) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, menthol, cavendish, cherry) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Pipe Tobacco Products	• Pipe Component	• Package type (e.g., box, bag, none) • Product quantity (e.g., 1 bowl, 1 stem, 100 filters)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
		• Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, cherry) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Pipe Tobacco Products	• Other	• Package type (e.g., bag, box, none) • Product quantity (e.g., 1 pipe) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, cherry) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Waterpipe Tobacco Products	• Waterpipe	• Package type (e.g., box, none) • Product quantity (e.g., 1 waterpipe) • Height (e.g., 200.0 mm, 500.1 mm) • Width (e.g., 100.1 mm, 300.0 mm) • Diameter (e.g., 100.1 mm, 300.0 mm) • Number of hoses (e.g., 1, 2, 4) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Waterpipe Tobacco Products	• Waterpipe Tobacco Filler	• Package type (e.g., bag, pouch) • Product quantity (e.g., 20.0 g, 16.1 oz.) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, apple) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Waterpipe Tobacco Products	• Waterpipe Heat Source	• Package type (e.g., box, film sleeve, bag, none) • Product quantity (e.g., 150.0 g, 680.0 g) • Portion count (e.g., 20 fingers, 10 discs, 1 base) • Portion mass (e.g., 15.0 g/finger, 10.0g/brick) • Portion length (e.g., 40.0 mm, 100.0 mm) • Portion width (e.g., 10.0 mm, 40.0 mm) • Portion thickness (e.g., 10.0 mm, 40.0 mm) • Source of energy (e.g., charcoal, battery, electrical) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, menthol, apple) • Additional properties needed to uniquely identify the tobacco product (if applicable)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
Waterpipe Tobacco Products	• Waterpipe Component	• Package type (e.g., bag, box, none) • Product quantity (e.g., 1 base, 1 bowl, 1 hose, 10 mouthpieces) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, menthol, cherry) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Waterpipe Tobacco Products	• Waterpipe Other	• Package type (e.g., bag, box, none) • Product quantity (e.g., 1 base, 1 bowl, 1 hose, 10 mouthpieces) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, cherry) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Heated Tobacco Products (HTP)	• Closed HTP	• Package type (e.g., box, none, plastic clamshell) • Product quantity (e.g., 1 device, 1 HTP) • Length (e.g., 100.0 mm, 120.0 mm) • Diameter (e.g., 6.0 mm, 8.1 mm) • Wattage (e.g., 100 W, 200 W) • Battery capacity (e.g., 100 mAh, 200 mAh) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Heated Tobacco Products (HTP)	• Open HTP	• Package type (e.g., box, none, plastic clamshell) • Product quantity (e.g., 1 device, 1 HTP) • Length (e.g., 100.0 mm, 120.0 mm) • Diameter (e.g., 6.0 mm, 8.1 mm) • Wattage (e.g., 100 W, 200 W) • Battery capacity (e.g., 100 mAh, 200 mAh) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Heated Tobacco Products (HTP)	• HTP Consumable	• Package type (e.g., hard pack, soft pack, plastic clamshell) • Product quantity (e.g., 20 sticks, 25 cartridges) • Length (e.g., 60.0 mm, 82.0 mm) • Diameter (e.g., 6.0 mm, 8.1 mm) • Filter ventilation percentage (e.g., none, 10.0%, 25.0%)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
		• Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Heated Tobacco Products (HTP)	• HTP Component	• Package type (e.g., box, none, plastic clamshell) • Product quantity (e.g., 1 mouthpiece, 1 spacer) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Heated Tobacco Products (HTP)	• Other	• Package type (e.g., box, bag, plastic clamshell, none) • Product quantity (e.g., 1 base, 5 capsules) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol) • Additional properties needed to uniquely identify the tobacco product (if applicable)
Other Tobacco Products	• Other	• Package type (e.g., box, bag, plastic clamshell, none) • Product quantity (e.g., 1 base, 5 capsules) • Nicotine source (i.e., tobacco-derived nicotine (TDN), non-tobacco derived nicotine (NTN), both, or none) • Characterizing flavor(s) (e.g., unflavored, tobacco, menthol, cherry) • Additional properties needed to uniquely identify the tobacco product (if applicable)

This information would enable the Agency to accurately identify each individual tobacco product in commercial distribution. Additionally, this information would allow for a 1:1 comparison to link tobacco products across submissions (e.g., ingredient listings, harmful and potentially harmful constituent listings, premarket orders). This would increase the efficiency with which FDA would be able to process those submissions.

We seek comments on other unique identification elements to require for cigars, pipes, waterpipes, ENDS, and other tobacco products beyond those identified in Table 1.

Please specifically identify the elements FDA should require and why they are needed to uniquely identify the product.

Proposed § 1108.24(e)(4) would require tobacco product listing information to include the FDA-assigned TP #, for updates to previous product list submissions, and the industry-assigned UPC. If a UPC number is not available, an alternative industry product identification number, to include the number itself and the type of identifier (e.g., SKU, Item #, or Catalog #) must be provided in lieu of the UPC. The UPC is obtained and implemented by the manufacturer or brand owner as a globally unique identifier for each individual product or product variation (e.g., different colors, sizes, or flavors of the same product). SKU and catalog/item numbers typically have a more limited scope for tracking product inventory or a general product line and may vary according to a retailer or manufacturer's needs.

Proposed § 1108.24(e)(5) would require the tobacco product listing information to include all FDA-assigned STNs, if any. STN would be defined to mean the number that FDA assigns to submissions that are received from an applicant, such as a PMTA, supplemental PMTA, SE reports, SE EX REQ, MRTPA, and submissions related to investigational tobacco products. Proposed § 1108.24(e)(6) would require the FDA-assigned Product Identification Number (PD #), if any. The PD # would be defined to mean the number that FDA assigns to each product within a submission to distinguish among the products included in that submission. A PD # is only relevant within the context of a specific STN. The FDA-assigned STN and PD #, if any, are required because section 905(i)(1)(A) of the FD&C Act sets forth that a listed tobacco product subject to a tobacco product standard established under section 907 of the FD&C Act or

which is subject to section 910 of the FD&C Act must provide a reference to the authority for the marketing of the tobacco product.

Proposed § 1108.24(e)(7) would require the listing to include the operations or processes that are conducted or done to the tobacco product at the establishment (e.g., compounding, repackaging, relabeling, remanufacturing, processing, contract manufacturing, specification development, manufacturing for export, or manufacturing activities other than those listed). This information would allow FDA to understand the stage of the manufacturing process that occurs for each tobacco product at each establishment location, which can help direct FDA inspections, aid in potential recalls, and assist with any enforcement actions. Additionally, the information would allow FDA to better prepare for each upcoming inspection. For example, a smokeless tobacco product may have manufacturing that occurs in one location, repackaging that occurs in a second location, and relabeling that occurs in a third location. The proposed requirement would require each establishment to list the operation or process that occurs at the establishment.

Proposed § 1108.24(e)(8) would require that the listing for a tobacco product manufactured in any domestic establishment for export that does not conform to tobacco product standards established pursuant to section 907 of the FD&C Act to include: (1) The manner in which the product does not conform to applicable tobacco product standards, (2) the destinations of the exported tobacco products for the previous year, and (3) the quantity of the product shipped to each country during the previous year. This information would need to be provided in the June biannual listing update required by

§ 1108.22(b)(2) and would assist FDA in preparing its tobacco product export report to Congress required under section 801(p) of the FD&C Act.

Proposed § 1108.24(e)(9) would require, per section 905(i)(1)(A) of the FD&C Act, registrants to submit, for a tobacco product subject to a tobacco product standard established under section 907 of the FD&C Act or which is subject to section 910 of the FD&C Act for any new tobacco product, a reference to the authority for the marketing of the tobacco product (the submitter would have a list to choose from to indicate the type of market authorization status, such as a marketing granted order, SE order, SE exemption order, and would be able to enter STN as free text, as applicable), a legible, full color copy of all labeling for the product, indication of the category (e.g., labeling) of material being submitted and the associated product(s), and the original date the labeling materials were first disseminated and date when their dissemination was discontinued. Proposed § 1108.24(e)(10) would require registrants to submit, for all tobacco products not covered by paragraph (9), a legible, full color copy of all consumer information and other labeling for the product, a representative sampling of advertisements for the product, indication of the category (i.e., labeling, advertising, consumer information) of material being submitted and the associated product(s), and the original date the materials were first disseminated and date when their dissemination was discontinued. For labeling under §§ (9) and (10), only one representative package label need be submitted where differences exist only in the bar code, tax stamp, or pricing sticker. A material change to product labeling would require resubmission. Resubmission would not be required if the labeling change is insignificant (e.g., pertains only to grammar, non-substantial typographical errors, or to the tax stamp or bar code).

The dates of dissemination will facilitate FDA's surveillance of labeling and advertising by helping FDA determine when a tobacco product with violative labeling is being sold and when violative advertising for a tobacco product is in use. This information will enable FDA to more efficiently and effectively identify violations for current tobacco product labeling and advertising and pursue compliance and enforcement as appropriate. For example, if in its review FDA identifies evidence of a violation in labeling and/or advertising for a tobacco product (e.g., product labeling indicating that the product presents a reduced health risk without a modified risk tobacco product order in effect, or labeling that is false or misleading), the dates of dissemination will help FDA target its surveillance to determine whether the violative labeling is for a product currently being sold and whether the violative advertising is currently being used. This information, in turn, will help FDA more effectively ensure compliance with the requirements of the law and take enforcement action as appropriate.

Currently, FDA reviews advertisements to help determine whether the advertisements and the product comply with the requirements in the FD&C Act.

The representative sampling of advertisements must include representative material from each medium being used to promote the product, such as advertisements that appear in or on magazines, newspapers, direct mail material, retail or point-of-sale displays, posters, billboards, and via internet and mobile communications (e.g., web pages, banner advertisements, text messages). For example, if more than one magazine advertisement is used for a brand of tobacco product, only one would need to be submitted, provided the promotional message is the same and the overall presentation only differs superficially, such as in background color, font type or border style.

In addition, the proposed requirement would require the product listing to include a copy of all consumer information. Consumer information would not include information directed at wholesalers, distributors, or retailers, where such information is not available to consumers or the public (i.e., potential consumers).

Proposed § 1108.24(f) states per section 905(i)(1)(C) of the FD&C Act that, upon FDA's request, each owner or operator must submit: (1) A brief statement of the basis of the determination, if the registrant has determined that a tobacco product being listed is not subject to a tobacco product standard established under section 907 of the FD&C Act, and (2) for good cause, a copy of all advertisements for a particular tobacco product not subject to a standard established under 907 of the FD&C Act or to section 910 of the FD&C Act. The required information would be required to be submitted within 30 calendar days of FDA's request.

FDA requests comments on whether to require an owner or operator that has manufactured a tobacco product for distribution under a label other than its own to submit, upon request by FDA, the names of all distributors for whom it has been manufactured. This requirement would help FDA to efficiently and effectively ensure that currently marketed tobacco products are not adulterated or misbranded and protect the public health, by enabling FDA, for example, to identify, locate, and take appropriate action regarding violative tobacco products, including in the event of a recall.

F. Maintaining a Historical File (Proposed § 1108.26)

We believe the creation and maintenance of a historical file is reasonably required under section 909 of the FD&C Act for FDA to ensure that the tobacco product is not adulterated or misbranded and to otherwise protect the public health. First, we believe

this information is necessary for FDA to have access to a complete and accurate picture of the consumer information, labeling, and advertisements for the tobacco product, to more effectively and efficiently ensure compliance with the requirements of the FD&C Act and its implementing regulations, which is necessary for the protection of the public health. Further, a historical file is necessary to ensure that the manufacturer can adequately comply with an FDA request made under section 905(i)(1)(B) of the FD&C Act, which allows FDA to request for good cause "a copy of all advertisements for a particular tobacco product." Moreover, the requirement for a historical file would not be unduly burdensome, taking into account that most manufacturers likely already maintain records of the labeling, advertising, and consumer information that a historical file would contain. FDA has observed on inspections of tobacco product manufacturers that most manufacturers are maintaining these types of records.

A historical file would help FDA to determine whether the labeling or advertising would render a tobacco product adulterated or misbranded. Under sections 903(a)(1) and (a)(7) of the FD&C Act, a tobacco product is misbranded if its labeling or advertising, respectively, is false or misleading in any particular, and under section 902(8) of the FD&C Act, a tobacco product is deemed adulterated if it is in violation of section 911 of the FD&C Act. A historical file would enable FDA and registrants to evaluate compliance across all labeling and advertising, whether included in a representative sample or not. For example, FDA may make a determination that a piece of advertising contained in the representative sample submitted to FDA indicates that a product is being marketed as a modified risk tobacco product without a modified risk tobacco product order from the FDA order in effect. This would violate section 911 of the FD&C Act and

render a tobacco product adulterated under section 902(8) of the FD&C Act. FDA may also determine, for instance, that a piece of labeling or advertising contains a claim that is false or misleading, which would render a product misbranded under section 903(a)(1) or section 903(a)(7)(A) of the FD&C Act. In either instance, without a historical file, the registrant may not be able to review all similar pieces of advertising or labeling to bring its product into compliance. A historical file would also enable FDA to determine whether changes to such labeling and advertising necessary to bring the product into compliance are made across all consumer information and other labeling and advertising. For example, a historical file could contain advertising first disseminated in previous years, and that continues to be disseminated for tobacco products sold or distributed to consumers but was not submitted under section 905(i) of the FD&C Act. A historical file requirement would also enable FDA, through a request made pursuant to section 905(i)(1)(B) of the FD&C Act, to determine whether such advertising, and in turn, the product on the market, is in compliance with the requirements of the FD&C Act and its implementing regulations (for example, to ensure that such advertising does not indicate that a product is a modified risk tobacco product without an FDA order in effect, or contain a claim that is false or misleading).

Moreover, a historical file is a critical tool for FDA to assess compliance during inspections. For example, during such inspections, FDA could review a firm's historical file to ensure that it accurately and correctly listed their tobacco products as required under proposed part 1108. In addition, FDA may review a registrant's historical file to ensure that it appropriately included required warnings on all labeling and advertising for such products on the market. Failure to include required warnings on labeling and

advertising, for example, would render a tobacco product misbranded under section 903 of the FD&C Act and would constitute a material change. Additionally, for products that are required to rotate required warning statements, reviewing a historical file would enable FDA to evaluate all advertisements disseminated over a specific timeframe to determine whether the advertisements adhere to the schedule of the quarterly rotation of the required warning statements in the applicable warning plan. Furthermore, reviewing a historical file would also enable FDA to evaluate compliance with warning statement requirements on all labels, such as random display and distribution requirements for warnings on packaging for certain products, including the requirement that such random display and distribution is done in accordance with an FDA approved warning plan.

Accordingly, proposed § 1108.26(a) and (b) would require each owner or operator to maintain a copy of all consumer information, labeling, and advertisements in use on the effective date of this rule for all tobacco products listed in accordance with this part. In addition, they would require each owner or operator to maintain a copy of all consumer information, labeling, and advertisements that is first used after the effective date of this rule. For the purposes of this subsection, consumer information, labeling, and advertisements are first used when the owner or operator had not used them previously or had used them previously but made a material change to them. This requirement would apply regardless of the type of consumer information, labeling, and advertisements, including when they are inserts, onserts, coupons, flyers, store circulars, direct mailers, email messages, social media sites, information contained in audio or video formats, point-of-sale materials, and any other promotional activities targeting consumers. This would include consumer information and other labeling (including package labels) for

each tobacco product included in the product listing and advertisements (including those advertisements not submitted to FDA as part of a representative sampling of advertisements) for such tobacco products.

To satisfy this requirement, a registrant could maintain actual copies of the consumer information and other labeling (including labels), and advertisements disseminated for tobacco products. Alternatively, a registrant could maintain artwork files that show the design, layout, and content of the consumer information, labeling, and advertisements disseminated for use on or for the tobacco products. For example, a manufacturer may have labeling materials with different warning statements or different product inserts or onserts. In this case, the manufacturer would have to include, or reference, the location of each of the materials with different warning statements.

Maintaining a copy of all consumer information, labeling, and advertisements can help provide FDA with a complete picture of how the product is marketed to consumers and whether it is compliant with the FD&C Act. For example, section 903 provides that a tobacco product is misbranded if, for example, its labeling or advertising is false or misleading in any particular or if the product does not bear labeling that is required by an applicable tobacco product standard established under section 907 (section 903(a)(1) and (a)(9) of the FD&C Act). The proposed rule's historical file requirements would also help enable FDA to determine if the tobacco products display required warning statements and are in compliance with the MRTP provisions in section 911 of the FD&C Act (21 U.S.C. 387k). Furthermore, the materials maintained in a historical file would help to determine, for example, whether a tobacco product is counterfeit, as it would contain records from a manufacturer of its actual labeling, advertising, and consumer

information, which could be used to compare to a potentially counterfeit tobacco product. The information maintained in a historical file would enable FDA to take enforcement action against counterfeit tobacco products more quickly and efficiently.

Proposed § 1108.26(c) would require each owner or operator required to register and list who also distributes or causes to be distributed free samples of a smokeless tobacco product under 21 CFR 1140.16(d)(2) to maintain in the historical file documentation of such activities associated with such free sample distribution, including the name, date, and location of each event at which free samples are distributed, the names of the designated representatives who distribute the samples on behalf of the owner or operator, documentation of compliance with § 1140.16(d)(2)(iii)(A), including the identification of the law enforcement officer or licensed security guard present at the event, and documentation of steps taken to comply with § 1140.16(d)(2)(iv). Requiring such documentation can help to ensure that firms are aware of all the requirements for free sample distribution and that all elements of a qualified adult-only facility are present at each event. In addition, retention of advertisements used at free sample events under proposed section 1108.26(a) could allow FDA to verify whether branded t-shirts, posters, or other advertisements displayed in a qualified adult-only facility contain the required warning statements and that brand name signs are only used to identify the adult-only facility. This information can help FDA to prioritize compliance and enforcement activities such as investigations of free sample events.

Maintaining such free sample distribution information in the historical file documentation can help FDA to ensure that the free sample distribution activity at an event did not render a tobacco product misbranded or adulterated. For example, FDA

could review the historical file to help verify whether owners or operators are in compliance with the qualified adult-only facility requirements for free sample distribution in 21 CFR 1140.16(d)(2)(iii) and (iv), to help ensure that such tobacco products were not distributed to a person younger than 21 years of age and were distributed in limited quantities. For example, FDA has received complaints alleging that some firms at promotional events were not checking identification and that particular firms distributed free samples that were not in compliance with 21 CFR 1140.16(d). This is particularly concerning to the extent free samples have allowed individuals younger than 21 years of age to obtain and use smokeless tobacco. FDA expects that owners or operators required to register and list are the entities that distribute, or cause the distribution of, most free samples of smokeless tobacco products. Nonetheless, in addition to this rulemaking, FDA would consider whether to expand this requirement to other entities that distribute, or cause the distribution of, free samples of smokeless tobacco products.

Proposed § 1108.26(d) would provide a timeframe for each owner or operator to maintain consumer information and other labeling or advertisements, as well as free sample distribution information for smokeless products, in the historical file. Specifically, this provision would state that each owner or operator must retain consumer information or other labeling or advertisements from the historical file while currently in use and retain for a period of not less than four years after the date of final dissemination for materials that are discontinued. In addition, each owner or operator would have to retain free sample distribution information for smokeless products for a period of not less than four years after the date of the event documented. The four-year timeframe is based on the particular material, not the continuous commercial distribution of the tobacco

product. For example, if an owner or operator creates a magazine advertisement for a tobacco product, it would be required to maintain a copy of that advertisement until four years after the last time that particular advertisement was disseminated. In addition, each owner or operator would be permitted to discard free sample distribution information for smokeless products four years after the date the event was held.

FDA's ability to address potentially violative labeling and advertising may be hampered if firms were not required to maintain a historical file of labeling, advertising, and consumer information it disseminated for a sufficient time period. For example, FDA would be limited in its ability to ensure that firms comply with the requirements of the FD&C Act and its implementing regulations if FDA could not demonstrate or verify that the firm commercially marketed violative products. In addition, FDA's ability to pursue violations of the FD&C Act identified through routine internet and publication surveillance and investigate reports of tobacco related violations received from consumer complaints would be similarly affected. The materials maintained in a historical file would help FDA to address potentially violative tobacco products on the market by providing information that a manufacturer commercially marketed a tobacco product in a particular timeframe and/or location(s). Such evidence can help FDA target surveillance, collect additional evidence, and take appropriate action with respect to violative tobacco products on the market.

FDA has selected four years to help ensure that the records would be available for at least one FDA inspection under sections 704 and 905(g) of the FD&C Act (21 U.S.C. 374). FDA's biennial inspections under section 905(g) are required to occur at least once in every 2-year period after a manufacturer registers an establishment with FDA, which

could result in inspections occurring nearly 4 years apart. The four-year timeframe also takes into account that advertising can and sometimes does remain in use for several years since it is first disseminated for tobacco products that are sold or distributed, such as advertising in retail environments accessible to youth. We seek comments on whether the four-year timeframes are an appropriate length of time for each owner or operator to maintain such information and documentation in the historical file. Please explain the basis for your comment and any sources for reference.

Proposed § 1108.26(e) contains the proposed requirements for the location of the historical file. Proposed § 1108.26(e)(1) and (e)(2) state that the contents of the historical file must be readily available at the registered establishment for inspection and copying by FDA and that it must be accessible within a reasonable time during inspection or upon FDA request. This provision, coupled with the requirements in proposed § 1108.26(a), would give FDA access to all consumer information, labeling, and advertising information that is needed to assess compliance with the FD&C Act and its implementing regulations and help prevent adulterated and misbranded products from further distribution.

G. Updating Tobacco Product Listing Information (Proposed § 1108.28)

Proposed § 1108.28 would provide the proposed requirements for an owner or operator to update its tobacco product listing information in accordance with section 905 of the FD&C Act. These updates would assist FDA in conducting inspections and any investigations into the source of a reported adverse experience or complaint. Inaccurate or outdated product listing information would interfere with FDA's ability to effectively perform inspections and understand the scope of any such issues. Additionally, this

information is important to enable FDA to stay current on those tobacco products introduced or delivered for introduction into interstate commerce in the United States and to make sure such tobacco products comply with the law.

Proposed § 1108.28(a)(1) would require tobacco product listing information to be updated if there is a change to the manufacture, preparation, compounding, or processing for commercial distribution of a listed tobacco product. Updates would be required when an establishment begins performing another activity on or to the tobacco product, discontinues manufacturing a tobacco product included in a list provided in proposed § 1108.24(e) for commercial distribution, or resumes manufacturing a tobacco product for which a notice of discontinuance was reported. For example, if an establishment registers in February as a facility that only manufactures finished tobacco products, but thereafter begins manufacturing bulk tobacco products at the same establishment in April, the establishment would have to provide that information in the June biannual listing of the same year according to the timeframe provided under proposed § 1108.22(b). Additionally, under proposed § 1108.28(a)(2), any material change to the listing information previously submitted would trigger the requirement to update the listing information. This would include when a registrant has begun to engage in manufacture, preparation, compounding, or processing of a listed tobacco product at an additional establishment added to the previously submitted registration or material changes to the previously submitted labeling, representative sampling of advertisements, or other consumer information for the product. Proposed § 1108.28(a)(3) would require updates to be made within the timeframes specified in § 1108.22(b) and to include the brand

name of the product and the date it was introduced or activities were begun, discontinued, or resumed.

Proposed § 1108.28(b) would require an owner or operator who intends to introduce a tobacco product into commercial distribution, which was not previously included on their product list, to add that product to their product listing and provide product information required by § 1108.24(e).

Proposed § 1108.28(c) and (d) would provide the proposed requirements for how to update product listing information when discontinuing a tobacco product and later resuming its commercial distribution, respectively. Proposed § 1108.28(c) would require an owner or operator who discontinues commercial distribution of a product to update the listing information using FDA's electronic tobacco product registration and listing system, except as provided in § 1108.40(b), to indicate the listed tobacco product is inactive. Additionally, proposed § 1108.28(d) would state that if commercial distribution is later resumed, the owner or operator must reactivate the previously inactivated product listed using FDA's electronic tobacco product registration and listing system and indicate the date on which commercial distribution resumed, except as provided in § 1108.40(b).

H. Assignment of an FDA Establishment Identifier (FEI) Number (Proposed § 1108.32)

Proposed § 1108.32 states that FDA would assign each establishment an FEI number after confirming that complete initial establishment registration information has been submitted. FDA would send this information to the official correspondent of the owner or operator by email or postal mail (if the establishment has been granted a waiver under § 1108.40(b) of this part). Because an establishment can have a different address from the owner or operator, each establishment is assigned a unique FEI number.

I. Electronic Registration of Establishments and Listing of Tobacco Products (Proposed § 1108.40)

Proposed § 1108.40 contains the procedural requirements for electronically registering an establishment and listing tobacco product(s) and for obtaining a waiver from electronic submission. The majority of facilities, both in the United States and outside of the United States, have access to the internet, either within their companies or via other public means (e.g., public libraries or internet cafes).

Proposed § 1108.40(a) states that all initial establishment registration information, updates to registration, initial tobacco product listing information, and updates to tobacco product listings would need to be provided to FDA via the electronic registration and listing system, except if FDA grants the owner or operator a waiver from electronic submission.

In April 2014, FDA replaced its original electronic submission system, eSubmitter, with the FDA Unified Registration and Listing System (FURLS) Tobacco Registration and Listing Module (TRLM). In 2020, FDA replaced the legacy FURLS TRLM system with a scalable tobacco registration system to handle large data processing and storage, the Tobacco Registration and Listing Module Next Generation (TRLM NG). TRLM NG makes the process of submitting registration and listing information more efficient for industry while providing faster access to this information for both FDA and industry.

Unlike the previous eSubmitter process, the current registration and listing electronic system is an online application that can be accessed from the TRLM NG website. This online system allows users to view and update their registration and listing

information from any location and at any time. This system makes registration and listing information more accessible for both FDA and industry. When an establishment wants to view its establishment registration and product listing data, TRLM NG allows the establishment to do so via one website. This system reduces the burden on industry by eliminating the need to submit first-party Freedom of Information Act requests (as was the case with eSubmitter). TRLM NG also allows establishments to distinguish the items that need to be updated from those that do not need to be updated, thereby eliminating any confusion that previously led to duplicate data submissions. Lowering the number of duplicate data submissions reduces the administrative burden on industry and FDA.

Electronic registration benefits both registering establishments and FDA. FDA can accept submissions from anywhere in the world, 24 hours a day and 7 days a week via the electronic tobacco product registration and listing system. Electronic registration enables the owner or operator to register more quickly than via the mail because confirmation occurs instantaneously with electronic registration. Additionally, electronic registration can be completed only when all of the required fields are complete, thereby ensuring all required data elements are entered and reducing the occurrence of incomplete registration. Moreover, the electronic registration system takes less time to complete than its paper counterpart, thus saving owners or operators additional time when registering more than one establishment. For example, the electronic registration would not require certain duplicative fields to be populated if the information is maintained in the submission. Finally, the electronic tobacco product registration and listing system (currently, TRLM NG) allows companies to update information or to indicate that no

changes were made. If changes have been made, the establishment would be required to submit only the information or documents that have been changed; they would not have to resubmit information or documents that have not been changed.

However, FDA recognizes that some owners or operators might be unable to access the internet and the electronic tobacco product registration and listing system. Proposed § 1108.40(b) states that waivers would be granted only if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants would be required to send a letter to FDA requesting the waiver and provide certain information. Under proposed § 1108.40(b)(1) and (b)(2), the owner or operator would be required to submit the name and address of the tobacco product establishment(s) to be registered, a contact person for the owner or operator of the establishment, and the telephone number at which that person can be reached. If the establishment(s) has/have registered in the past, the letter would also have to include the RGID # and each registered establishment's FEI number. The owner or operator would also be required to submit a signed statement that use of the internet is not reasonable for the person requesting the waiver, and an explanation of why such use is not reasonable. Waiver requests may be granted if the owner or operator does not have an email address, access to a computer, or an internet service provider that can access the electronic tobacco product registration and listing system. FDA's experience is that a majority of establishment registration and product listing submissions are electronic and that paper submissions are rare. The Agency anticipates that requests for waivers will be minimal.

Proposed § 1108.40(c) explains that FDA would provide instructions on how to submit information to FDA if an owner or operator is granted a waiver. Generally,

individuals granted a waiver from electronic filing would be required to submit the information specified in proposed § 1108.24 by postal mail in the timeframe specified in proposed § 1108.22. These timeframe requirements are the same as the requirements for those individuals submitting their registration and listing information electronically. Individuals granted a waiver would have to ensure their establishment registration is received by FDA annually by December 31st of each year and tobacco product listing information biannually in June and December – the same requirements for electronic filers.

Proposed § 1108.40(d) would provide that owners and operators who have obtained a waiver from filing electronically must notify FDA within 30 calendar days of any changes regarding the reasonableness of the waiver. For the owner or operator to be in compliance with the 30-calendar-day requirement, FDA would have to receive any notification of changes within 30 days of such change. These changes may include obtaining an internet service provider or other access to the internet. Proposed § 1108.40(d) is consistent with FDA's drug registration and listing requirements, which state that FDA may limit the duration and specify terms of a waiver from filing electronically (see 21 CFR 207.65(c)).

FDA is requesting comments from owners or operators who believe they would be unable to register electronically.

Lastly, proposed § 1108.40(e) would require that all registration and listing information must be provided in the English language. If a company publishes or disseminates consumer information, other labeling, or advertisements in a foreign language in the United States, the company would be required to submit the

advertisement, other labeling, or consumer information in the foreign language as well as a true and accurate English translation of the material, along with a signed statement by an authorized representative of the establishment certifying that the English language translation is complete and accurate and a brief statement of the qualifications of the person that made the translation.

J. Establishment Registration and Tobacco Product Listing for Foreign Establishments Importing or Offering for Import Tobacco Products into the United States (Proposed § 1108.50)

Proposed § 1108.50 sets forth the proposed establishment registration and tobacco product listing requirements for foreign tobacco product establishments. The proposed requirements are similar to those we are proposing for domestic owners or operators. FDA believes that applying these requirements similarly to domestic and foreign owners or operators would bring parity between them and improve FDA's understanding of the types of tobacco products being manufactured, the tobacco products sold in the United States, and the location of all establishments engaged in manufacturing them. This approach is consistent with FDA's drug registration and listing requirements, which likewise apply requirements similarly to domestic and foreign establishments (see 21 CFR 207).

Under proposed § 1108.50(a), any foreign establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product that is imported or offered for import into the United States would have to register such establishment and submit its tobacco product listing information for products manufactured for commercial distribution in the United States.

Proposed § 1108.50(a)(1) would require the foreign establishment's official correspondent to facilitate communication among the establishment, the government of such foreign country, and representatives of FDA regarding matters related to establishment registration and tobacco product listing under section 905(h) of the FD&C Act. Having a designated correspondent would foster consistent, efficient, and effective communication among these parties to make arrangements with the government of such foreign country or to otherwise ensure that adequate and effective means are available to enable FDA to determine whether tobacco products manufactured in such establishment, if imported or offered for import into the United States, are in compliance with the FD&C Act. An official correspondent may also assist in coordinating FDA inspection of the registered establishment with the government of such foreign country or otherwise.

Proposed § 1108.50(a)(2) would establish that certain foreign establishments would not be required to register or list. Specifically, the proposed requirements state that establishments that only manufacture, prepare, compound, or process tobacco products that have entered a foreign trade zone (FTZ) and are exported from that FTZ without being further distributed in the United States (15 CFR part 400 and 19 CFR part 146) would not have to register or list. In contrast, if tobacco products are further distributed in the United States from an FTZ, the foreign establishment would be required to register and list its products in the same fashion as other foreign establishments that distribute tobacco products in the United States. Additionally, under the proposed rule, a foreign establishment would not be required to register if it is otherwise not required to register or list in accordance with proposed § 1108.20(c).

K. Conditions for Registration of Foreign Tobacco Product Establishments (Proposed § 1108.52)

Proposed § 1108.52 outlines the conditions of registration for foreign tobacco product establishments. Section 905(h) of the FD&C Act grants the authority to issue regulations requiring foreign establishment registration and product listing provided that adequate and effective means are available to enable FDA to determine whether the manufacturer's products shall be refused entry on grounds set forth in section 801(a). Such means would exist through these proposed regulations to enable the Agency to identify listed foreign tobacco products for inspection and examination under section 801(a) that may include requesting copies of documents, taking photographs, collecting samples of finished tobacco products, components or parts, packaging, labeling, or labels, or other information.

L. Public Availability of Registration and Tobacco Product Listing Information (Proposed § 1108.60)

Proposed § 1108.60 outlines the proposed public availability of registration and tobacco product listing information. The proposed requirements in this section implement section 905(f) of the FD&C Act, which expressly requires FDA to make establishment registration information available to the public for inspection. Proposed § 1108.60 states that establishment registration and tobacco product listing information would be available for public inspection and would be posted on the FDA website, in a manner consistent with 21 CFR part 20. Additionally, the proposed provision provides information for where to send requests for information for those without internet access.

M. Misbranding (Proposed § 1108.62)

Proposed § 1108.62 states that the registration of a tobacco product establishment or assignment of a registration number would not in any way denote FDA approval of the establishment or marketing authorization for its tobacco products. Any representation in consumer information, labeling, or advertising that creates an impression of FDA approval of a registered establishment, or an impression of FDA marketing authorization of a listed tobacco product, or an impression that a listed tobacco product is safe or less harmful because of registration or possession of a registration number, would be misleading and would result in the product being deemed misbranded under section 903 of the FD&C Act. If a tobacco product is manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), is not included in a product list required by section 905(i), or its labeling or advertising is false or misleading in any particular, the product would be deemed misbranded under section 903(a) of the FD&C Act. Section 301 of the FD&C Act prohibits, among other things, the introduction or delivery for introduction into interstate commerce of any tobacco product that is misbranded. The failure to register in accordance with section 905 of the FD&C Act and the implementing regulations in this part, the failure to provide any information required by section 905(i) of the FD&C Act and the implementing regulations in this part, or the failure to provide a notice required by section 905(i)(3) of the FD&C Act and the implementing regulations in this part is a prohibited act under section 301(p) of the FD&C Act.

VI. Proposed Effective Date

FDA proposes that any final rule that issues based on this proposal become effective 60 days after the final rule publishes in the *Federal Register*. FDA requests comments on this proposed effective date.

VII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under E.O. 12866, E.O. 13563, E.O. 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 direct us to assess all benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are economically significant under E.O. 12866 if they have an annual effect on the economy of $100 million or more; 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, or Tribal governments or communities. The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is a significant regulatory action under E.O. 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant regulatory actions "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 regulatory action.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the additional

costs per entity of this rule are small, 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 estimates of anticipated impacts, 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 1 year." The current threshold after adjustment for inflation is $187 million, using the most current (2024) 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. Overview of Benefits, Costs, and Transfers

Section 905 of the FD&C Act (21 U.S.C § 387e) requires owners and operators of domestic establishments, upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product, to immediately register their establishment, and to register annually thereafter.[7] It also requires owners and operators who register their establishment to submit, at the time of registration, a list of all tobacco products it manufactures, prepares, compounds, or processes.[8] Changes to the product list are to be reported twice a year. Section 905 also requires foreign establishments to register in accordance with regulations published by FDA. This proposed rule would prescribe the format, content, and procedures for registration and product listing of domestic establishments and extend those requirements to foreign establishments

[7] See Section 905(b), (c).
[8] See Section 905(i). The product listing includes additional information, such as a copy of all consumer information and other labeling as well as a representative sample of advertising for certain listed tobacco products.

engaged in the manufacture, preparation, compounding, or processing of a tobacco product that is imported or offered for import into the United States.

Table 2 presents estimated annualized total costs associated with the provisions in this proposed rule for both domestic and foreign establishments as well as for FDA. The 20-year annualized total costs range from $6.80 million to $26.55 million at a 7 percent discount rate, with a primary estimate of $15.57 million. The annualized total costs range from $6.81 million to $26.55 million at a 3 percent discount rate, with a primary estimate of $15.57 million. Estimated costs to establishments are derived from registration and listing activities and from inspection costs. Total annualized costs to domestic tobacco product establishments are estimated at $13,574 and $13,429 per year using a discount rate of 7 and 3 percent respectively (primary estimate), over a period of 20 years. Total annualized costs to foreign tobacco product establishments are estimated at $370,215 and $377,071 per year using a discount rate of 7 and 3 percent respectively (primary estimate). Annualized costs to FDA are approximately $15.18 million, also using a discount rate of 7 percent and 3 percent (primary estimate). These costs include costs to FDA associated with conducting both domestic and foreign inspections.

The proposed establishment registration and product listing requirements would generate several categories of benefits including several increased efficiencies in FDA enforcement and compliance activities, faster public health response, enhanced deterrence and compliance, reduced availability of unauthorized products, and reduced public health burden. We describe these benefits qualitatively due to data limitations and modeling constraints. To illustrate the potential economic benefits of the proposed rule, we provide an example of the potential reduction in illegal imported e-cigarette products.

Table 2.--Summary of Benefits, Costs, and Distributional Effects of the Proposed Rule (millions of 2024 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $/year					7%		
						3%		Not Quantified
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $/year	$15.57	$6.80	$26.55	2024	7%	2027-2046	Costs incurred by domestic establishments are $13,574 (primary estimate at 7% discount rate) representing 0.1% of total costs. Estimated foreign costs are $370,215 at 7 percent discount rate representing 2.4% of total costs. FDA costs account for the remaining 97.5% of total costs.[1]
		$15.57	$6.81	$26.55	2024	3%		
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized $/year					7%		
						3%		
	From/To	From:			To:			

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Effects	State, Local or Tribal Government: Small Business: none Wages: none Growth: none							

[1] This rule would not affect the total amount of user fees set by statute nor the size of the federal budget.

In line with E.O. 14192, in Table 3 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. We estimate that this proposed rule would generate $12.56 million in annualized net costs at a 7 percent discount rate (primary estimate), discounted relative to year 2024 over a perpetual time horizon. The majority of these net costs are FDA costs.

Table 3.--Executive Order 14192 Summary Table (millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate).

	Primary Estimate	Low Estimate	High Estimate
Present Value of Costs	$179.40	$77.52	$307.14
Present Value of Cost Savings	$0	$0	$0
Present Value of Net Costs	$179.40	$77.52	$307.14
Annualized Costs	$12.56	$5.43	$21.50
Annualized Cost Savings	$0	$0	$0
Annualized Net Costs	$12.56	$5.43	$21.50

We have developed a Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 3, FDA) and at https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.

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. No

extraordinary circumstances exist to indicate that the specific proposed action may significantly affect the quality of 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 PRA. A description of these provisions is given in the Description section with an estimate of the annual reporting and recordkeeping burden. Included in the estimate 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 would 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: Establishment Registration and Product Listing for Tobacco Products. OMB Control Number 0910-0650 – Revision

Description: The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products. The Agency is proposing a rule, in accordance with section 905 of the FD&C Act, requiring

owners or operators of domestic and foreign establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products, to register their establishments. Further, the proposed rule would require owners or operators of both domestic and foreign establishments to, at the time of registration, list all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution. Currently, in accordance with section 905 of the FD&C Act, only domestic owners and operators are required to register their establishments and list their tobacco products with FDA while foreign owners and operators are not subject to these requirements, creating significant gaps in Agency information. If finalized, this rule would extend registration and listing requirements to include owners and operators of foreign establishments.

Description of Respondents: This proposed rule would require owners or operators of an establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product to register those establishments and list their tobacco products that are being manufactured, prepared, compounded, or processed by that person for commercial distribution. The proposed rule applies to owners or operators of domestic and foreign establishments. Manufacturers of tobacco products include specification developers, third-party manufacturers, bulk tobacco product manufacturers, repackagers/relabelers, any owner or operator of any domestic establishment that manufactures a tobacco product for export, or any owner or operator of an establishment that manufactures free smokeless tobacco samples. The proposed rule includes some exceptions, including persons who solely manufacture a tobacco product intended solely for investigational use under section 910(g) of the FD&C Act; manufacturers of only raw

materials other than tobacco used in manufacturing a component or part of a tobacco product who would not otherwise be required to register; and common carriers in the receipt, carriage, holding, or delivery of a tobacco product in the usual course of business as carriers. This rule enables FDA to get a full and accurate inventory of establishments that engage in the manufacture, preparation, compounding, or processing of tobacco products, including their corporate structure, if applicable, and their supply chain. To avoid unnecessary duplicate registrations and listings, proposed § 1108.20(a) would permit a parent, subsidiary, or affiliate company to submit registration information for all establishments when operations are conducted at more than one establishment and the establishments are under common or joint ownership or control.

Proposed § 1108.22(a) provides that an owner or operator of a domestic establishment engaged in an operation described in § 1108.20(a) would have to register the establishment and submit tobacco product listing information within five business days from first engaging in the operation. Further, this regulation would require owners or operators of foreign establishments engaged in an operation described in § 1108.20(a) to register the establishment and submit tobacco product listing information before any tobacco product manufactured, prepared, compounded or processed at the establishment is imported or offered for import into the United States, which comports with FDA's initial drug registration requirements for foreign establishments (see 21 CFR 207.21(b)). Proposed § 1108.50 would describe additional conditions and exceptions for foreign tobacco product establishments.

Proposed § 1108.22(b)(1) would require that annual registration be completed and submitted to FDA by December 31st of each year, even if there are no changes to the establishment registration.

As required by section 905(i)(3) of the FD&C Act, proposed § 1108.22(b)(2) would require owners or operators to review and update their tobacco product listing information in June and December of every year. Owners or operators would be required to report any changes or deletions to listings described in § 1108.28 and list any new products not previously reported. For example, if the labeling for a product is changed in October, the product listing information would have to be updated accordingly in December of the same year. This information would be used to help ensure the products marketed are in compliance with the FD&C Act and implementing regulations.

Proposed § 1108.24(a) would specify the information required for tobacco product establishment registration (e.g., information about the establishment, owner and operator, official correspondent, trade names, website address(es), RGID #, FEI number, Tribe). Proposed § 1108.24(e) would specify the tobacco listing information to be provided for each tobacco product listed (e.g., RGID # and name of each establishment, product information, product numbers and tracking information, operation and process information, product standard information, marketing authority, labeling information). In addition, proposed § 1108.24(f) would specify that owners or operators may be required to submit to FDA upon request information for products that have been determined to not be subject to tobacco product standards or products manufactured for distribution under a label other than its own.

Proposed § 1108.26 would require owners or operators who manufacture a tobacco product to maintain a historical file containing a copy of all consumer information, labeling, and advertisements in use as of the effective date of the rule for all tobacco products contained in the product list for four years (including any information which has had a material change after the effective date of the rule). Additionally, those who distribute smokeless samples must keep, for four years after the date of the event, information about the events (e.g., compliance information, details about the event). The authority for the proposed § 1108.26 recordkeeping requirements comes from sections 905 and 909 of the FD&C Act.

Proposed § 1108.28 would include requirements for updating tobacco product listing information, including what changes would require an update; the timeframe for making updates; and how to add, discontinue, or renew product listings.

FDA currently collects the information (OMB control number 0910-0650) submitted pursuant to section 905 of the FD&C Act through the Tobacco Registration and Product Listing Module Next Generation (TRLM NG) electronic portal and FDA Forms 3741 and 3741b. TRLM NG is designed to streamline the data entry process for registration and product listing. Electronic submission through TRLM NG, available at https://www.fda.gov/tobacco-products/manufacturing/tobacco-registration-and-listing-module-next-generation-trlm-ng-instructions, would be required under proposed § 1108.40 unless a registrant receives a waiver from FDA under proposed § 1108.40(b). To request a waiver, § 1108.40(b) would require applicants to send a letter to FDA's Center for Tobacco Products with information about the establishment and a signed statement explaining the need for a waiver. For owners or operators that have obtained a

waiver, if information changes that might result in termination of the waiver, § 1108.40(d) would require that the owner or operator to notify FDA within 30 calendar days.

FDA's burden estimates are based on FDA's experience with tobacco registration and listing, FDA inspection reports, and Preliminary Regulatory Impact Analysis assumptions. The requirements in the proposed rule would apply to both domestic and foreign manufacturers of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution in the United States.

The currently approved information collection under OMB Control Number 0910-0650 includes the following annual burden estimates for establishment registration and product listing activities:

Table 4.--Existing Burden for OMB Control Number 0910-0650, Estimated Annual Reporting Burden

FDA Form/Activity/FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741, Form FDA 3741a, and the new Form FDA 3741 (Electronic and Paper submissions)[1] Sections 905(b), 905(c), 905(d), 905(h), or 905(i)	37	1	37	1.65 (99 minutes)	61
Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741, Form FDA 3741a, and the new Form FDA 3741 (Electronic and Paper submissions)[2] Sections 905(b), 905(c), 905(d), 905(h), or 905(i)	900	1	900	0.28 (17 minutes)	252

Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, "Tobacco Product List Spreadsheet"	37	1	37	0.22 (13 minutes)	8
Total			974		321

[1] This initial submission is averaged over the three years of the information collection utilizing the current Form FDA 3741 and 3741a, which will be combined in updated Form FDA 3741 in Spring 2026.

[2] This renewal submission is averaged over the three years of the information collection utilizing the current Form FDA 3741 and 3741a, which will be combined in Form FDA 3741 "Registration and Product Listing of Tobacco Product Manufacturing Establishments" with product listing and material file information updates.

The currently approved information collection also includes burden for ingredient listing activities under Form FDA 3742 (180 hours) and obtaining a D-U-N-S number (19 hours), which total 199 hours. These activities are not part of this proposed rule and are therefore excluded from the comparison. The total currently approved burden is 520 hours, but only 321 hours are relevant to the establishment registration and product listing activities covered by this proposed rule (see Table 4). The currently approved information collection does not include registration and listing requirements for foreign establishments and historical file maintenance requirements under proposed § 1108.26.

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

Table 5.--Estimated Annual Reporting Burden – Domestic Establishments[1]

FDA Form/Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
First Time Burden					
Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741 Proposed 1108.22(a), 1108.24, 1108.22(b)(1)	47	1	47	1.83 (110 minutes)	86
Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, "Product List Spreadsheet" 1108.24, 1108.22(b)(2)	47	1	47	0.42 (25 minutes)	20

Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741 1108.24, 1108.28 (update to Product Listing)	947	1	947	0.33 (20 minutes)	313
Waiver from electronic submission requirement 1108.40	2	1	2	0.25 (15 minutes)	1
Total First Time Burden Hours – Domestic					419
Annual Recurring					
Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741 Proposed 1108.22(a), 1108.24, 1108.22(b)(1)	37	1	37	1.83 (110 minutes)	68
Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, "Product List Spreadsheet" 1108.24, 1108.22(b)(2)	37	1	37	0.42 (25 minutes)	16
Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741 1108.24, 1108.28 (update to Product Listing)	910	1	910	0.33 (20 minutes)	300
Waiver from electronic submission requirement 1108.40	1	1	1	0.25 (15 minutes)	1
Total Annual Recurring Burden Hours – Domestic					384
Total Burden Hours– Domestic					803

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

Table 6.--Estimated Annual Reporting Burden – Foreign Establishments[1]

FDA Form/Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response[2]	Total Hours
First Time Burden					

Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741 (foreign) Proposed 1108.22(a), 1108.24, 1108.22(b)(1)	3,253	1	3,253	2.61 (157 minutes)	8,490
Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, "Product List Spreadsheet" (foreign) 1108.24, 1108.22(b)(2)	3,253	1	3,253	0.60 (36 minutes)	1,952
Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741 (foreign) 1108.24, 1108.28 (update to Product Listing)	3,253	1	3,253	0.47 (28 minutes)	1,529
Waiver from electronic submission requirement 1108.40	130	1	130	0.36 (22 minutes)	47
Total First Time Burden Hours – Foreign					12,018
Annual Recurring					
Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741 Proposed 1108.22(a), 1108.24, 1108.22(b)(1)	134	1	134	2.61 (157 minutes)	350
Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, "Product List Spreadsheet" 1108.24, 1108.22(b)(2)	134	1	134	0.60 (36 minutes)	80
Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741 1108.24, 1108.28 (update to Product Listing)	3,253	1	3,253	0.47 (28 minutes)	1,529
Waiver from electronic submission requirement 1108.40	5	1	5	0.36 (22 minutes)	2
Total Annual Recurring Burden Hours – Foreign					1,961
Total Burden Hours – Foreign					13,979

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

[2] Foreign Hours per response = domestic hours multiplied by 1.43 (adjustment for English Proficiency/Internet Access)

For this proposed rule, FDA has based the estimates on the experience with current registration and listing submissions through OMB Control Number 0910-0650, tobacco import data, and FDA experience and subject matter expertise as discussed in the regulatory impact analysis. Taking into consideration the clarification of industry requirements provided by this rule and the extension of establishment registration and product listing requirements to foreign establishments, FDA estimates an increase in registrants and consequently an increase in estimated annual burden.

The currently approved total annual hours for domestic establishments, covering registration and listing only, is 321 hours, as reflected in Table 4 above. Under the proposed rule, the total annual recurring hours for domestic establishments would increase to 384 hours, representing an increase of 63 hours. This increase is attributable to enhanced data elements and clarified requirements introduced by the proposed rule. The proposed rule includes a total first-time burden of 419 hours due to 10 additional domestic establishments expected to register in the initial year of implementation, reflecting the transition to the new requirements. The proposed rule includes a total first-time burden of 12,018 hours for foreign establishments in the initial year of implementation, reflecting the new requirement for foreign establishments to register and list their products. We expect a total annual recurring burden for foreign establishments to be 1,961 hours.

Further, FDA estimates an overall increase in average hours per response associated with initial registration using Form FDA 3741 (from 100 minutes to 110

minutes), and the initial product listing spreadsheet (Form FDA 3741b) submission (from 20 minutes to 25 minutes) for domestic entities. Separate tables for domestic and foreign estimated annual hourly burden are provided.

Table 5 displays the estimated annual reporting burden for domestic tobacco establishments and Table 6 displays the estimated annual reporting burden for foreign tobacco establishments. The foreign hours per response rate were adjusted by multiplying the domestic hours per response by 1.43. This adjustment accounts for potential differences in English proficiency and availability of internet access.

Proposed § 1108.22(a) and § 1108.24 set forth when to submit initial establishment registration and product listing and the information required for submission. FDA estimates that domestic establishments will need approximately 110 minutes (1.83 hours) to complete the initial Form FDA 3741 for establishment registration and labeling, advertising, and consumer information submission, while foreign establishments will require 157 minutes (=1.43 x 1.83 hours, or 2.61 hours). The Agency estimates that with 47 domestic and 3,253 foreign tobacco establishments each submitting one initial form, the total burden would result in 3,300 total respondents and 8,576 burden hours (86 hours domestic + 8,490 hours foreign) for the initial year after the rule goes into effect. In the following years, FDA estimates the number of initial registrations to decrease to 37 domestic and 134 foreign establishments submissions via Form FDA 3741, resulting in a total burden of 418 hours (68 hours domestic + 350 hours foreign) annually.

FDA also estimates that it would take approximately 25 minutes (0.42 hours) to prepare and complete the initial product listing registration using Form FDA 3741b for a

domestic establishment, and approximately 36 minutes (=1.43 x 0.42, or 0.60 hours) for foreign establishments. The Agency estimates that the same 3,300 total respondents will each submit 1 initial product listing Form FDA 3741b, for a combined total of 1,972 burden hours (20 hours domestic + 1,952 hours foreign). In the following years, FDA estimates these numbers to decrease to 37 domestic and 134 foreign establishments submitting initial product listings via Form FDA 3741b, resulting in a total burden of 96 hours (16 hours domestic + 80 hours foreign) annually.

Both domestic and foreign establishment submissions would be required to be completed electronically using Form FDA 3741 and Form FDA 3741b via TRLM-NG or, if FDA has granted a waiver, through paper submissions.

In terms of proposed § 1108.22 (b) and § 1108.28, continued establishment registration and product list filing via Form FDA 3741 (i.e., the confirmation or updating of establishment registration and product listing information as required by section 905 of the FD&C Act), FDA estimates that it will take each domestic respondent approximately 20 minutes (0.33 hours) to complete the renewal submission, while foreign establishments will require approximately 28 minutes (=1.43 x 0.33 hours, or 0.47 hours). FDA estimates that up to 947 domestic and 3,253 foreign owners or operators will be submitting registration renewals during the first year after the proposed rule goes into effect. This results in a total of 4,200 respondents and a total burden of 1,842 hours (313 hours domestic + 1,529 hours foreign) for the initial year after the rule goes into effect. These renewals may encompass an acknowledgment of accurate product listing through a certification statement, or a more substantive review that includes updates to product listings, with updates typically occurring in June and the completion of the renewal

processes taking place in December. In the following years, FDA estimates these renewal submission numbers to decrease to 910 for domestic establishments and to remain at 3,253 for foreign establishments submitting renewal registrations and product listings via Form FDA 3741, resulting in a total burden of 1,829 hours (300 hours domestic + 1,529 hours foreign) annually.

Proposed § 1108.40 would require an applicant to submit Forms FDA 3741 and 3741b and all supporting and related documents to FDA in electronic format that FDA can process, review, and archive unless an applicant requests, and FDA grants, a waiver from this requirement under proposed § 1108.40(b). FDA estimates that 4 percent of the respondents may request a waiver. Consistent with our other application estimates for waivers, we estimate it would take 15 minutes (0.25 hours) per waiver for domestic establishments, and approximately 22 minutes (=1.43 x 0.25, or 0.36 hours) for foreign establishments. During the initial year after the proposed rule takes effect, the Agency estimates that approximately 2 domestic and 130 foreign waiver applications will be submitted, for a total of 48 burden hours (1 hours domestic + 47 hours foreign). In the following years, FDA estimates these numbers to decrease to 1 domestic and 5 foreign waiver applications, resulting in a total burden of 3 hours (1 hour domestic + 2 hours foreign) annually.

Table 7.--Estimated Annual Recordkeeping Burden[1]

FDA Form/Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
First Time – Single Year Burden (Domestic and Foreign)					
Maintaining historical file 1108.26	4,200	1	4,200	0.10 (6 minutes)	420
Recurring Annual (Domestic and Foreign)					

Maintaining historical file 1108.26	4,163	1	4,163	0.10 (6 minutes)	416
Total Recordkeeping Burden					836

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

Table 7 describes the annual recordkeeping burden per the requirements in this proposed rule. The currently approved collection has no recordkeeping burden, therefore all burden hours for recordkeeping are new. FDA estimates that in the initial year 4,200 recordkeepers, encompassing both domestic and foreign establishments, will maintain records at 0.10 hours per record, for a total of 420 hours. In the following years, FDA estimates these numbers to decrease to 4,163 recordkeepers, resulting in a total burden of 416 hours annually. Firms would have already established the required records when submitting the initial or renewal registration and listing submission. We believe this time is usual and customary for these firms and it would take 6 minutes to establish and/or update the required historical file. Proposed § 1108.26 requires respondents to maintain a historical file for 4 years and keep records related to smokeless tobacco product sample distribution for 4 years.

FDA estimates that the total burden for the activities in this rulemaking is 15,618 hours (14,782 hours reporting + 836 hours recordkeeping).

If finalized, the new collections of information will revise OMB Control Number 0910-0650. Our estimated burden for the proposed rule reflects an overall increase of 15,098 hours from the currently approved information collection. We attribute this increase to the proposed rule's clarification of industry requirements and the extension of establishment registration and product listing requirements to owners and operators of foreign establishments.

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through https://www.reginfo.gov/public/do/PRAMain (see ADDRESSES). All comments should be identified with the title of the information collection.

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has 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 E.O. 13132. Section 4(a) of the E.O. requires Agencies to "construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."

Section 916(a)(2) of the FD&C Act (21 U.S.C. 387p) is an express preemption provision. Section 916(a)(2) provides that "no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to . . . registration." Thus, if this proposed rule is made final, the final rule would create requirements that fall within the scope of section 916(a)(2) of the FD&C Act.

XI. Severability

In accordance with section 5 of the Tobacco Control Act, which provides for the severability of, *inter alia*, all "regulations promulgated under" the authorities provided by that Act, FDA would consider the various requirements and prohibitions established by this rule, if finalized, to be severable. It is FDA's interpretation and position that the invalidity of any provision of a final rule would not affect the validity of any other part of the rule. In the event any court or other lawful authority were to temporarily or permanently invalidate, restrain, enjoin, or suspend any provision of a final rule, FDA intends for the remaining parts to continue to be valid. Additionally, as further stated in section 5 of the Tobacco Control Act, if certain applications of a final rule to persons or circumstances (discussed in the preamble or otherwise) are held to be invalid, application of such provisions to any other person or circumstance will not be affected and will continue to be enforced to the fullest extent possible. Each provision of the rule is independently supported by data and analysis as described or referenced in this preamble and, if issued separately, would remain a proper exercise of FDA authority.

XII. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively determined that the 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XIII. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are 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. Draft Form FDA 3741 (Registration of Tobacco Product Establishments and Listing of Tobacco Products in Commercial Distribution).

2. FDA. Draft Form FDA 3741b (Tobacco Product List Spreadsheet).

3. FDA. *Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, Establishment Registration and Product Listing for Tobacco Products.* Silver Spring, MD: U.S. Department of Health and Human Services, FDA, Center for Tobacco Products, 2026. Available at https://www.fda.gov/economics-staff/regulatory-impact-analyses-ria.

List of Subjects

21 CFR Part 1108

Tobacco products, Registration, Product listing.

Therefore, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended by adding part 1108 to subchapter K to read as follows:

PART 1108 – REGISTRATION OF TOBACCO PRODUCT ESTABLISHMENTS AND LISTING OF TOBACCO PRODUCTS IN COMMERCIAL DISTRIBUTION

Subpart A – General Provisions

Subpart B – Procedures for Tobacco Product Establishments

Subpart C – Format for Establishment Registration and Tobacco Product Listing

Subpart D – Procedures for Foreign Tobacco Product Establishments

Subpart E – Miscellaneous

Authority: 21 U.S.C. 331, 371(a), 374, 381(p), 387b, 387c, 387e, 387g, 387i, 387j, and 387k.

Subpart A – General Provisions

§ 1108.1 Scope.

(a) This part prescribes the format and content for registration of domestic and foreign establishments that manufacture tobacco products and listing of tobacco products manufactured by such establishments, along with requirements of this part that will help ensure tobacco products are not adulterated or misbranded and comply with FDA's premarket authorities. The requirements of this part apply to domestic and foreign establishments that manufacture, prepare, compound, or process tobacco products that are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

(b) The requirements in this part are intended to protect the public health and ensure that tobacco products are in compliance with the relevant provisions of the FD&C Act and its implementing regulations.

§ 1108.3 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco or nicotine, and is not made or derived from tobacco or nicotine from any source; and meets either of the following:

(a) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(b) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but:

(1) Solely controls moisture and/or temperature of a stored tobacco product; or

(2) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Brand means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes.

Brand owner means a person that owns a brand, through creation, acquisition, trademark, patent, copyright, or otherwise, and has directly or through license, the control and/or direction of the brand.

Bulk tobacco product means a tobacco product not sealed in final packaging but otherwise suitable for consumer use as a tobacco product.

Commercial distribution means any distribution of a tobacco product, whether domestic or imported, to consumers or to any person, but does not include interplant transfers of a tobacco product between establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for consumption or resale. “Commercial distribution” does not include the handling or transfer of a tobacco product from one consumer to another for personal consumption. For foreign establishments, the term “commercial distribution” has the same meaning, except that it does not include distribution of a tobacco product that is neither imported nor offered for import into the United States. Nor does it include shipment of a tobacco product into a foreign trade zone if the product is then exported and not further distributed in the United States.

Component or part means any software or assembly of materials intended or reasonably expected:

(a) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or:

(b) 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.

Domestic establishment means an establishment in any State or Territory or possession of the United States.

Establishment means a place of business, under one ownership at one general physical location, engaged in an operation described in § 1108.20(a). A single building may house more than one distinct establishment if the establishments are under separate ownership. Establishment refers to both domestic and foreign establishments unless otherwise noted.

Finished tobacco product means a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter tubes sold separately to consumers or as part of kits).

Foreign establishment means an establishment other than a domestic establishment.

Industry product identification number means a unique, product-specific identifier or alphanumeric code, such as a universal product code (UPC), stock keeping unit (SKU), Item #, or Catalog #, that industry generates for internal record keeping and tracking. FDA intends to utilize an industry product identification number when corresponding with industry as a point of reference to help distinguish a specific product from other

similar products made by the same manufacturer but with slight differences in product attributes (such as volume or quantity or packaging).

Labeling means all labels and other written, printed, or graphic matter:

(a) upon any tobacco product or any of its containers or wrappers, or;

(b) accompanying such tobacco product.

Manufacturer means any person who manufactures, prepares, compounds, or processes a tobacco product, including repackaging or relabeling of any tobacco product. Examples of manufacturing include assembling, processing, homogenizing, mixing, formulating, labeling, or packaging. Manufacturers include specification developers, third-party manufacturers, bulk tobacco product manufacturers, and repackagers/relabelers.

Material change includes:

(a) any change in the tobacco product name (including brand or subbrand), warnings, or instructions for use;

(b) any change in the owner or operator, or establishment;

(c) any other significant change with respect to consumer information, to other labeling, or to the advertisements for the tobacco product, such as changes to the logo(s), identifiable patterns of color, or product descriptors;

(d) any change in the marketing authorization or status for the marketing of such product; and

(e) any change with respect to whether or not the product is subject to a tobacco product standard established under section 907 of the FD&C Act (21 U.S.C. 387g).

With respect to changes in consumer information or other labeling of the tobacco product, changes that are not significant include changes to grammar, correction of typographical errors that do not change the content of the labeling, and changes in tax stamp or bar code.

Operator means a person, as defined in section 201(e) of the FD&C Act, who has management authority over an establishment.

Owner means a person, as defined in section 201(e) of the FD&C Act, who has an ownership interest in an establishment.

Product Identification Number (PD #) means the number that FDA assigns to each product within a submission to distinguish among the products included in that submission. A PD # is only relevant within the context of a specific STN.

Registration Identification Number (RGID #) means the FDA-assigned unique identifier for a registered establishment's registration. The RGID # is assigned to each new electronic tobacco product registration and listing system submission and attaches to the establishment(s) and the product(s) in the initial submission.

Representative sampling of advertisements means advertising material that gives a comprehensive picture of the promotional claims and campaigns in use for each brand of tobacco product and which includes representative material from each medium being used to promote the product (e.g., advertisements that appear in or on magazines, newspapers, direct mail materials, retail or point-of-sale displays, posters, billboards, and via internet and mobile communications, such as web pages, banner advertisements, and text messages).

Specification developer means a person who controls the design and development of a tobacco product or initiates or creates the specifications for the product.

Submission Tracking Number (STN) means the number that FDA assigns to submissions that are received from an applicant, such as a Premarket Tobacco Product Application (PMTA), supplemental PMTA, Substantial Equivalence (SE) reports, SE exemption requests (EX REQ), Modified Risk Tobacco Product Application (MRTPA), and submissions related to investigational tobacco products.

Third-party manufacturer means an entity, including a contract manufacturer, that physically manufactures a tobacco product on behalf of, or to specifications established by, another party, such as a brand owner or specification developer.

Tobacco product means 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 under section 201(g)(1) (21 U.S.C. 321(g)(1)), a device under section 201(h) (21 U.S.C. 321(h)), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)). The term "tobacco product" does not mean an article that is a food under section 201(f) (21 U.S.C. 321(f)), if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

Tobacco Product Number (TP #) refers to a product-specific number that is generated by FDA for each product listed on an establishment's registration.

Subpart B – Procedures for Tobacco Product Establishments

§ 1108.20 Who must register and submit a tobacco product list.

(a) An owner or operator of any establishment, except those entities as provided in paragraph (c) of this section, engaged in the manufacture, preparation, compounding, or processing of a tobacco product must register in accordance with section 905 of the FD&C Act, including specification developers, third-party manufacturers, bulk tobacco product manufacturers, repackagers/relabelers, any owner or operator of any domestic establishment that manufactures a tobacco product for export, and any owner or operator of any establishment that manufactures free smokeless tobacco samples. When operations are conducted at more than one establishment and the establishments are under common or joint ownership or control, the parent, subsidiary, or affiliate company may submit registration information for all establishments on behalf of their respective owners and operators, in lieu of each establishment registering separately. In this case, duplicative registration for any establishment need not also be submitted by the owner and operator of the establishments.

(b) Every person who registers under this part must submit a list of all tobacco products that are being manufactured, prepared, compounded, or processed by that person for commercial distribution in the form and manner prescribed in this part in accordance with section 905(i) of the FD&C Act (21 U.S.C. § 387e(i)). When operations are conducted at more than one establishment and the establishments are under common or joint ownership or control, the parent, subsidiary, or affiliate company may submit listing information for all establishments.

(c) Persons not required to register their establishments or submit a tobacco product list:

(1) Persons engaged only in manufacturing investigational use tobacco products where the product is not available for sale or distribution other than as part of an investigation.

(2) Manufacturers of only raw materials, other than tobacco, used in manufacturing a component or part of a tobacco product.

(3) Common carriers, in their receipt, carriage, holding, or delivery of a tobacco product in the usual course of business.

(d) Registration and listing do not constitute an admission, agreement, or determination by FDA that a product is a tobacco product within the meaning of section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)). In addition, registration and listing do not denote FDA authorization for the marketing of tobacco products in the United States within the meaning of sections 905 or 910 of the FD&C Act. Listed products that are subject to sections 905 and 910 of the FD&C Act are not authorized for the legal sale and distribution in the United States unless they have an FDA marketing authorization order in effect.

§ 1108.22 When to submit establishment registration and tobacco product listing.

(a) *Initial establishment registration and product listing*. An owner or operator of a domestic establishment engaged in an operation described in § 1108.20(a) must register the establishment and submit tobacco product listing information within five business days from first engaging in the operation. An owner or operator of a foreign establishment engaged in an operation described in § 1108.20(a) must

register the establishment and submit tobacco product listing information before any tobacco product manufactured, prepared, compounded, or processed at the establishment is imported or offered for import into the United States.

(b) *Continued establishment registration and product list filing*. Owners or operators shall review, change as needed, or confirm there have been no changes to, their establishment registration and tobacco product listing information that is on file with FDA, documenting any changes that were not previously reported as follows:

(1) *Annual establishment registration*. By December 31 of each year, each owner or operator of an establishment engaged in an operation described in § 1108.20(a) must register each of its establishments, and certify that all information associated with the registered establishments and its listed products is accurate and up to date. Each owner or operator of a registered establishment must review, change as needed, or confirm there have been no changes to, the registered establishment information and listed products. Annual registration is still required even to confirm that there have been no changes.

(2) In June and December of every year, each owner or operator of an establishment engaged in an operation described in § 1108.20(a) shall review, change as needed, or confirm there have been no changes to, their tobacco product listing information that is on file with FDA, reporting any changes or deletions to listings as described in § 1108.28 and any new listings that were not previously reported.

§ 1108.24 Information required for tobacco product establishment registration and tobacco product listing.

(a) Owners or operators of establishments that are subject to the registration and listing requirements of this part must provide the following information, if applicable, to FDA using FDA's electronic tobacco product registration and listing system, except as provided in § 1108.40(b):

(1) The full name, physical address, mailing address, and contact information for the establishment;

(2) The name, address, phone number, fax number, and email address of the owner and operator; if a partnership, the name of each partner; if a corporation, the place of incorporation and the name of each corporate officer and director; any trade names used by the owner and operator or other names under which the owner and operator conducts business or additional names by which the owner and operator is known;

(3) The name, address, phone number, fax number, and email address of the official correspondent designated by the owner or operator as required under paragraph (c) of this section;

(4) Any trade names used by the establishment or other names under which the establishment conducts business or additional names by which the establishment is known;

(5) The establishment's website address(es) that concern tobacco products;

(6) The Registration Identification Number (RGID #) of the establishment, if previously assigned by FDA; and

(7) The FDA Establishment Identifier (FEI) number of the establishment, if previously assigned by FDA. If not previously assigned by FDA, FDA will assign an FEI number as provided in § 1108.32. An additional unique establishment identifier, such as a Data Universal Numbering System (DUNS) Number, for the place of business of the owner, the place of business of the operator, and the location of the establishment, is optional.

(8) The name of the Tribe if the establishment is located on Indian Country.

(b) Owners or operators who have been granted a waiver under § 1108.40(b) from filing electronically through FDA's tobacco product registration and listing system must submit the establishment registration information described in paragraph (a) of this section in paper form using the procedures provided by FDA in accordance with § 1108.40(c).

(c) An official correspondent for the registration must be designated by the owner or operator to serve as a point of contact with FDA on matters relating to the registration of tobacco product establishments and the listing of tobacco products. The official correspondent is responsible for:

(1) Electronically transmitting to FDA all required registration and listing information unless a waiver from electronic submission has been granted in accordance with § 1108.40(b); and

(2) Serving as a liaison for all correspondence with FDA concerning registration and listing.

(d) The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual

under section 301(p) of the FD&C Act or any other provision of the FD&C Act and its implementing regulations.

(e) Tobacco product listing information must be submitted to FDA electronically through FDA's tobacco product registration and listing system unless a waiver from electronic submission has been granted in accordance with § 1108.40(b). Owners or operators who have been granted a waiver must submit, in accordance with § 1108.20, the required tobacco product listing information, including information required by this paragraph, and any additional listing information required under § 1108.28, in paper form using the procedures provided by FDA in accordance with § 1108.40(c). The following listing information must be provided for each tobacco product manufactured, prepared, compounded, or processed for commercial distribution by the registrant:

(1) The current electronic Registration Identification Number (RGID #) and name of each establishment.

(2) The name, including brand and subbrand name, or other commercial name(s) used in commercial distribution, for each tobacco product manufactured, prepared, compounded, or processed at a registered establishment.

(3) Uniquely identifying information for each tobacco product manufactured, prepared, compounded, or processed, including, product category, product subcategory, package type, characterizing flavor, and, as applicable, nicotine source, product quantity, portion size, length, width, diameter, filter ventilation percentage, e-liquid volume, nicotine concentration, propylene glycol (PG) (numeric value) and vegetable glycerin (VG) (numeric value),

wattage, battery capacity, and any additional properties needed to uniquely identify the tobacco product.

(4) The FDA-assigned Tobacco Product Number (TP #), if an update to a previous submission, and the industry-assigned Universal Product Code (UPC). If a UPC number is not available, an alternative industry product identification number, to include the number itself and the type of identifier (e.g., SKU, Item #, or Catalog #) must be provided in lieu of the UPC.

(5) All FDA-assigned Submission Tracking Numbers (STN), if any.

(6) The FDA-assigned Product Identification Number (PD #), if any.

(7) The operations or processes that are conducted or done to the tobacco product at the establishment (e.g., compounding, repackaging, relabeling, remanufacturing, processing, contract manufacturing, specification development, manufacturing for export, or manufacturing activities other than those listed).

(8) In the case of a tobacco product manufactured in any domestic establishment for export that does not conform to tobacco product standards established pursuant to section 907 of the FD&C Act, the following information shall be provided each year with the June biannual listing update required by § 1108.22(b)(2):

(i) The manner in which the exported tobacco product does not conform to applicable tobacco product standards;

(ii) Each country of destination of the exported tobacco product during the previous calendar year; and

(iii) The quantity of the tobacco product shipped to each country of destination during the previous calendar year.

(9) In the case of a tobacco product subject to a tobacco product standard established under section 907 of the FD&C Act or which is subject to section 910 of the FD&C Act, a reference to the authority for the marketing of the tobacco product, a legible, full color copy of all labeling for the product (except that only one representative package label need be submitted where differences exist only in the bar code, tax stamp, or pricing sticker), indication of the category (e.g., labeling) of material being submitted and the associated product(s), and the original date the labeling materials were first disseminated and date when their dissemination was discontinued.

(10) For all tobacco products not covered by Paragraph (e)(9) of this section, a legible, full color copy of all consumer information and other labeling for the product (except that only one representative package label need be submitted where differences exist only in the bar code, tax stamp, or pricing sticker), a representative sampling of advertisements for the product, indication of the category (i.e., labeling, advertising, consumer information) of the material being submitted and the associated product(s), and the original date the materials were first disseminated and date when their dissemination was discontinued.

(f) An owner or operator shall submit to FDA, upon request (for good cause for paragraph (2)), the following information:

(1) If the registrant has determined that a tobacco product being listed is not subject to a tobacco product standard established under section 907 of the FD&C Act, a brief statement of the basis for that determination.

(2) A copy of all advertisements for a particular tobacco product that is not subject to section 907 or section 910 of the FD&C Act. Such information must be submitted within 30 calendar days of the date of FDA's request.

§ 1108.26 Maintaining a historical file.

(a) Each owner or operator shall maintain a historical file containing a copy of all consumer information, labeling, and advertisements in use on the effective date of this rule for all tobacco products contained in the product list.

(b) In addition to the requirements set forth in paragraph (a) of this section, each owner or operator shall maintain in the historical file a copy of all consumer information, labeling, and advertisements that is first used after the effective date of this rule. For the purposes of this subsection, consumer information, labeling, and advertisements is first used if the owner or operator had not used it previously or had used it previously but made a material change to it.

(c) Each owner or operator required to register and list who also distributes or causes to be distributed free samples of a smokeless tobacco product under 21 CFR 1140.16(d)(2) shall maintain in the historical file for that product documentation of the name, date, and location of each event at which free samples have been distributed, the names of its designated representatives who distributed the samples on behalf of the owner or operator, documentation of compliance with § 1140.16(d)(2)(iii)(A), including identification of the law enforcement officer or

licensed security guard present at the event, and documentation of the steps taken to comply with § 1140.16(d)(2)(iv).

(d) Each owner or operator must retain consumer information, labeling, or advertisements from the historical file while currently in use and retain for a period of not less than four years after the date of final dissemination for materials that are discontinued. Each owner or operator must retain free sample distribution information for smokeless products for a period of not less than four years after the date of the event documented.

(e) Location of the file:

(1) The contents of the historical file must be readily available at the registered establishment for inspection and copying by officers or employees duly designated by the Secretary.

(2) The contents of the historical file must be made accessible within a reasonable time during inspection or upon FDA request.

§ 1108.28 Updating tobacco product listing information.

(a) Each owner or operator shall update its tobacco product listing with the following information:

(1) All changes to the manufacture, preparation, compounding, or processing for commercial distribution of a listed tobacco product, such as when a registrant begins or discontinues performing such activity on or to the tobacco product, or resumes performing such activity if notice of discontinuance was previously reported.

(2) All material changes to product listing information previously submitted, including when a registrant has begun to engage in manufacture, preparation, compounding or processing of a listed tobacco product at an additional establishment added to the previously submitted registration or material changes to the previously submitted labeling, representative sampling of advertisements, or other consumer information for the product.

(3) Updates shall be made within the timeframes specified in § 1108.22(b) and shall include the brand name of the product and the date it was introduced, or activities were begun, discontinued, or resumed.

(b) An owner or operator who intends to introduce into commercial distribution a tobacco product that was not previously included on its product list must add that product to its product listing and provide product information required by § 1108.24(e).

(c) An owner or operator who discontinues commercial distribution of a tobacco product must inactivate the listed tobacco product and must do so using the FDA electronic tobacco product registration and listing system except as provided in § 1108.40(b).

(d) If commercial distribution of a discontinued tobacco product is resumed, the owner or operator must reactivate the previously inactivated product listed and must do so using the electronic tobacco product registration and listing system except as provided in § 1108.40(b).

§ 1108.32 Assignment of an FDA Establishment Identifier (FEI) number.

FDA will assign each establishment an FDA Establishment Identifier (FEI) number after confirming that complete establishment registration information has been submitted. All numbers will be sent to the official correspondent by email, or by postal mail if the owner or operator has been granted a waiver under § 1108.40(b) from the requirement to file registration and listing information electronically.

Subpart C – Format for Establishment Registration and Tobacco Product Listing

§ 1108.40 Electronic registration of establishments and listing of tobacco products.

(a) *Electronic format requirement.* Owners and operators that are subject to the registration and listing requirements of this part must provide the following information to FDA using the electronic tobacco product registration and listing system, except as provided in paragraphs (b), (c), and (d) of this section:

(1) Initial establishment registration information as required by §§ 1108.22(a) and 1108.24;

(2) Updates to registration information as required by §§ 1108.22(b) and 1108.24;

(3) Initial tobacco product listing information as required by §§ 1108.22(a), 1108.24, and 1108.28;

(4) Updates to tobacco product listing information as required by §§ 1108.22(b), 1108.24, and 1108.28.

(b) *Waivers from electronic format requirement.* If the establishment registration and tobacco product listing information cannot be submitted electronically through FDA's tobacco product registration and listing system, a waiver may be requested. Waivers will be granted only if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants

must send a letter to the Food and Drug Administration, Center for Tobacco Products, Attn: Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, which includes the following information:

(1) The name and address of the tobacco product establishment(s) to be registered, a contact person for the owner or operator of the establishment, and the telephone number at which that person can be reached. If the establishment(s) has/have registered in the past, the letter should also include the Registration Identification Number (RGID #) and each registered establishment's FDA Establishment Identifier (FEI) number.

(2) A signed statement that use of the internet is not reasonable for the person requesting the waiver, and an explanation of why such use is not reasonable. Waiver requests may be granted if the owner or operator does not have an email address, access to a computer, or an internet service provider that can access the electronic tobacco product registration and listing system. This statement must be signed by the owner or operator of the establishment or by an employee of the owner or operator who is authorized to make the declaration on behalf of the owner or operator.

(c) If FDA grants the waiver from filing registration and listing information electronically, FDA will provide information on how to submit such information.

(d) *Termination of waivers.* Those owners or operators who have obtained a waiver from filing registration and listing information electronically must notify FDA within 30 calendar days of any changes in the information described in paragraph

(b)(2) of this section, including if the owner or operator obtains an email address, access to a computer, or an internet service provider that can access the electronic tobacco product registration and listing system. This notification must be submitted by letter to the Food and Drug Administration, Center for Tobacco Products, Attn: Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Changes in this information terminate the owner or operator's waiver. Owners or operators whose waivers are terminated must follow the procedures outlined in paragraph (a) of this section for submitting registration and listing information, or must apply for a new waiver under paragraph (b) of this section and explain why use of the internet is still not reasonable for the person.

(e) *English language.* Registration and listing information must be provided in the English language, except that if any part or whole of any consumer information or other labeling, or advertisements is in a foreign language, a copy of the material shall be provided in the language in which it is published or disseminated. If any such foreign language consumer information or other labeling, or advertisements are submitted, an accurate and complete English translation of the material must be appended to that part of the submission along with a signed statement by an authorized representative of the establishment certifying that the English language translation is complete and accurate and a brief statement of the qualifications of the person that made the translation.

Subpart D – Procedures for Foreign Tobacco Product Establishments

§ 1108.50 Establishment registration and tobacco product listing for foreign establishments importing or offering for import tobacco products into the United States.

(a) Any foreign establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product that is imported or offered for import into the United States must register such establishment and list such tobacco products in conformance with the procedures in this section and subparts B and C of this part.

(1) The official correspondent for the foreign establishment shall facilitate communication among the foreign establishment, the government of such foreign country, and representatives of FDA regarding matters related to establishment registration and tobacco product listing under section 905(h) of the FD&C Act.

(2) Exceptions to registration of foreign establishments:

(i) If an establishment only manufactures, prepares, compounds, or processes a tobacco product that has entered a foreign trade zone and is exported from that foreign trade zone without being further distributed in the United States, it is not required to register or list its products.

(ii) If the establishment is otherwise not required to register or submit a tobacco product list in accordance with subpart B of this part.

§ 1108.52 Conditions for registration of foreign tobacco product establishments.

Any establishment in a foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product that is imported or offered for import into the United States shall register under the provisions of section 905 of the FD&C Act

and this part provided that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether a tobacco product manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import, shall be refused admission on any of the grounds set forth in section 801(a).

Subpart E – Miscellaneous

§ 1108.60 Public availability of registration and tobacco product listing information.

Establishment registration and tobacco product listing information is available for public inspection and will be posted on the FDA website in a manner consistent with 21 CFR part 20. Requests for information by persons who do not have access to the internet should be directed to the Food and Drug Administration, Center for Tobacco Products, Freedom of Information Staff, Attn: Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

§ 1108.62 Misbranding.

Registration of a tobacco product establishment or assignment of a registration number does not in any way denote FDA approval of the establishment or marketing authorization for its tobacco products. Any representation in consumer information, labeling, or advertising that creates an impression of FDA approval of a registered establishment, or an impression of FDA marketing authorization of a listed tobacco product, or an impression that a listed tobacco product is safe or less harmful because of registration or possession of a registration number, is misleading and constitutes misbranding. If a tobacco product is manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905(b), 905(c), 905(d), or

905(h), is not included in a product list required by section 905(i), or its labeling or advertising is false or misleading in any particular, the product is deemed misbranded under section 903(a) of the FD&C Act. Section 301 of the FD&C Act prohibits, among other things, the introduction or delivery for introduction into interstate commerce of any tobacco product that is misbranded. The failure to register in accordance with section 905 of the FD&C Act and the implementing regulations in this part, the failure to provide any information required by section 905(i) of the FD&C Act and the implementing regulations in this part, or the failure to provide a notice required by section 905(i)(3) of the FD&C Act and the implementing regulations in this part is a prohibited act under section 301(p) of the FD&C Act.

Robert F. Kennedy, Jr.

Secretary, Department of Health and Human Services.

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