

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised*)

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <http://www.regulations.gov>. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with Docket No. FDA-2009-D-0500.

For questions regarding this guidance, contact the Center for Tobacco Products at 1-877-CTP-1373 (1-877-287-1373), Monday – Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products**

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See additional PRA statement in section V of the guidance.

* This is the second revision to the first edition of this guidance, which issued in November 2009. Revisions are noted by date at the end of the guidance.

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document is intended to assist owners and operators of domestic tobacco product establishments with the registration and product listing submissions required by section 905 of the Food, Drug, and Cosmetic Act (FD&C Act).² The guidance document explains, among other things:

- The statutory requirement to make establishment registration and product listing submissions;
- The definitions of terms used in the statute and this guidance;
- Who should make establishment registration and product listing submissions;
- What information to include in the submissions;
- How to submit the information;
- When to submit the information; and
- FDA's compliance policies.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should

¹ This guidance was prepared by the Office of Regulations and the Office of Compliance and Enforcement in the Center for Tobacco Products at FDA.

² Foreign establishments are not required to register and list until FDA issues regulations establishing such requirements in accordance with section 905(h) of the FD&C Act (21 U.S.C. 387e(h)).

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be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), enacted on June 22, 2009, amends the FD&C Act and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health (Pub. L. 111– 31, 123 Stat. 1776.) Among other things, the Tobacco Control Act adds 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.

Cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), and smokeless tobacco were immediately covered by FDA’s tobacco product authorities in chapter IX of the Act, including section 905, when the Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of the FD&CA Act (21 U.S.C. 387a(b)) grants FDA authority to deem those products subject to chapter IX of the FD&C Act. Pursuant to that authority, FDA issued a proposed rule seeking to deem all other products that meet the statutory definition of tobacco product set forth in section 201(rr) of the FD&CA Act (21 U.S.C. 321(rr)) (except for accessories of those products) (79 FR 23142, April 25, 2014).³ After review and consideration of comments on the proposed rule, the final rule published on May 10, 2016 (81 FR 28974) (the deeming rule) with the effective date of August 8, 2016. As a result, owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products subject to the deeming rule are now required to comply with chapter IX of the FD&C Act, including the establishment registration and product listing requirements in section 905.⁴

Section 905(b) of the FD&C Act requires that “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” register with FDA the name, places of business, and all establishments engaged in these activities owned or operated by that person. Following the initial registration, every person must register annually by December 31 of each year.

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 all labeling. In addition, section 905(i)(3) of the FD&C Act requires that certain changes in the product list be submitted biannually.

³ Accessories of tobacco products subject to the deeming rule are explicitly excluded from the rule’s deeming provision.

⁴ Examples of currently marketed products that are subject to the deeming rule include: cigars, pipe tobacco, nicotine gel, dissolvable nicotine products, and electronic nicotine delivery systems (“ENDS”), including electronic cigarettes (also known as e-cigarettes or e-cigs), e-hookah, e-cigars, vape pens, personal vaporizers (also known as advanced personal vaporizers or APVs), electronic pipes, and nicotine-containing liquids, including the e-liquids used with ENDS products, among other products.

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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), or the failure to provide a notice required by section 905(i)(3) is a prohibited act under section 301(p) of the FD&C Act (21 U.S.C. 331(p)). In addition, under section 903(a)(6) of the FD&C Act (21 U.S.C. 387c), a tobacco product is deemed misbranded if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905 or if it was not included in a list required by section 905(i). Violations relating to registration and product listing under section 905 are subject to regulatory and enforcement action, including, but not limited to, seizure and injunction.

III. DEFINITIONS

FDA intends to use the following definitions in implementing the establishment registration and product listing requirements of section 905 of the FD&C Act.

- ***Accessory***: The term *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 and is not made or derived from tobacco; and meets either of the following:
 - (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or
 - (2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but
 - (i) Solely controls moisture and/or temperature of a stored tobacco product; or
 - (ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.
- ***Commercial distribution***: The term *commercial distribution* means any distribution of a tobacco product to consumers or to another person through sale or otherwise, but does not include internal or interplant transfer of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such products are not made available for consumption or resale. For example, the term includes the distribution of a tobacco product as a promotional sample and the delivery of a tobacco product to another manufacturer for further processing via contract without a change in the formal ownership of the product.
- ***Component or part***: The term *component or part* means any software or assembly of materials intended or reasonably expected:
 - (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or
 - (2) To be used with or for the human consumption of a tobacco product.

Component or part excludes anything that is an accessory of a tobacco product.

FDA notes that *component* and *part* are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this guidance, FDA is using the terms component

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and part interchangeably and without emphasizing the distinction. FDA may clarify the distinctions between component and part in the future.

- ***Domestic establishment:*** The term *domestic establishment* means an establishment in any State or Territory or possession of the United States.
- ***Establishment:*** The term *establishment* means a place of business under one ownership at one general physical location. A single building may house more than one distinct establishment if the establishments are under separate ownership.
- ***Finished tobacco product:*** The term *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).
- ***Labeling :*** The term *labeling*, based on section 201(m) of the FD&C Act, means all labels and other written, printed, or graphic matter (1) upon any tobacco product or any of its containers or wrappers, or (2) accompanying such tobacco product.
- ***Manufacturing:*** The term *manufacturing* means the manufacture, preparation, compounding, or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package (section 905(a)(1) of the FD&C Act). This term includes the activities of reconstituting and blending tobacco leaf; testing for quality control and product release; and applying any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist. This term excludes the activities of de-stemming, drying, or packing tobacco leaf; mechanically removing foreign material from tobacco leaves; and humidifying tobacco leaf with nothing other than potable water in the form of steam or mist.
- ***Owner:*** The term *owner* means a person, as defined in section 201(e) of the FD&C Act, who has an ownership interest in an establishment.
- ***Operator:*** The term *operator* means a person, as defined in section 201(e) of the FD&C Act, who has management authority over an establishment.
- ***Tobacco product:*** The term *tobacco product* is defined in section 201(rr) of the FD&C Act, which states in relevant part:
 - (1) The term “tobacco product” means any product made or derived from tobacco 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).”
 - (2) The term “tobacco product” does not include an article that is a drug under [section 201(g)(1)], a device under [section 201(h)], or a combination product described in section 503(g) [of the FD&C Act].

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Note that this definition includes accessories and components and parts of tobacco products, whether they are made or derived from tobacco, and whether they are sold or distributed as finished tobacco products.⁵

IV. DISCUSSION

A. Who Registers Their Establishment and Submits Product Listing Information Under Section 905 of the FD&C Act?

Every person who owns or operates any domestic establishment engaged in manufacturing regulated tobacco products must register under section 905(b) of the FD&C Act, and every registrant must file a list of its regulated tobacco products in accordance with section 905(i) of the FD&C Act. An owner or operator may authorize a third party agent to register their establishment and submit product listing information on its behalf. Establishment registration and product listing requirements currently apply only to those persons who own or operate domestic establishments engaged in manufacturing tobacco products; an importer who does not own or operate such an establishment is not subject to the requirements of section 905(b) or section 905(i) of the FD&C Act.

In order to reduce redundant submissions, FDA strongly encourages that the owner act as the agent for all operators within a given business structure in submitting establishment registration and product listing information. Under this approach, the owner would register all establishments it owns and submit the associated product listing information, and the owner would also register on behalf of all operators with management authority over those establishments. An owner acting as the agent for one or more operators would need to submit all information required of the operator(s) (e.g., the operator name(s) and place(s) of business), but could submit all information for both the owner and the operator(s) in a single registration. If an owner registers/lists all of its establishments using this approach, the operators of those establishments would not need to register. For scenarios in which an owner is also the operator of a given establishment, the owner/operator can register in a single registration.

The following example illustrates the registration and product listing requirements for a complex business structure: Firm A owns establishment X, which is engaged in manufacturing tobacco products. Firm B does not own an establishment engaged in manufacturing tobacco products. Firm A and Firm B are wholly owned subsidiaries of Holding Company C. Holding Company C does not own or operate any establishments engaged in manufacturing tobacco products. In this scenario, Firm A would be required to register establishment X and list products, but neither Firm B nor Holding Company C would be subject to registration or product listing requirements.

⁵ However, and as explained above, accessories of tobacco products subject to the deeming rule are explicitly excluded from the rule's deeming provision. Thus, although they meet the definition of tobacco product, such accessories are not currently subject to regulation under the FD&C Act (including section 905). See below for details on FDA's compliance policy for tobacco products that are sold or distributed solely for further manufacturing.

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B. FDA's Compliance Policy for Regulated Tobacco Products

At this time, with respect to all tobacco products, including cigarettes, cigarette tobacco, RYO, and smokeless tobacco, as well as other tobacco products now regulated as a result of the deeming rule, FDA intends to enforce the registration and listing requirements of section 905 with respect to finished tobacco products only. FDA does not, at this time, intend to enforce these requirements with respect to products that are sold or distributed solely for further manufacturing.

As defined above, the term *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).

Components and parts that are sold separately from other tobacco products are also finished tobacco products if they are sold in final packaging intended for consumer use. FDA intends to enforce the registration and listing requirements under section 905 with respect to such products. Examples of components and parts that are sold or may be sold as finished tobacco products include pipe tobacco filler, filter tubes, e-cigarette batteries, and e-liquids, whether sold separately to consumers or as part of kits.⁶

Based on our experience with cigarettes, cigarette tobacco, RYO, and smokeless tobacco, we are amending our previous compliance policy. Under our previous policy, FDA intended to enforce the establishment registration and product listing requirements with respect to owners and operators engaged in the manufacture of tobacco, paper, filters, and pouches whether or not such products were for further manufacturing of, or for consumer use as, regulated tobacco products. However, FDA is announcing a change to that policy because we believe we can obtain the necessary information about tobacco product components and parts through other means, such as premarket applications for finished tobacco products and through the use of master files, as explained in the guidance *Tobacco Product Master Files*.⁷ Additionally, we are aligning our compliance policy for cigarettes, cigarette tobacco, RYO, and smokeless tobacco with the products now regulated as a result of the deeming rule to reduce burden on industry. Should FDA find that additional information is needed to protect the public health, the Agency may reconsider this compliance policy. We intend to communicate any compliance policy changes by guidance or rulemaking.

C. What Information Is Submitted as Part of Establishment Registration and Product Listing Submissions?

1. Registration Information

Section 905(b) of the FD&C Act sets forth the requirements for submission of establishment registration information. As required by the statute, any person engaged in the manufacturing of tobacco products must register with FDA and submit the following information:

⁶ As explained above, the Secretary has not deemed accessories of tobacco products other than cigarettes, cigarette tobacco, RYO, and smokeless tobacco, and so they are not currently subject to section 905.

⁷ This guidance is available on the CTP guidance Web page at <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

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- The name and full address of each establishment engaged in manufacturing the registrant owns or operates, as of the date of registration.
- The name and places of business of the owner or operator. In the case of a partnership, include the name of each partner. In the case of a corporation, include the name of each corporate officer and director, and the State of incorporation.

The registration and listing electronic submission system and the paper form request additional optional information that FDA also recommends be submitted, including:

- An email address, to facilitate correspondence between registrants and FDA.
- A Data Universal Numbering System (D-U-N-S) number⁸ or other unique identifier (codes) for the place of business of the owner, the place of business of the operator, and the location of the establishment. The business entity identifier recognized by the FDA Data Standards Council is the D-U-N-S number, and providing the site-specific D-U-N-S number for an entity will help prevent inaccuracies in FDA's database.

2. Product Listing Information

Section 905(i) of the FD&C Act sets forth the requirements for submitting product listing information. The FD&C Act requires that, at the time of registration, the registrant submit a list of all tobacco products that are being manufactured by the registrant for commercial distribution.

The product listing must include certain accompanying information, which will vary depending on the circumstances. These circumstances are as follows:

- Under section 905(i)(1)(A), if a tobacco product standard has been established under section 907 of the FD&C Act (21 U.S.C. 387g) with respect to the tobacco product or the tobacco product is subject to premarket review under section 910 of the FD&C Act (21 U.S.C. 387j), then the product listing must include a reference to the authority for the marketing of the tobacco product and a copy of all labeling for that product. We interpret this to mean that labeling is to be submitted as an exact, legible, full color copy.
- Under section 905(i)(1)(B), the product listing for all other tobacco products must include all labeling for that product. It must also include "a representative sampling of advertisements" for the product. If requested by FDA for good cause, a copy of all advertisements for a particular tobacco product must be submitted. We interpret "a representative sampling of advertisements" to mean typical advertising material that reflects the full range of promotional statements made for the tobacco product. For example, if more than one magazine advertisement is used but the promotional content is

⁸ D-U-N-S numbers are proprietary to and controlled by Dun & Bradstreet. If the D-U-N-S number for a location has not been assigned, a business may obtain one for no cost directly from Dun & Bradstreet (<http://www.dnb.com>). Please note that registrants who wish to obtain a new D-U-N-S number should obtain one well in advance of FDA's deadline, because it may take 30 days (or longer) to process a new number. Please note that the D-U-N-S Number is not required. Alternatively, you may elect to receive a D-U-N-S number within one business day by paying a fee. Please consult Dun & Bradstreet (<http://www.dnb.com>) directly for more information.

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essentially identical, only one need be submitted. In addition, the product listing must include “a copy of all consumer information” to the extent the information is not advertising and has not already been provided as a form of product labeling. Consumer information does not include information directed at wholesalers, distributors or retailers, where such information is not available to consumers.

If a registrant has determined that a product in its product listing is not subject to a tobacco product standard established under section 907 of the FD&C Act, FDA may request that the registrant provide a brief statement of the basis for that determination.

We are interpreting section 905(i) of the FD&C Act to require that each product included in a product listing be clearly identified and distinguished. Products that differ in any way, including a difference in any component or part, should be listed separately for purposes of section 905(i). For example, a soft pack and a hard pack of cigarettes should be listed separately, even if the cigarettes included in the pack are identical.

Each product is to be clearly and uniquely identified by the product category⁹ (e.g., cigarette, smokeless tobacco, paper, filter) and unique name (i.e., brand/sub-brand or other commercial name used in commercial distribution). Tobacco products are to be identified in this way because such names are needed to determine whether products in commercial distribution are listed as required. You are to include product identification numbers (e.g., SKU, catalog number, UPC) as needed to uniquely identify the product.

Section 905(i)(3) of the FD&C Act requires the following changes to the product list to be reported twice a year:

- For any tobacco products you have introduced for commercial distribution and have not included in a previous product listing, the complete product listing information as described above.
- For any tobacco products you have discontinued manufacturing for commercial distribution since the last report, notice of the discontinuance containing the established name of the product as previously listed and the date of discontinuance.
- For any tobacco products you had given notice as being discontinued and have since resumed manufacturing for commercial distribution, notice of the resumption containing the date of resumption and complete product listing information as described above.
- Any material change in any information previously submitted

D. How to Make Establishment Registration and Product Listing Submissions

The registration and listing electronic submission system is designed to streamline the data entry process for registration and product listing at the Center for Tobacco Products (CTP). Although

⁹ At this time, some product categories used for product listing may fall under a subcategory for a premarket tobacco product submission (e.g., a filter is a category for listing purposes, but a subcategory under roll your own for a premarket submission).

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electronic submission is not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data submission and management. The electronic submission system and FDA Form 3741, an alternative tool for paper submissions, are available at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm>.

E. When Must You Register Your Establishment and List Your Products Under Section 905 of the FD&C Act?

Section 905(b) of the FD&C Act requires establishment registration information to be submitted by December 31, 2009, and to be resubmitted annually on or before December 31st of each year.

Section 905(c) of the FD&C Act requires every person upon first engaging in the manufacturing of a tobacco product in any domestic establishment owned or operated by that person to immediately register. In addition, section 905(d) requires registered owners and operators to immediately register any new establishment that begins manufacturing tobacco products.

Section 905(i)(1) of the FD&C Act requires the complete product list information to be submitted at the time of first registration. In addition, section 905(i)(3) of the Act requires that certain changes in the product list be submitted biannually, once during June and once during December.

- As of August 8, 2016, persons who own or operate domestic manufacturing establishments engaged in the manufacture of newly deemed tobacco products will be required to register with FDA and submit product listing under section 905 of the FD&C Act. As such, domestic establishments engaged in the manufacture of newly deemed products prior to August 8, 2016 will be required to register and submit product listing under section 905 of the FD&C Act by December 31, 2016.

V. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 3.75 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0650 (expires 1/31/2019).

DOCUMENT HISTORY

November 2009 — First edition of guidance issued.

April 2014 — Section III of guidance revised to reflect the change in the electronic submission tool for registration and listing from eSubmitter to a new system available on FDA's Web page at <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ForManufacturers/default.htm> and to remove obsolete timeframe information.

- Throughout section III — The phrase “registration and listing electronic submission system” replaces the phrases “eSubmitter application,” and “FDA eSubmitter tool.”
- Section III, page 2 — First paragraph in section III describing eSubmitter tool deleted.
- Section III.D, page 7 — Sentences in first paragraph describing eSubmitter tool deleted.
- Section III.D, page 7 — Web site address where the electronic submission system and FDA Form 3741 are available updated from <http://www.fda.gov/tobacco> to <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ForManufacturers/default.htm>.
- Section III.D, page 7 — Third paragraph describing how to access the eSubmitter tool deleted.
- Section III.E, page 8 — Paragraph describing when to submit information for registration and listing information in 2010 deleted.
- Section III.E, page 8 — Paragraph providing November 2009 as the availability date for the eSubmitter tool deleted.
- Section IV, page 8 — Expiration date for the information collection updated from 12/31/2012 to 10/31/2015.

May 2014 — Cover page, and section IV, Page 8 — Physical mailing address changed to reflect the center's relocation to the White Oak Campus.

June 2016 — Registration and listing guidance revised to reflect changes in FDA authorities over “deemed” tobacco products.

- Throughout the document — A number of nonsubstantive changes were made for clarification purposes.

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- Section II, page 2 — Background updated to reflect changes in FDA authorities over “deemed” tobacco products arising from “deeming” rule.
- Section III, page 3 — Accessory, components or part, and finished tobacco product definitions added.
- Section IV.B, page 5 — Former Section B “Who Registers and Submits Product Listing Information under Section 905 of the Act” becomes Section A. Compliance policy for cigarettes, cigarette tobacco, RYO, and smokeless tobacco deleted.
- Section IV.B, page 6 — “FDA’s Compliance Policy for Regulated Tobacco Products” added; compliance policy for cigarettes, cigarette tobacco, RYO, and smokeless tobacco amended.
- Section IV.C, page 6 — Title changed.
- Section IV.C, page 7 — Information on Data Universal Numbering System is updated.
- Section IV.D, page 9 — Title changed.
- Section IV.E page 9 — Title changed.
- Section IV.E, page 9 — Last paragraph added to explain when owners and operators of domestic manufacturing establishments engaged in the manufacture of newly deemed tobacco products will need to register and submit product listings.
- Section IV.E — Data Universal Numbering System information incorporated to section C.