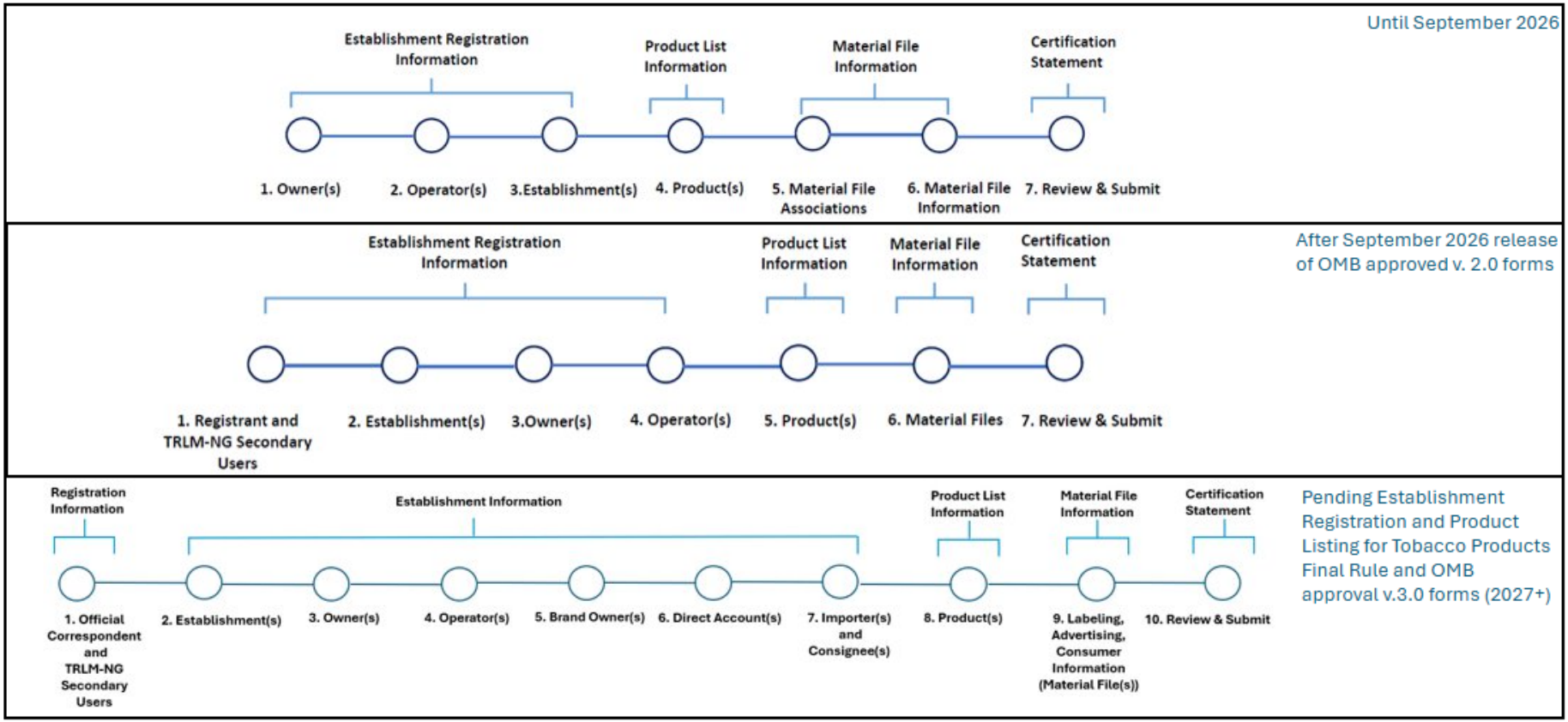
FDA Forms 3741 and 3741b Net Change Tracker

FDA currently collects establishment registration and tobacco product listing information (OMB control number 0910-0650) submitted pursuant to section 905 of the Federal Food, Drug, and Cosmetic (FD&C) Act through the Tobacco Registration and Product Listing Module Next Generation (TRLM NG) portal for electronic submissions and the corresponding OMB approved forms for paper submissions (i.e., FDA Forms 3741 and 3741a (v.1.0) until September 2026, or FDA Forms 3741 and 3741b (v.2.0) after September 2026). FDA's Registration of Tobacco Product Establishments and Listing of Tobacco Products NPRM, if finalized, would require electronic submission through TRLM NG unless a registrant receives a waiver from FDA for paper submissions. This document has been provided to delineate the changes between Forms FDA 3741 and 3741b Version 2.0 under OMB control number 0910-0650 and Forms FDA 3741 and 3741b Version 3.0 to be proposed alongside FDA's Registration of Tobacco Product Establishments and Listing of Tobacco Products NPRM. All changes below pertain to Form FDA 3741 v.2.0, except as otherwise noted in Section V – Product List Information for Initial Submission.

<u>Figure 1:</u> Comparison of current high level TRLM-NG workflow (top, v.1.0) vs. restructured workflow (v.2.0, middle and v.3.0, bottom) based on FDA Form 3741 updates.



Section (from v. 2.0)	**Net Change v. 2.0 to v.3.0**	**Rationale**
Form Title	(v.2.0) Registration and Product Listing of Tobacco Product Manufacturing Establishments → Registration of Tobacco Product Establishments and Listing of Tobacco Products in Commercial Distribution (v.3.0)	Since the proposed rule will require specification developers to register and list, the title name change places greater focus on establishments involved in the "commercial distribution" of tobacco products and not just their immediate "manufacturing."
Disclaimer Statement (above Table of Contents)	Updated references to paper/mail submission with the prerequisite of having submitted and obtained FDA approval of waiver from electronic submission.	Once the proposed rule is finalized, FDA's Document Control Center (DCC) will no longer accept paper/mix-media submissions for processing, unless a waiver has been approved.
Table of Contents	Additional Parts (D-F) to Section IV – Establishment Information for Initial Submission • Part D – Establishment Brand Owner Information for Initial Submission • Part E – Establishment Direct Account Information for Initial Submission • Part F – Establishment Importer(s) and Consignee(s) information for Initial Submission Additional Parts (D-F) to Section VIII – Updates to Establishment Information • Part D – Updates to Establishment Brand Owner Information • Part E – Updates to Establishment Direct Account Information • Part F – Updates to Establishment Importer(s) and Consignee(s) information	Additional sections referenced for information on establishments involved in the commercial distribution of tobacco products, but which are not required to directly register and list.

Section (from v. 2.0)	**Net Change v. 2.0 to v.3.0**	**Rationale**
Notice (under Table of Contents)	1. Added language about needing a waiver for paper submissions by mail. 2. Added language that FDA strongly encourages review of the navigation guide and completion of the submission checklist.	1. Once the proposed rule is finalized, DCC will no longer accept paper/mix-media submissions for processing, unless a waiver has been approved. 2. To clarify that the checklist and navigation guide are tools for encouraging complete submissions but are not a requirement.
Section I – Submission Type	1. Added additional submission type option for confirmation of no change. 2. Added submission method subsection with request to provide proof of electronic submission waiver (waiver STN# and status) if submitting by mail.	1. The proposed rule requires confirmation if no change in addition to a report of changes. 2. FDA will need to verify if the submitter has an accepted waiver to be able to process the submissions provided via mail.
Section II - Form FDA 3741 Navigation Guide and Submission Checklist	1. Streamlined/simplified form navigation guide and checklist and updated with additional column for confirming no change from previous submission. 2. Removed acknowledgement requirement and implication of needing to complete and submit checklist to be able to complete registration and listing.	1. Sections have navigation instructions incorporated to inform industry if they need to complete the section or can skip certain subsections or parts. Navigation guide now provides a short summary of which sections are needed to complete, depending on submission type. 2. Removed to reduce industry burden and because it is not in the codified.
Section III – Registration Information for Initial Submission	1. Updated “registrant point of contact” to “official correspondent.” 2. Removed references to “Tribe Name.” 3. Expanded selectable option for “authorized representative” to “authorized representative for owner” and “authorized representative of operator.”	1. Updated terminology to match the codified. 2. Updated to match codified (will only ask for Tribe Name in the context of Establishments on Tribal Lands). 3. To aid FDA to determine whether the authorized representative is acting on behalf of the owner, operator, or both.
Section IV – Establishment Information for Initial Submission	1. Renamed “designated establishment point of contact” as “establishment contact information.”	1. To match codified and to delineate between the contact information for the “official correspondent,” (i.e., TRLM-NG account

Section (from v. 2.0)	**Net Change v. 2.0 to v.3.0**	**Rationale**
	2. Updated Establishment Detail questions a. Added (optional) corporate affiliations b. Made previously required "ENDS retailer," "personal residence," and "primary language spoken at establishment" questions optional c. Simplified the required question regarding Tribal Lands d. Made previously required Tribal contact information optional 3. Updated Establishment Operations subsection. 4. Consolidated mobile and work phone number requests to just one phone # (can indicate type). 5. Removed "Tribe" references in the context of Owner and Operator Business Structure. 6. Renamed "Owner/Operator designated point of contact" to "Owner/Operator contact information." 7. Additional of optional parts for Brand Owner, Direct Account, and Importer/Consignee Information.	manager/3741 submitter) who could be an authorized representative not physically located at the registered establishment, and contact information for the establishment itself. 2. To reduce industry burden for information that will be obtained/verified during inspection; Tribal information is expected to be provided voluntarily. 3. To enable tracking of entities newly required to register and list and those previously required to register and list. 4. To reduce burden to industry. 5. Per codified, will only ask for Tribe Name in the context of establishments located on Tribal Lands. 6. To match codified. 7. To acknowledge these entities play key roles in either initiating or facilitating products coming into commercial distribution but are themselves currently not required to register and list. Some of this information will be collected during inspections but would be more efficient to acquire directly from industry during registration and listing. FDA is requesting public comment regarding this information collection.

Section (from v. 2.0)	**Net Change v. 2.0 to v.3.0**	**Rationale**
Section V – Product List Information for Initial Submission	**Form FDA 3741b** 1. Replaced "Intent of Use" with "Tobacco Product Type" 2. Added "Bulk Packaging" as a "Package Type" option 3. Added "Country of Origin" and "Commercial Distribution Destination" fields 4. Added additional options for "Alternative Industry Product Identification Number Type" (i.e., International Article Number (EAN) and Global Trade Item Number (GTIN)) **Form FDA 3741** 5. Additional questions on product standards and information on quantity and destination of domestic manufactured products not conforming to an available product standard intended for export. 6. Streamlined marketing authorization questions.	**Form FDA 3741b** 1. To combine the previous "for consumer use" vs. "for further manufacturing use" within the context of distinguishing finished tobacco products, bulk tobacco products, and for further manufacturing tobacco products. 2. The proposed rule requires bulk tobacco product manufacturers to register and list., Their listed products will not be in finished product packaging and many of the current finished packaging options would not be applicable. 3. To provide product level context needed when assessing marketing authorization implications for products entering the U.S. vs. those being exported out of the U.S., as well as metrics on foreign vs. domestic manufactured products to ensure compliance of foreign manufacturers registering and listing their products intended for import into the U.S. 4. To ensure consistency in other FDA forms, such as FDA Form 3742 (Ingredient Listings), and is expected to be more applicable for foreign manufacturers if they do not have a UPC to provide. **Form FDA 3741** 5. To match codified. 6. To assist with tracking marketing authorization and applications per product while minimizing burden to industry.

Section (from v. 2.0)	**Net Change v. 2.0 to v.3.0**	**Rationale**
Section VI – Material File Information for Initial Submission	1. Updated section to "Labeling, Advertising, Consumer Information (Material File)" 2. Removed fields for material file "unique ID or internal ID", "material file title", "material file description." 3. Made required fields optional ("location of label", confirmation of whether there will be "submission of a package label plan", and "what variables are captured in the product variation index"). Added a statement that FDA strongly recommends completing all fields for timely and efficient processing of material file submissions. 4. Updated material type options, removed restriction that only certain types would be selectable based on material file category selected (i.e., labeling, advertising, consumer information). 5. Added a disclaimer acknowledging that industry is self-designating whether their submitted material is categorized as labeling, advertising, or consumer information but does not reflect FDA's actual interpretation or designation.	1. Updating "material file" to reflect language from the statute "labeling, advertising, consumer information." 2. To leverage individual (internal system) URLs to track each individual material file submitted to reduce industry burden. 3. User interface (UI) updates to the FDA internal TRLM-NG module should assist in providing answers to these questions. FDA has prioritized keeping required (*) questions to the bare minimum needed to process a paper or electronic submission, while strongly encouraging completion of all fields to reduce overall burden to both industry and FDA. 4. Since "material file description" and "material file title" were removed, industry will be able to use the selectable options for "material type" to convey the contents of their submitted material in a more straightforward and less burdensome way. 5. To permit continuation of current workflow that industry is familiar with and align with how other Centers within FDA process similar materials.
Section VII – Updates to Registration Information	1. Incorporated changes from "Initial Submission" fields from Section III 2. Not requiring "effective date of change" for updates to registration information	1. Consistency. 2. Optional because it is not in the codified.
Section VIII – Updates to Establishment Information	1. Incorporated changes from "Initial Submission" fields from Section IV	1. Consistency. 2. Optional because it is not in the codified.

Section (from v. 2.0)	**Net Change v. 2.0 to v.3.0**	**Rationale**
	2. Not requiring "effective date of change" for updates to establishment information	
Section IX – Updates to Product List Information	1. Incorporated changes from "Initial Submission" fields from Section V	1. Consistency.
Section X – Updates to Material File Information	1. Renamed "Updates to Labeling, Advertising, Consumer Information (Material File) Information" 2. Incorporated changes from "Initial Submission" fields from Section VI	1. Updating "material file" to reflect language from the statute "labeling, advertising, consumer information." 2. Consistency.
Section XI – Certification Statement	Added checkbox to distinguish Authorized Representative of Owner vs. Authorized Representative of Operator	To better track who the authorized representative is working on behalf of.
Section XII - Appendices	Appendix A - Terminology	Added or revised definitions to align with codified.
	Appendix B – Statutory Requirements • Added reference to 905(h)	More comprehensive with 905 subsections.
	Appendix C – Additional Resources	No changes anticipated other than providing reference to new guidance document(s).