#1 – Merging Form FDA 3741 and FDA 3741a into consolidated FDA 3741		
Net Change	**Summary of Change**	**Reason/Benefit of Change**
• New FDA Form 3741 will handle initial and updates to establishment registration information, initial and updates to product – associated material files, and updates to product list information. • New FDA Form 3741b (tobacco product list spreadsheet) will handle initial product list information. • The new 3741 form and 3741b spreadsheet will replace the previous two forms (3741 and 3741a).	• New FDA Form 3741 will better align with TRLM-NG functionality. • Industry will no longer have to differentiate between “traditional” vs. “deemed” tobacco products. • Creation of 3741b spreadsheet will allow those who still utilize paper submissions to include a USB or printout of the 3741b product spreadsheet that will help standardize product data collected from the paper form and electronically through TRLM-NG.	• Reduced redundancy and improved efficiency for users relying on paper forms for submission (i.e., paper submitters who manufactured pipe tobacco products and cigarette products had to use two different forms). • Better alignment of end user burden between paper and electronic submissions.

#2 – Restructuring and Redeveloping Sections for Ease of Navigation and Data Input		
Net Change	**Summary of Change**	**Reason/Benefit of Change**
Streamlining Establishment Registration and Product Listing Workflows	• Added Submission Checklist and Navigation Guide so industry knows which sections they need to complete depending on submission type and can focus on those applicable questions. • Simplified "Registrant Identification" and removed numerous follow-up questions. • Instead of having to reach out to CTP or the TRLM-NG helpdesk to initiate transfer of TRLM-NG account management for their registration, industry will be able to provide the necessary information directly in TRLM-NG (for electronic submissions) or directly on the form (for paper submissions). • Streamlined and standardized required data fields for businesses vs. individuals to clarify where name refers to an individual Point of Contact (i.e., account manager/registrant, Owner Point of Contact, Operator Point of Contact, Additional User, Establishment Point of Contact) vs. the business entity they represent. • Updated Establishment "Operations" to better align with industry operations communicated through "Other (Specify)" operations option. • Added "Establishment Details Questions." • Improvements to workflow when updating product manufacturing sites (product-establishment associations). • Simplified Registration and Establishment Inactivation Reasons and improved workflow when inactivating duplicate registrations or establishments. • Updated certification statement to be applicable to initial submission as well as updates to establishment registration information and/or product listing information. • Ability to clearly distinguish between businesses' physical vs. mailing address.	• Will allow industry to better convey what information they are updating, which will allow CTP to better track updates that would count toward annual and biannual certification requirements. • Updated Registration and Establishment Inactivation Reasons to better reflect reasons industry would need to inactivate with less ambiguity. • Streamlines the process for industry to identify establishment operations from increased selectable options. • Reduces navigation burden to industry, as they no longer have different directions depending on whether they are an owner registering alone, owner registering on behalf of operator, operator registering alone, or operator registering on behalf of owner. Each designation previously required completing different parts of the form and resulted in a lack of data consistency with owner and operator point of contact information. • Allowing better tracking of when the manufacturing site of a product changes or during data clean up when duplicate establishments or registrations are inactivated. • Ensures CTP has the establishment's physical address for inspections and mailing address (if different) for written correspondence.

Figure 1 for #2: Comparison of current TRLM-NG workflow (top) vs. restructured workflow based on 3741 updates (bottom)

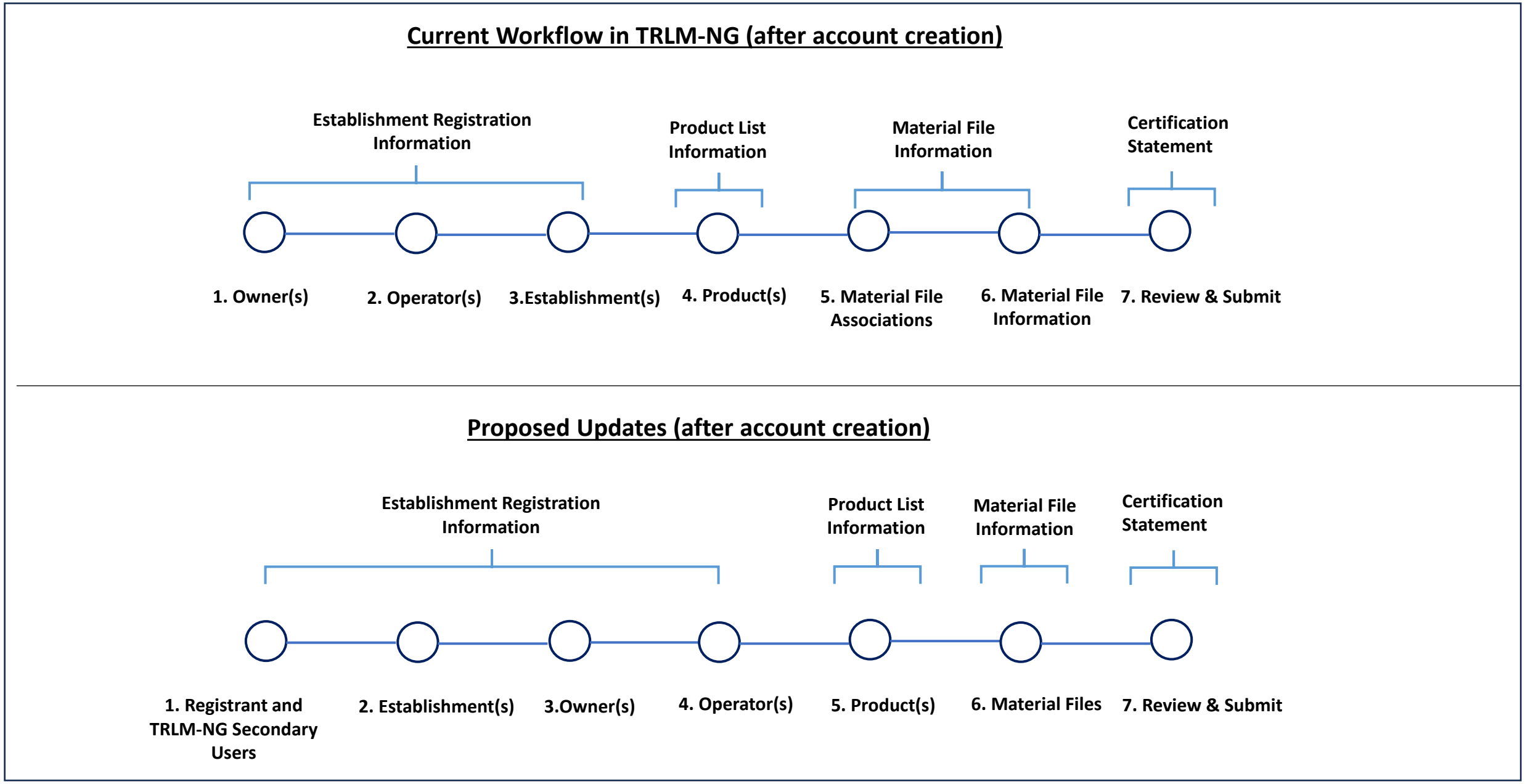


Figure 2 for #2: Setting Up Your Registration – Identifying Your Role

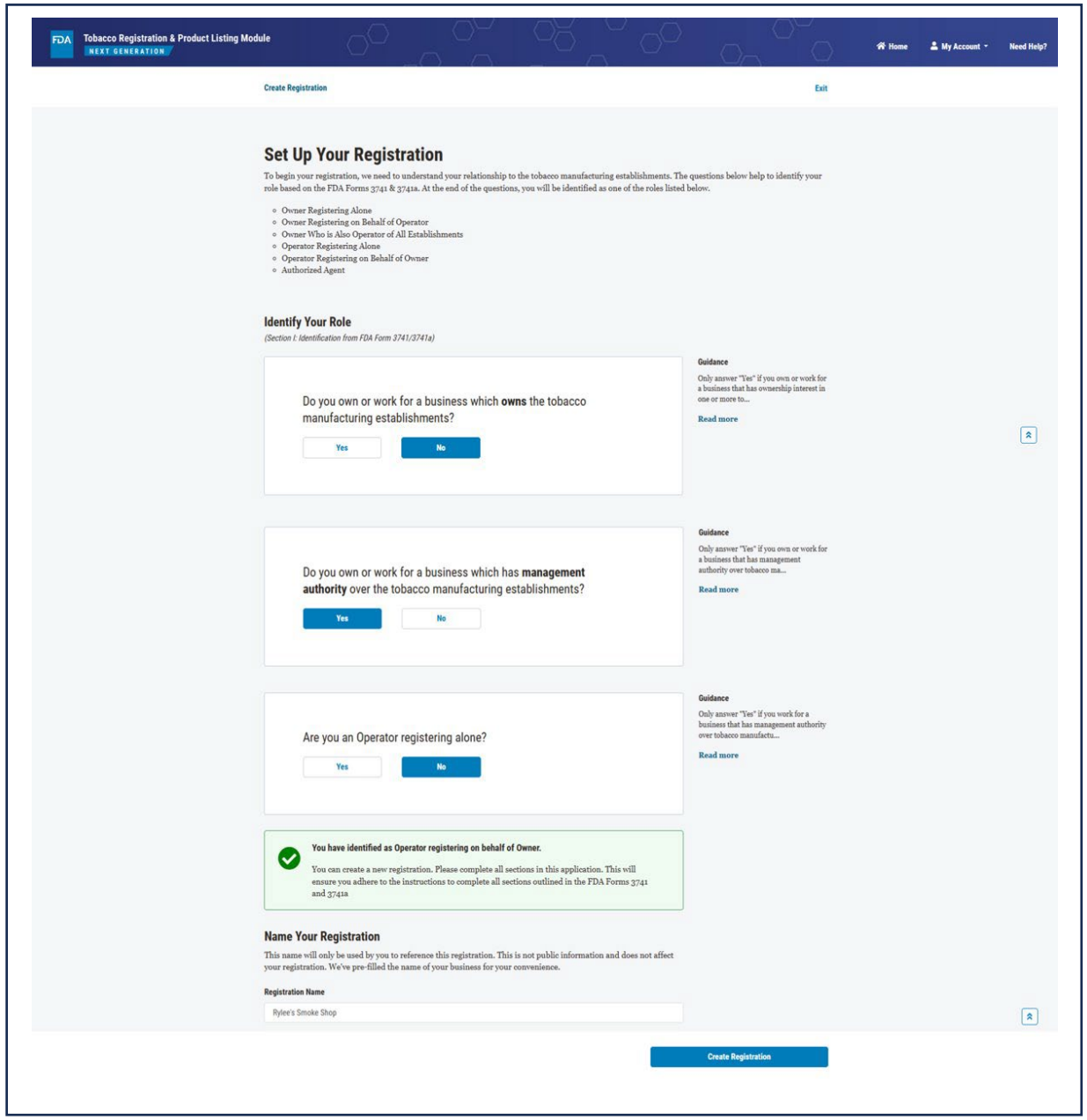
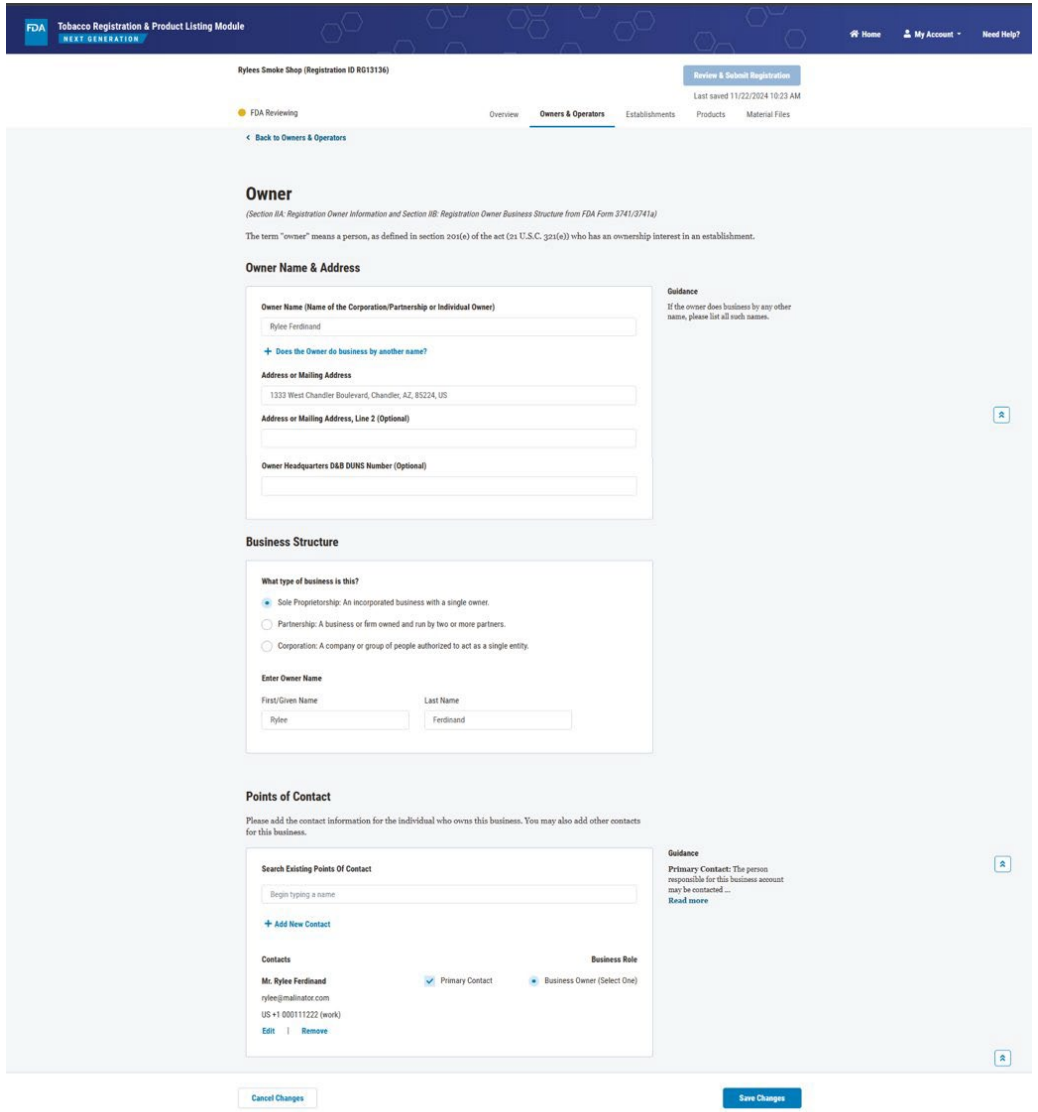


Figure 3 for #2: Owner Information (left) and Operator Information (right)



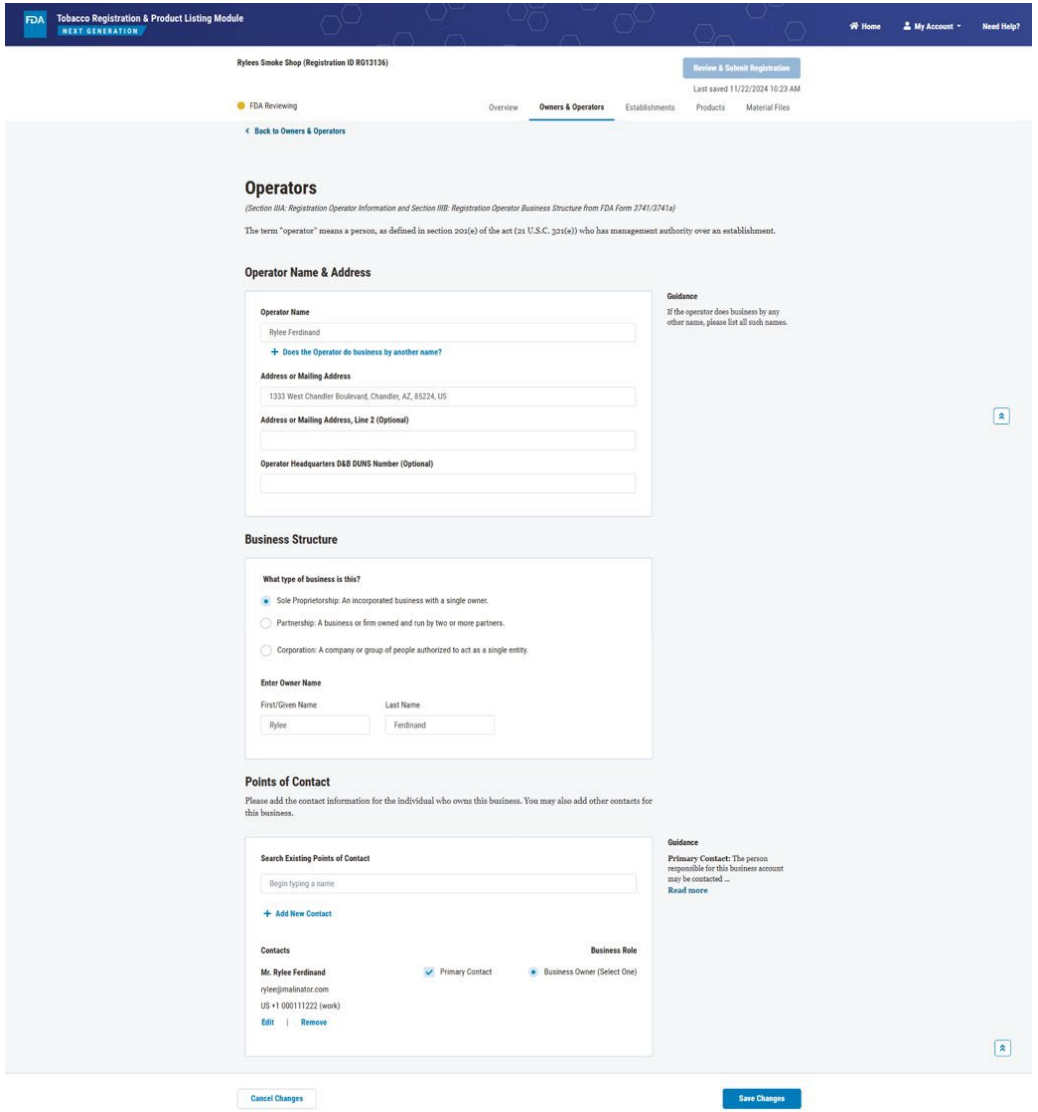
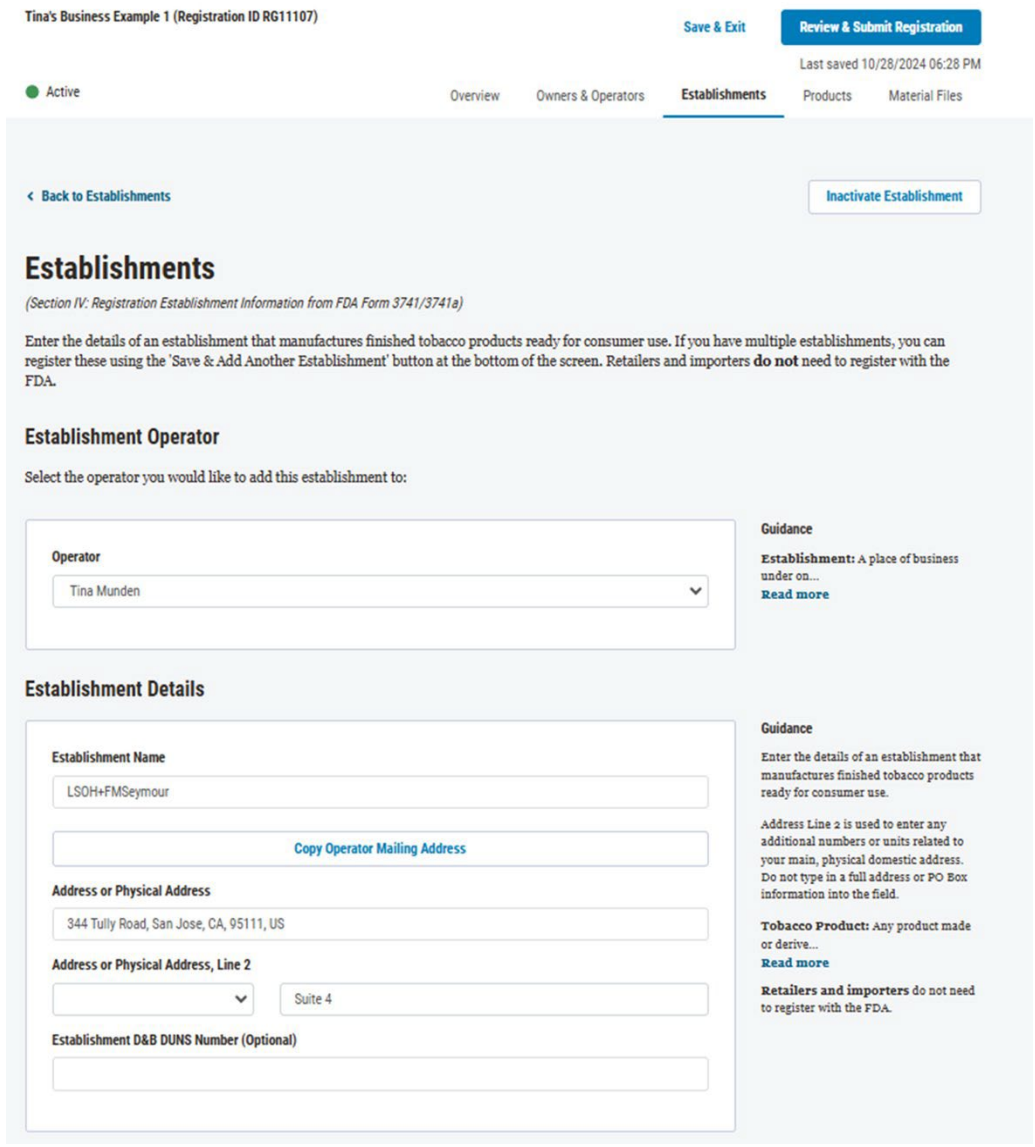


Figure 4 for #2: Establishment Details (left) and Establishment Operations and Point of Contact (right)



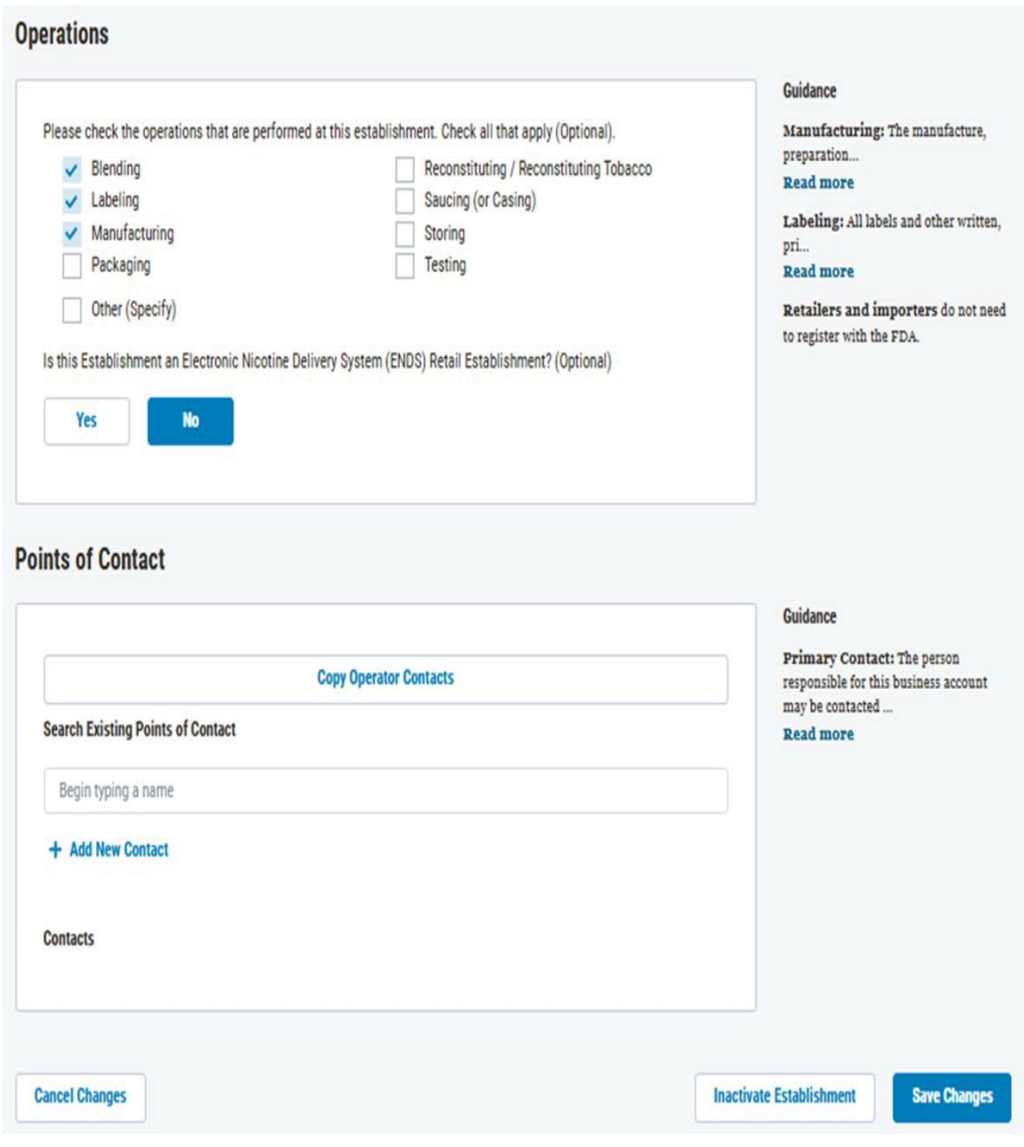


Table 1 for # 2: Comparison of Current (left) vs. Proposed (right) Establishment Operations

Current Establishment Operations Options	Proposed Updated Establishment Operations Options

• Blending
• Manufacturing
• Reconstituting
• Packaging
• Labeling
• Saucing (or Casing)
• Storing
• Testing
• Other (Specify)
	Distinguish whether registered establishment is manufacturing finished tobacco product or tobacco products for further manufacturing, and then select all applicable operations in which the establishment engages.
	
	General Operations
	• Assembling, Modifying, or Repairing Tobacco Products
	• Labeling/Re-Labeling Tobacco Products
	• Packaging/Re-Packaging Tobacco Products
	• Contract Manufacturing Tobacco Products
	• Co-Packing (3rd party packaging/labeling) Tobacco Products
	
	Product Specific Operations
	• Blending, Casing, Processing, Mixing or Reconstituting Tobacco
	• E-Liquid Production (mixing/blending nicotine, flavorings, PG/VG or other ingredients)
	• E-Liquid Filling/Packaging (bottling or pod filling)
	• Artisanal Pipe Making
	• Slitting, Rolling, Printing, Perforating, Cutting (for RYO products)
	
	Additional Operations
	• Distributing Tobacco Products
	• Importing Tobacco Products
	• Retailing Tobacco Products
	• Specify types of tobacco products distributed, imported, or sold
	  ○ Cigarettes
	  ○ Cigars
	  ○ Electronic Nicotine Delivery Systems (ENDS/Vapes)
	  ○ Heated Tobacco Products (HTP)
	  ○ Pipe Tobacco Products
	  ○ Roll-Your-Own Tobacco Products (RYO)
	  ○ Smokeless Tobacco Products
	  ○ Waterpipe Tobacco Products (Hookah)
	  ○ Oral Nicotine Products
	  ○ Other (Specify)
	• Storing Tobacco Products
	• Testing Tobacco Products
	• Other (specify)

Figure 5 for #2: Certification Statement

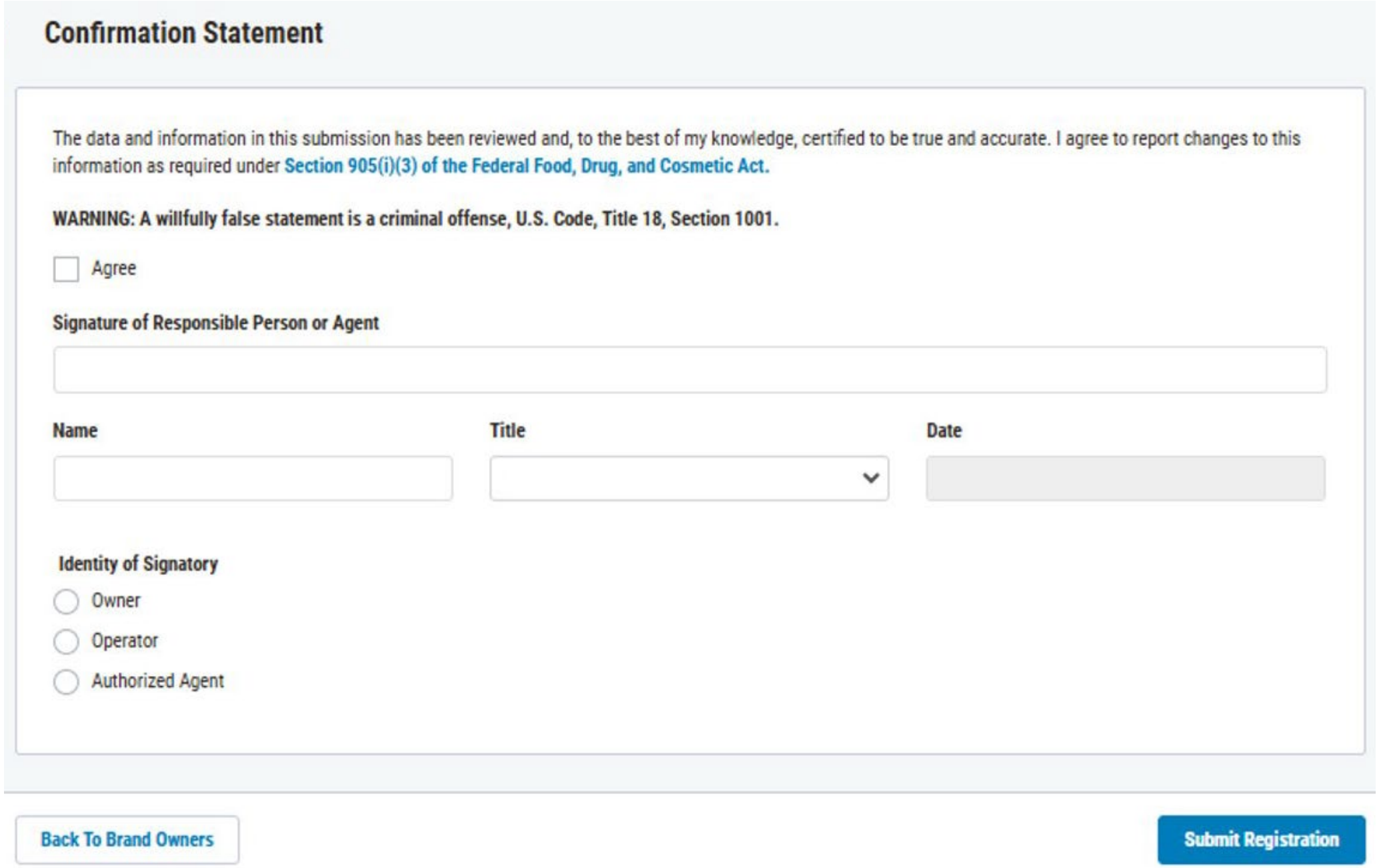
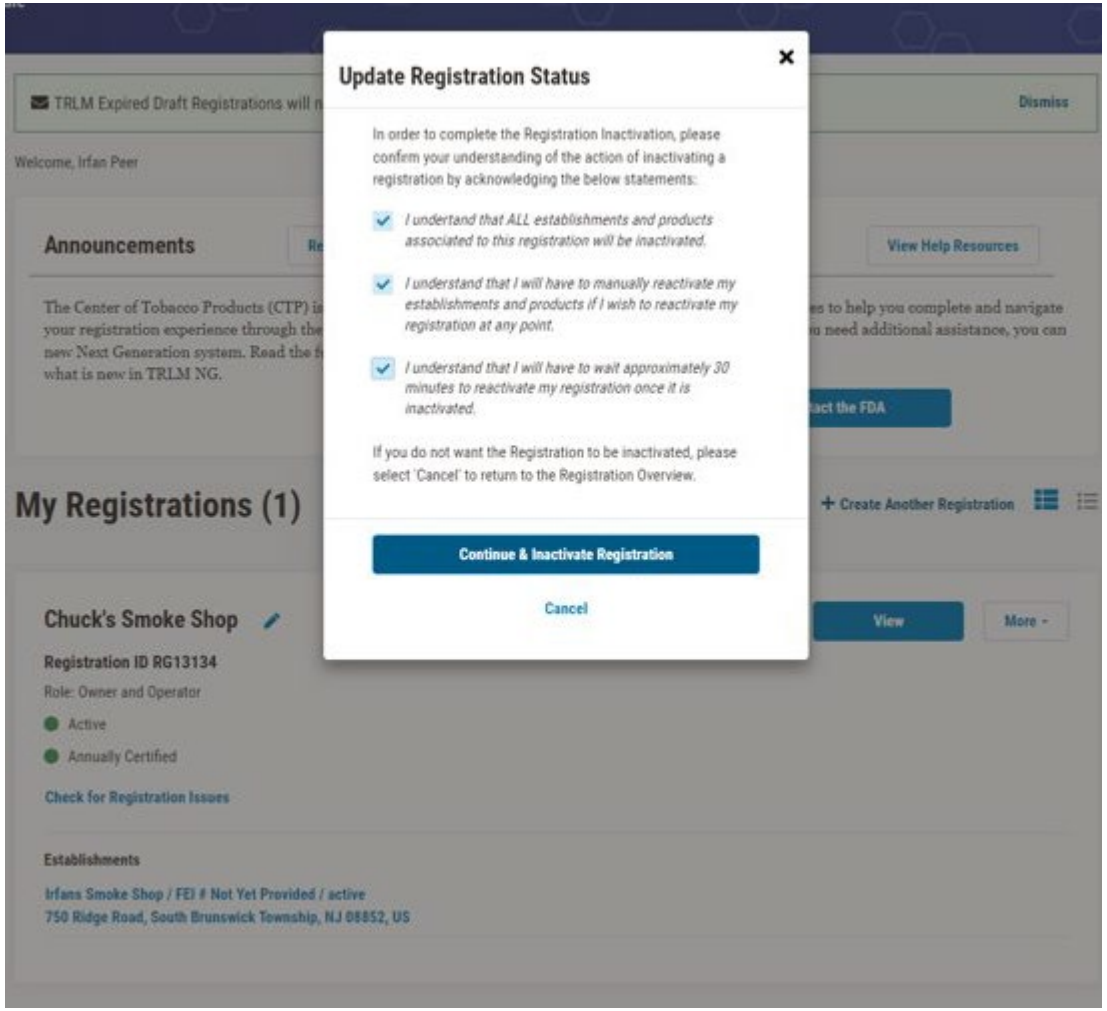


Figure 6 for #2: Updating Registration Status (left) and (right)



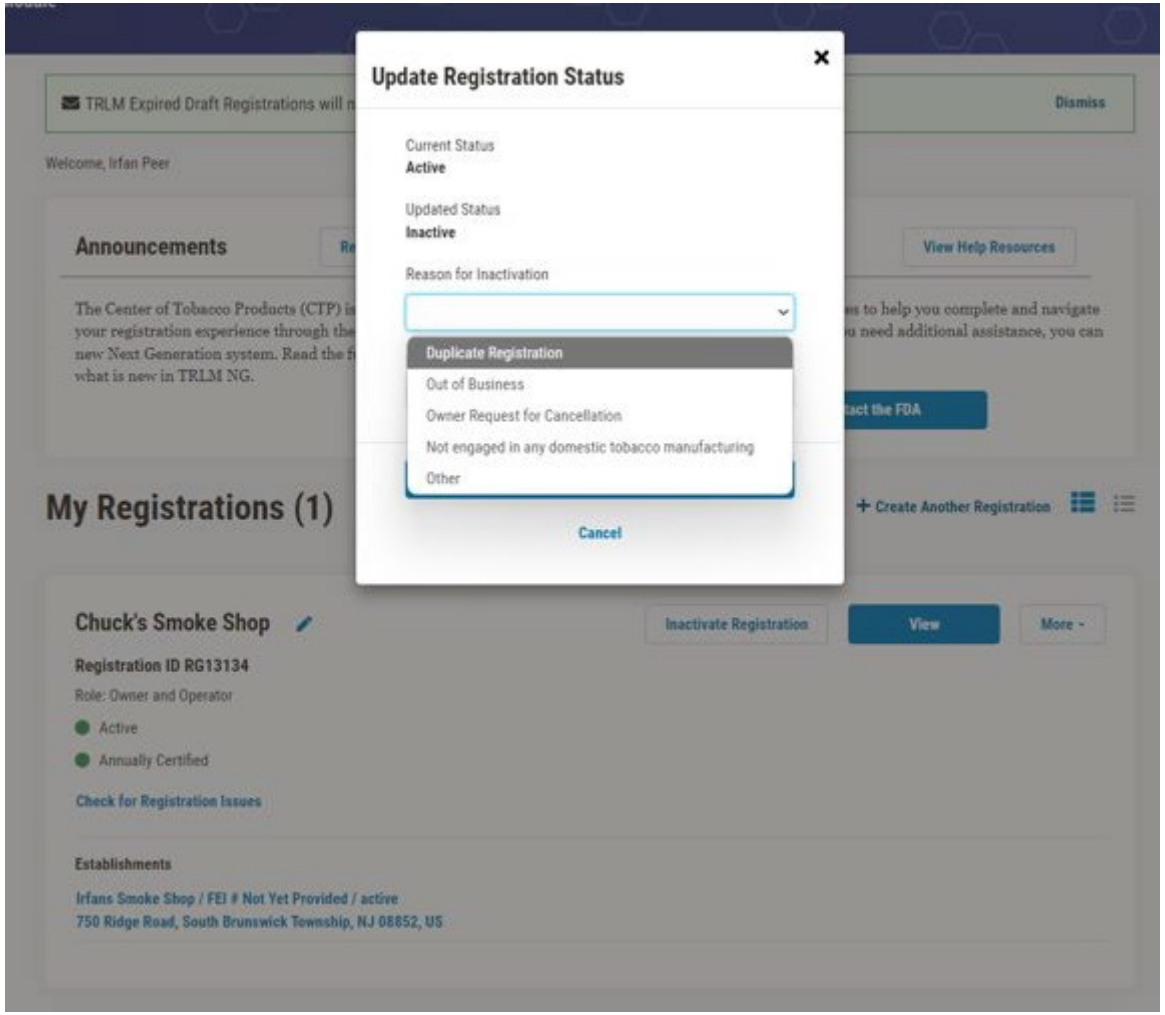


Table 2 for # 2: Proposed Establishment and Registration Inactivation Reasons

Current Inactivation Reasons	Proposed Inactivation Reasons
Registration Inactivation • Duplicate Registration • Out of Business • Owner Request for Cancellation • Not Engaged in Any Domestic Tobacco Manufacturing • Other Establishment Inactivation • Duplicate Registration • Out of Business • Operational, But Not Making Regulated Products • Other	Registration/Establishment Inactivation • Data Clean-Up • Not Engaged in Tobacco Product Manufacturing Activities • Manufacturing only tobacco products that are not finished tobacco products • Out of Business • Other (Specify) • Operational, But Not Making Regulated Products • Other

#3 – Proposed Terminology		
Net Change	**Summary of Change**	**Reason/Benefit of Change**

Updated existing definitions and added new definitions to reflect current terminology.	• Updated definitions
	  ○ Commercial Distribution
	• Added new definitions
	  ○ “Registrant” (added to distinguish between person registering the establishment vs. the actual establishment “registration” information itself
	  ○ Tobacco-Derived Nicotine (TDN)
	  ○ Non-Tobacco Nicotine (NTN)
	  ○ Retailer
	  ○ Submission Tracking Number (STN#) and Product Identifier Number (PD#)
	  ○ Material File
	  ○ Contract Manufacturer
	  ○ Electronic Nicotine Delivery System (ENDS)
	  ○ Component or part
	  ○ Authorized representative
		• Form has largely remained unchanged since 2017 and is missing relevant terminology for today’s tobacco products

Figure 1 for #3: Definitions in Current 3741 Form (left) vs. Proposed Definitions (right)

DEFINITIONS

FDA intends to use the following definitions in implementing the registration and product listing requirements of section 905 of the act.

1. **Commercial Distribution:** The term "commercial distribution" includes any distribution of a tobacco product to consumers or to another person for future manufacturing through sale or otherwise. As examples, it 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. Commercial distribution does not include internal or interplant transfer of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company and it does not include providing a tobacco product for product testing in cases where such products are not made available for consumption or resale.

2. **Domestic Establishment:** The term "domestic establishment" means an establishment in any State or Territory or possession of the United States.

3. **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.

(Continued on next page)

DEFINITIONS *(Continued)*

4. **Labeling:** The term "labeling," based on section 201(m) of the act (21 U.S.C. 321(m)), 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.

5. **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 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.

6. **Operator:** The term "operator" means a person, as defined in section 201(e) of the act (21 U.S.C. 321(e)) who has management authority over an establishment.

7. **Owner:** The term "owner" means a person, as defined in section 201(e) of the act (21 U.S.C. 321(e)) who has an ownership interest in an establishment.

8. **Pouch:** The term "pouch" means a permeable pouch, intended to be filled with pre-portioned tobacco product and placed in the oral cavity with the tobacco product.

9. **Tobacco Product:** 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)" (section 201(rr) of the act (21 U.S.C. 321 (rr)). This term does not include an article that is a drug, a device, or a combination product as defined in the act (section 201(rr) of the act (21 U.S.C. 321 (rr)). Thus, the term is not limited to products containing tobacco, but also includes components, parts and accessories of tobacco products, whether they are sold for further manufacturing or are ready for consumer use. For example, tobacco papers and filters are tobacco products, whether they are sold to consumers for use with roll-your-own tobacco or are sold for further manufacturing into a product sold to a consumer, such as a cigarette.

Terminology

In this form, FDA intends to use the following terminology in implementing the registration and product listing requirements of section 905 of the FD&C Act.

1. **Authorized Representative:** Authorized representative or Authorized agent (for a foreign applicant), who can provide information related to registration and listing of the subject tobacco product manufacturer including the name, address, and contact information (including email address).
2. **Commercial Distribution:** 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 personal consumption or resale. "Commercial distribution" does not include the handing or transfer of a tobacco product from one consumer to another for personal consumption.
3. **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.
4. **Contract Manufacturer:** Manufactures a finished tobacco product to another establishment's specifications.
5. **Domestic Establishment:** The term "domestic establishment" means an establishment in any State or Territory or possession of the United States.
6. **Electronic Nicotine Delivery System (ENDS):** Refers to an electronic device that delivers e-liquid (liquid nicotine combined with colorings, flavorings, and/or other ingredients such as propylene glycol (PG) and vegetable glycerin (VG)) in aerosol form into the mouth and lungs when inhaled, serving as an aerosolizing apparatus. The term may refer to vapes, vape pens, personal vaporizers, cigalikes, e-pens, e-hookahs, e-cigars, e-pipes, and e-cigarettes.
7. **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.
8. **Finished Tobacco Product:** The term "finished tobacco product" means a tobacco product, including all components and parts, sealed in final packaging (e.g., filters or filter tubes sold to consumers separately or as part of kits) or in the final form in which it is intended to be sold to consumers.
9. **Labeling:** The term "labeling," based on section 201(m) of the FD&C Act (21 U.S.C. 321(m)), 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.
10. **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.
11. **Material File:** For any listed tobacco product subject to section 905(i)(1)(A) of the FD&C Act, a material file includes a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product. For any listed tobacco product subject to section 905(i)(1)(B) of the FD&C Act, a material file includes a copy of all consumer information and other labeling for such tobacco product and a representative sampling of advertisements for such tobacco product.
12. **Non-Tobacco Nicotine (NTN):** The nicotine in the tobacco product is not made or derived from tobacco, such as synthetic nicotine.
13. **Operator:** The term "operator" means a person, as defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) who has management authority over an establishment.
14. **Owner:** The term "owner" means a person, as defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) who has an ownership interest in an establishment
15. **Pouch:** The term "pouch" means a permeable pouch, intended to be filled with pre-portioned tobacco product and placed in the oral cavity with the tobacco product.
16. **Product Identifier Number (PD #):** The number FDA assigns to each product within a submission to distinguish among the products included in that submission. PD#'s are only relevant within the context of a specific STN.
17. **Registrant:** FDA defines "registrant" as any person that registers a tobacco manufacturing facility and submits a product list for tobacco products commercially marketed in the United States.
18. **Retailer:** The term "retailer" means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.
19. **Submission Tracking Number (STN):** The number that FDA assigns to submissions that are received from an applicant, such as a PMTA, supplemental PMTA, SE reports, exemption requests, MRTPAs, and submissions related to investigational tobacco products.
20. **Tobacco-Derived Nicotine (TDN):** The nicotine in the tobacco product is derived from tobacco.
21. **Tobacco Product:** The term "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)" This term does not include an article that is a drug, a device, a combination product, or a food if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine, as defined in the act (section 201(rr) of the FD&C Act (21 U.S.C. 321 (rr); as amended by section 111(a) of the Consolidated Appropriations Act, 2022 (Pub. L. 117-103)).

#4 – Aligning Tobacco Product Categories and Sub-Categories		
Net Change	**Summary of Change**	**Reason/Benefit of Change**
Updated Product Category and Product Sub-Category Options	• Consolidating current **24** product categories, which are dependent on Intent of Use (i.e., Consumer Use vs. For Further Manufacturing) to **10** product categories independent on Intent of Use. • Consolidating current **79** product sub-categories to **48** product sub-categories.	• Will improve product searches on public registration and listing website, as drop-down lists with available options for Product Category and Product Sub-category will be provided. • Will make it easier for industry to accurately categorize their products and provide all necessary attributes. • Better standardization of product categories across CTP offices and OMB forms (i.e., industry will no longer have to reference discordant product categories and attributes for marketing order applications vs. registration and product listing). • More accurate data that better reflects the nature of industry's products and emerging product trends. • Fewer items for industry to have to review to find an option that best represents their products. • Reduce industry confusion and need to reach out to CTP for guidance on how to best categorize their products and ensures more accurate and reliable data. • Enables CTP to better evaluate submitted information. • Will allow CTP to collect vital product attributes.

Table 1 for #4: Comparison of Current (left) vs. Proposed (right) Product Category Options

Current Product Categories in TRLM-NG	Proposed Product Category Options
3741 (traditional tobacco products) Consumer Use • Cigarettes • Chewing Tobacco • Dissolvables • Accessory Filters • Roll-Your-Own Tobacco • Roll-Your-Own Paper • Roll-Your-Own Filters • Dry Snuff • Moist Snuff • Snus • Other (Specify) For Further Manufacturing Use • Tobacco • Paper • Filters • Pouch for Portioned Tobacco • Additive • Other (Specify) **3741a (deemed tobacco products)** • Cigar • Cigar Component or Part • Pipe Tobacco • Waterpipe Tobacco • Waterpipe Tobacco Component or Part • Electronic Nicotine Delivery System • Electronic Nicotine Delivery System Component or Part • Other (Specify)	• Cigarettes • Cigars • Electronic Nicotine Delivery Systems (ENDS/Vapes) • Heated Tobacco Products (HTP) • Pipe Tobacco Products • Roll-Your-Own Tobacco Products (RYO) • Smokeless Tobacco Products • Waterpipe Tobacco Products • Oral Nicotine Products • Other (Specify)

Table 2 for #4: Comparison of Current (left) vs. Proposed (right) Product Sub-Category Options

3741 (traditional tobacco products)

Consumer Use
- Cigarettes
- Chewing Tobacco
- Dissolvables
- Accessory Filters
- Roll-Your-Own Tobacco
- Roll-Your-Own Paper
- Roll-Your-Own Filters
- Dry Snuff
- Moist Snuff
- Snus
- Other (Specify)

For Further Manufacturing Use
- Tobacco
- Paper
- Filters
- Pouch for Portioned Tobacco
- Additive
- Other (Specify)

3741a (deemed tobacco products)

- Cigar
  - Cigar Tobacco
  - Cigar
  - Other (Specify)
- Cigar Component or Part
  - Cigar Filter
  - Cigar Paper
  - Cigar Tip
  - Cigar Tipping Paper
  - Cigar Wrapper
  - Other (Specify)
- Pipe Tobacco
  - Pipe Tobacco
  - Pipe Tobacco Kit
  - Other (Specify)
- Waterpipe Tobacco
  - Waterpipe Tobacco
  - Other (Specify)
- Waterpipe Tobacco Component or Part
  - Waterpipe Tobacco Base
  - Waterpipe Tobacco Bowl
  - Waterpipe Tobacco Cinder
  - Waterpipe Tobacco Diffuser
  - Waterpipe Tobacco Flavor Enhancer
  - Waterpipe Tobacco Foil/Screen
  - Waterpipe Tobacco Gasket
  - Waterpipe Tobacco Grommet
  - Waterpipe Tobacco Hose
  - Waterpipe Tobacco Hose Cooling Attachment
  - Waterpipe Tobacco Mouthpiece
  - Waterpipe Tobacco Valve
  - Waterpipe Tobacco Stem
  - Waterpipe Tobacco Filtration Base Additives
  - Other (Specify)
- Electronic Nicotine Delivery System
  - E-Cigarette
  - E-Cigarette Kit
  - E-Hookah
  - E-Hookah Kit
  - E-Cigar
  - E-Cigar Kit
  - E-Pipe
  - E-Pipe Kit
  - Advanced Personal Vaporizer
  - Advanced Personal Vaporizer Kit
  - Vape Pen
  - Vape Pen Kit
- Electronic Nicotine Delivery System Component or Part
  - E-Liquid
  - ENDS Adapter
  - ENDS Atomizer
  - ENDS Battery
  - ENDS Bridge
  - ENDS Cartomizer
  - ENDS Cartomizer
  - ENDS Cartridge
  - ENDS Charger
  - ENDS Clearomizer
  - ENDS Coil
  - ENDS Digital Display/Lights
  - ENDS Drip Tip
  - ENDS Drip Well
  - ENDS Filler Material
  - ENDS Filter
  - ENDS Mouthpiece
  - ENDS Software
  - ENDS Tank
  - Other (Specify)
- Other (Specify)

- Cigarettes
  - Filtered
  - Non-Filtered
  - Other (Specify)
- Cigars
  - Cigar Component
  - Cigar Tobacco Filler
  - Filtered, Sheet-Wrapped
  - Unfiltered, Leaf-Wrapped
  - Unfiltered, Sheet-Wrapped
  - Other (Specify)
- Electronic Nicotine Delivery Systems (ENDS/Vapes)
  - Closed E-Cigarette
  - Closed E-Liquid
  - ENDS Component
  - Open E-Cigarette
  - Open E-Liquid
  - Other (Specify)
- Heated Tobacco Products (HTP)
  - Closed HTP
  - Open HTP
  - HTP Consumable
  - HTP Component
  - Other Specify
- Pipe Tobacco Products
  - Pipe
  - Pipe Component
  - Pipe Tobacco Filler
  - Other (Specify)
- Roll-Your-Own Tobacco Products (RYO)
  - Filter
  - Filtered Cigarette Tube
  - Non-Filtered Cigarette Tube
  - Paper Tip
  - Roll-Your-Own Tobacco Filler
  - Rolling Paper
  - Other (Specify)
- Smokeless Tobacco Products
  - Dissolvable
  - Loose Chewing Tobacco
  - Loose Dry Snuff
  - Loose Moist Snuff
  - Loose Snus
  - Portioned Chewing Tobacco
  - Portioned Moist Snuff
  - Portioned Snus
  - Other (Specify)
- Waterpipe Tobacco Products
  - Waterpipe
  - Waterpipe Component
  - Waterpipe Heat Source
  - Waterpipe Tobacco Filler
  - Other (Specify)
- Oral Nicotine Products
  - Nicotine Pouch
  - Other (Specify)
- Other (Specify)