

#### **Tobacco Registration & Product Listing Module** NEXT GENERATION



U.S. Department of Health and Human Services



- . Section 905(b) of the FD&C Act requires establishment registrations to be re-submitted annually on or before December 31st of each year
- Section 905(i)(3) of the FD&C Act requires that certain changes in the product list be submitted bi-annually; once during June and once during December
- · For more information on the changes to product listing to be submitted bi-annually see the Section 905 Food, Drug & Cosmetic Act Annual Registration Guidance

To begin, log into your TRLM NG account to view and update your registration and product listing including material files prior to the deadline: December 31st, 2020 at 11:59pm EST.

## Register Your Tobacco **Establishments & Products**

Create an account to register your tobacco manufacturing establishment(s) and manage your product listing as per the FDA's Section 905 of the Food, Drug, and Cosmetic Act (FD&C Act).

Create Account

(i) Notice: New legislation enacted on March 15, 2022, makes clear that FDA has the authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine. The changes to the law take effect April 14, 2022.

Manufacturers of tobacco products containing nicotine not derived from tobacco (NTN) must ensure compliance with applicable requirements under the FD&C Act resulting from this law, such as:

· Register with FDA and list all NTN products that they manufacture, prepare, compound, or process for commercial distribution

Please see the CTP Newsroom announcement.

#### Returning User? Sign in.

UI Build 05.18.2022 06:47:01 PM EDT

API Build: DB:

assword	
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orgot Password?	
orgot Password? Please acknowledge the following	Expand 🚜
	materially false,

Create Account Exit

## **Getting Started**

To get started, we need to ask you a few questions to determine whether your tobacco manufacturing establishments and the products you produce meet the requirements of section 905(b) of the Family Smoking Prevention and Tobacco Control Act.

In this section, we will ask you some basic questions about the location and operation of your tobacco manufacturing establishments. To complete this section, please have the address of each establishment you intend to register.

The information you enter in this section will not be saved until you complete the step 'Create Account'.

Rectangular Sni

### Does my Business Need to Register?

Please answer the following questions to determine whether your tobacco manufacturing establishments and the products they produce meet the requirements of section 905(b) of the Family Smoking Prevention and Tobacco Act

#### Question 1 of 3

Are any of your tobacco manufacturing establishments located in the United States, including any territory of the U.S.?

Yes

This question is asking for the physical location of the establishments that manufac...

Read more

#### Question 2 of 3

Are any of the tobacco manufacturing establishments engaged in any of the following activities?

- Blending
- Reconstituting
- Manufacturing
- Packaging

Labeling
 Relabeling

- Repackaging
- Saucing (or Casing)

Yes

#### Guidance

The term tobacco product means any product made or derived from tobacco that is inte...

Read more

#### Question 3 of 3

Are any of the products manufactured at these establishments considered "finished" by the FDA?

Yes

No

#### uidance

The term "finished tobacco product" means a tobacco product, including all component...

Read more

## **Check Establishment's Registration Status**

Now let's check to make sure your establishments are not already registered. To do so, add the address of each tobacco manfuacturing establishment you want to register with FDA.

Please note, you should only enter addresses for domestic establishments which manufacture tobacco products that are finished and intended for consumer use. DO NOT add addresses for retail only establishments.

## **Tobacco Manufacturing Establishments (0)**

+ Add Establishment Address

#### Guidance

This question is asking for the physical location of the establishments that manufacture tobacco pro...

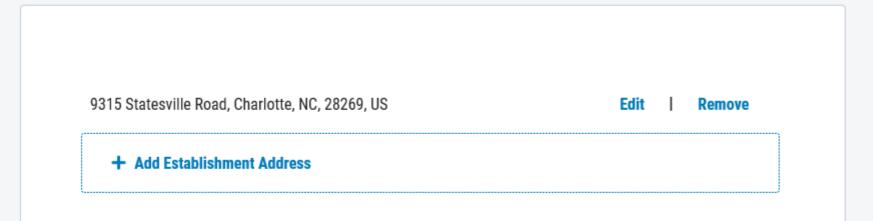
#### Read more

## **Check Establishment's Registration Status**

Now let's check to make sure your establishments are not already registered. To do so, add the address of each tobacco manfuacturing establishment you want to register with FDA.

Please note, you should only enter addresses for domestic establishments which manufacture tobacco products that are finished and intended for consumer use. DO NOT add addresses for retail only establishments.

## **Tobacco Manufacturing Establishments (1)**



#### Guidance

This question is asking for the physical location of the establishments that manufacture tobacco pro...

#### Read more

**Previous** 

Check Establishments



# No Establishments are Registered, Please Continue.

The addresses you entered are not associated with any registrations with FDA.

Next we will ask you some simple questions to learn more about your role as it relates to the manufacturing establishments.

## **Tobacco Manufacturing Establishments (1)**

9315 Statesville Road, Charlotte, NC, 28269, US



#### Guidance

This question is asking for the physical location of the establishments that manufacture tobacco pro...

#### Read more

**Change Establishments** 

Continue

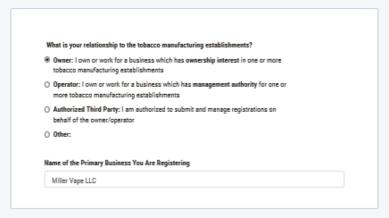
Create Account Exit



#### **Create Account**

To continue with your registration, please create an account. Your account will enable you to access the Tobacco Registration and Listing Module Next Generation (TRLM NG) to manage your registration and future updates.

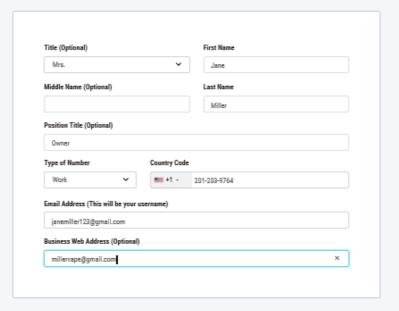
#### Provide Business Details



#### What if I'm applying on behalf of the owner or operator?

Please enter your information, even if you are applying on behalf of the owner or operator. This information is used to create your own account, which you can use to access one or more registrations within TRLM NG. You will be prompted to enter the Owner and Operator information later.

#### Your Details



Previous

Create Account

#### Rectangular Sni

## **Confirm Your Account**

A confirmation email has been sent to the address below which will include a verification link needed in order to confirm and sign in to your account.

#### Email

janemiller123@gmail.com

## **Having Trouble?**

Click the 'Resend Confirmation Email' button below to send a new verification link to the email listed above. If you still do not receive the verification link, please contact the FDA.



## **Set Up Your Registration**

To begin your registration, we need to understand your relationship to the tobacco manufacturing establishments. The questions below help to identify your role based on the FDA Forms 3741 & 3741a. At the end of the questions, you will be identified as one of the roles listed below.

- · Owner Registering Alone
- · Owner Registering on Behalf of Operator
- · Owner Who is Also Operator of All Establishments
- · Operator Registering Alone
- · Operator Registering on Behalf of Owner
- · Authorized Agent

## **Identify Your Role**

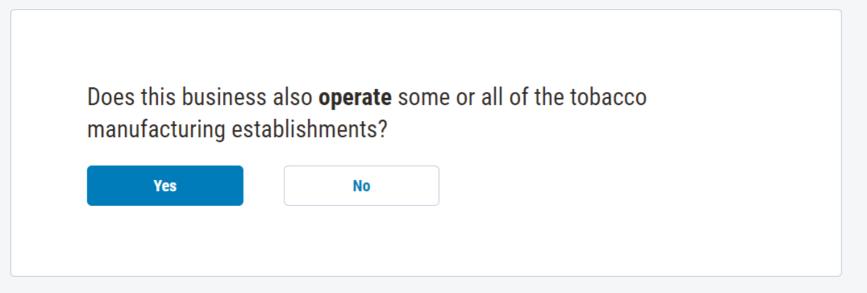
(Section 1: Identification from FDA Form 3741/3741a)



#### Guidance

Only answer "Yes" if you own or work for a business that has ownership interest in one or more to...

#### Read more





Only answer "Yes" if you own or work for a business that has management authority over tobacco ma...

Read more



You have identified as Owner who is also Operator of all establishments.

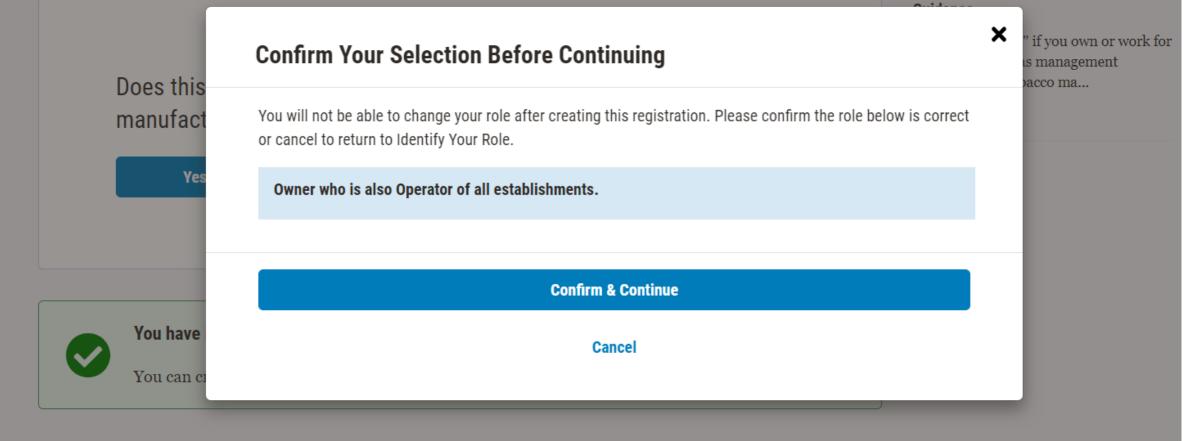
You can create a new registration.

## Name Your Registration

This name will only be used by you to reference this registration. This is not public information and does not affect your registration. We've pre-filled the name of your business for your convenience.

### **Registration Name**

Miller Vape

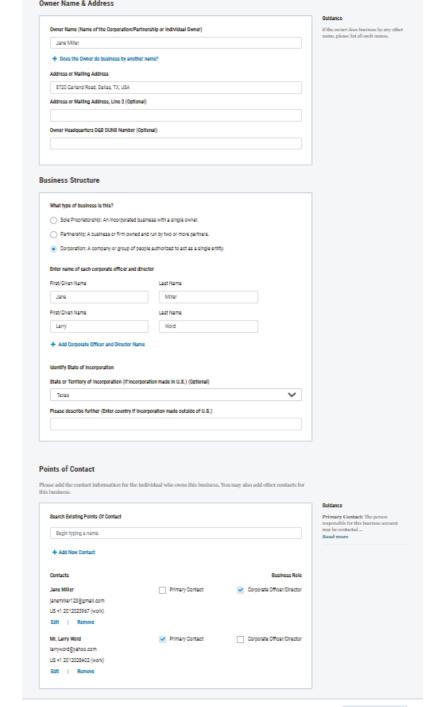


## **Name Your Registration**

This name will only be used by you to reference this registration. This is not public information and does not affect your registration. We've pre-filled the name of your business for your convenience.

### **Registration Name**

Miller Vape



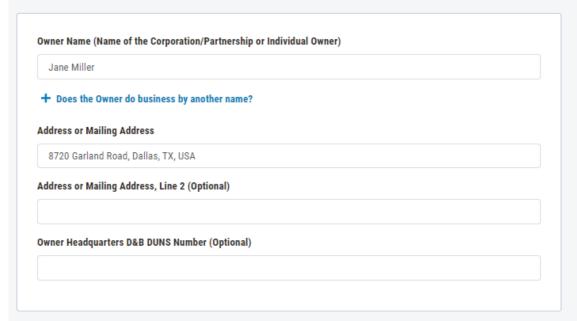
Save Owner & Continue

## **Owner**

(Section IIA: Registration Owner Information and Section IIB: Registration Owner Business Structure from FDA Form 3741/3741a)

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.

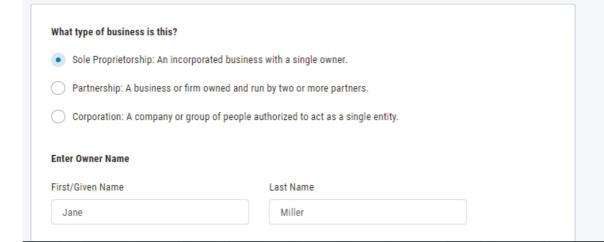
#### **Owner Name & Address**



#### Guidance

If the owner does business by any other name, please list all such names.

#### **Business Structure**



## **Business Structure**

Sole Proprietorship: An incorp	orated business with a single owner.	
Partnership: A business or firr	n owned and run by two or more partners.	
Corporation: A company or gro	oup of people authorized to act as a single entity.	
Enter name of each partner		
First/Given Name	Last Name	
Jane	Miller	
First/Given Name	Last Name	
Larry	Word	

## **Business Structure**

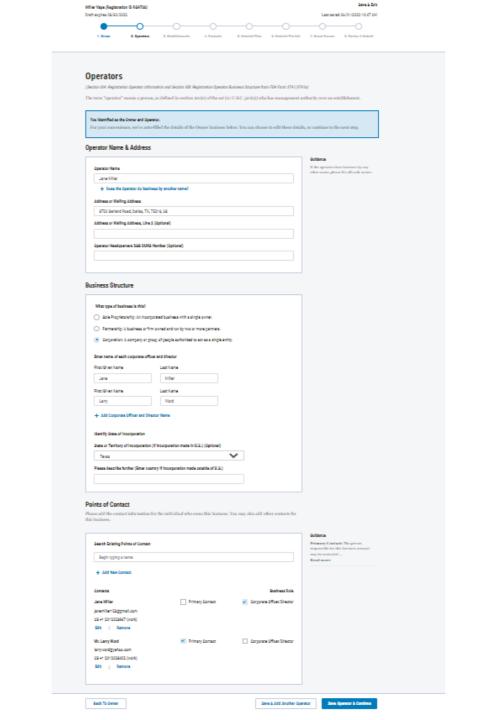
business with a single owner.	
ed and run by two or more partners.	
people authorized to act as a single entity.	
director	
Miller	
Last Name	
Word	
incorporation made outside of U.S.)	`
	Last Name  Word  ame  orporation made in U.S.) (Optional)

## **Points of Contact**

Please add the contact information for the individual who owns this business. You may also add other contacts for this business.

			Guidance
Search Existing Points Of Contact			Primary Contact: The person responsible for this business account
Begin typing a name			may be contacted  Read more
+ Add New Contact			
Contacts		Business Role	
Jane Miller	Primary Contact	Corporate Officer/Director	
janemiller123@gmail.com			
US +1 2012023967 (work)			
Edit   Remove			
Mr. Larry Word	Primary Contact	Corporate Officer/Director	
larryword@yahoo.com			
US +1 2012028402 (work)			
Edit   Remove			

Save Owner & Continue



#### Establishments

(Section IV: Registration Establishment Information from FDA Form 2741/2741s)

Exter the details of an establishment that manufactures finished tobuson products ready for consumer use. If you have multiple establishments, you can regime these using the Sure & Add Another Establishment between the bottom of the surees. Betailers and importers do not need to register with the FDA.

#### Establishment Operator

Select the operator you would like to add this establishment to:

Jane Miller	~
-------------	---

#### Establishment Details

Miller Vage		
	Copy Operator Walling Address	
ddress or Physical Add	THEE.	
8700 Serland Road, D	alias, T.I., 79219, US	
ddrees or Physical Add	recs, Line 2 (Optional)	
assibilishmen: 049 00H	û Humber (Optional)	

#### Goldance

Geldance Read more

Enter the details of an establishment that manufactures finished inharm products

Read more

Retailers and impariers in our next in register with the FDA.

#### Operations

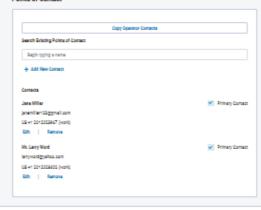


Read more

 $\textbf{Labelings} \ All \ \textbf{labels and other written},$ 

Retailers and impuriers its sai need in register with the FDA.

#### Points of Contact



#### Geldance

Read more

Previous

Sava & Add Another Scrabilehmers Sava Scrabilehmers & Continue



## **Establishments**

(Section IV: Registration Establishment Information from FDA Form 3741/3741a)

Enter the details of an establishment that manufactures finished tobacco products ready for consumer use. If you have multiple establishments, you can register these using the 'Save & Add Another Establishment' button at the bottom of the screen. Retailers and importers **do not** need to register with the FDA.

## **Establishment Operator**

Select the operator you would like to add this establishment to:

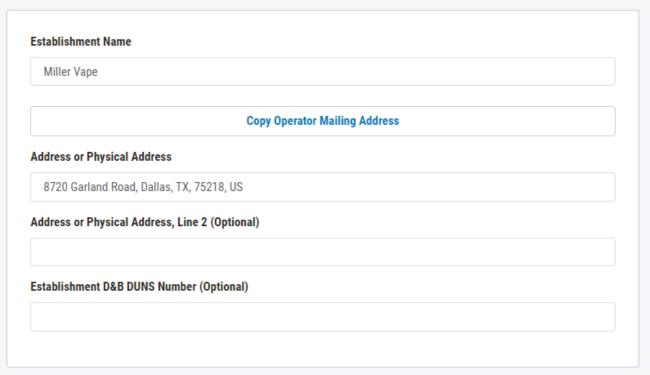
ane Miller	
ane miller	

#### Guidance

Establishment: A place of business under on...

Read more

### **Establishment Details**



#### Guidance

Enter the details of an establishment that manufactures finished tobacco products ready for consumer use.

**Tobacco Product:** Any product made or derive...

Read more

**Retailers and importers** do not need to register with the FDA.

### **Operations**

#### Guidance

Manufacturing: The manufacture, preparation...

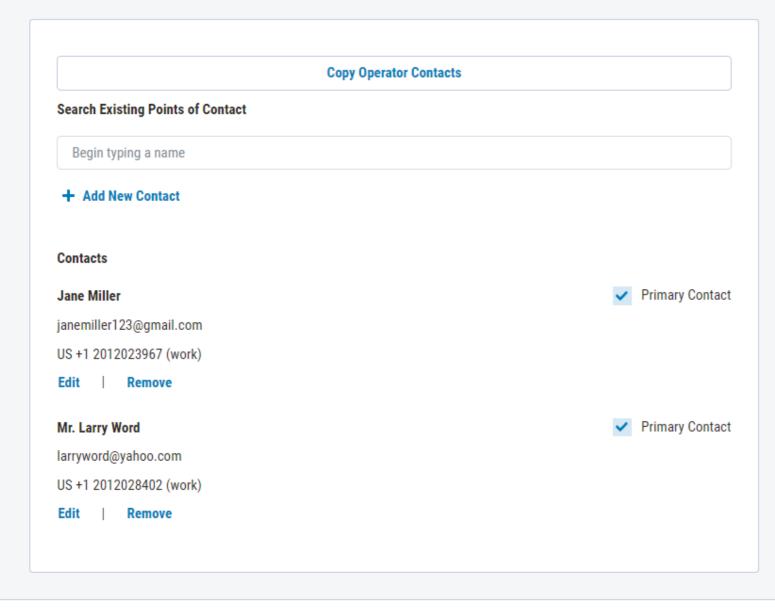
Read more

**Labeling:** All labels and other written, pri...

Read more

**Retailers and importers** do not need to register with the FDA.

### **Points of Contact**



#### Guidance

**Primary Contact:** The person responsible for this business account may be contacted ...

Read more

**Previous** 

Save & Add Another Establishment

Save Establishment & Continue

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## **Review Establishment(s)**

Review the details of the tobacco manufacturing establishment(s).

## Miller Vape

Operated by Jane Miller

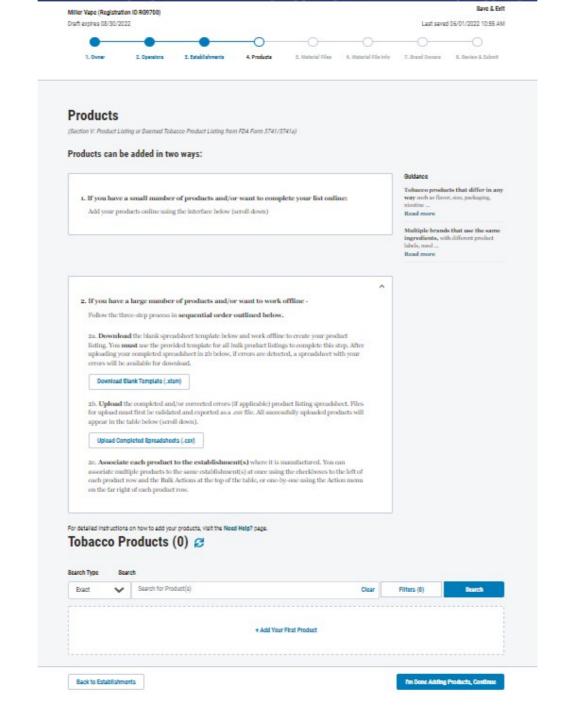
8720 Garland Road, Dallas, TX 75218, US Blending, Labeling, Manufacturing 2 Point(s) of Contact

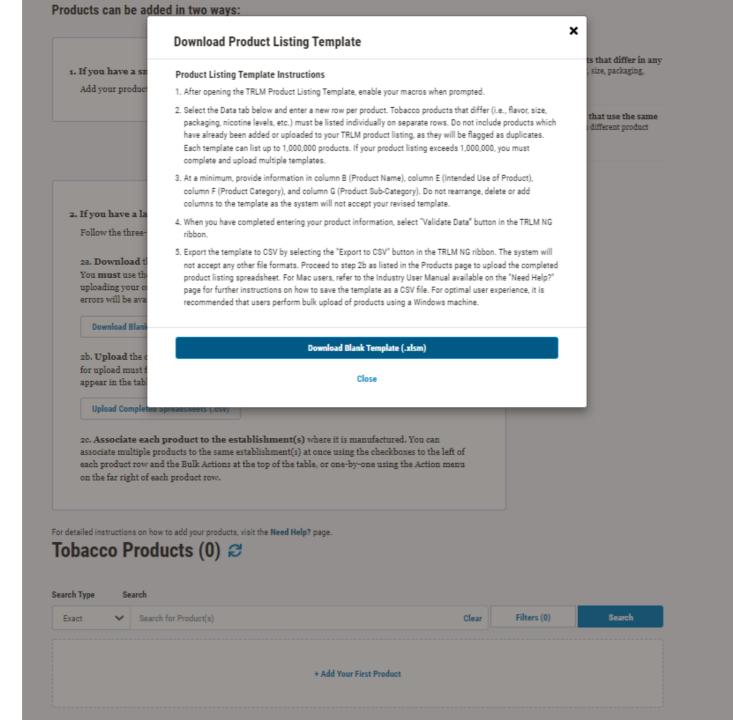
Add Establishment

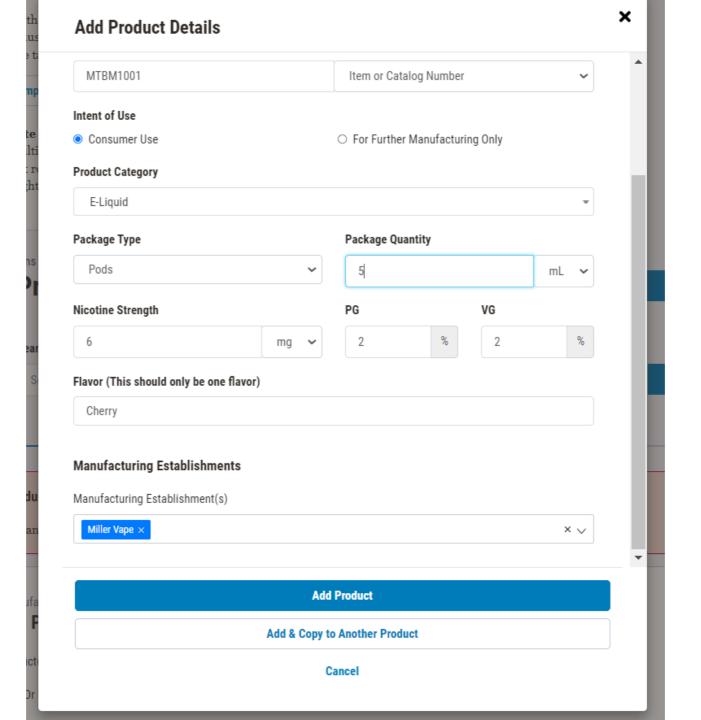
I am Done Adding Establishments, Continue

Back To Operators

Edit Delete



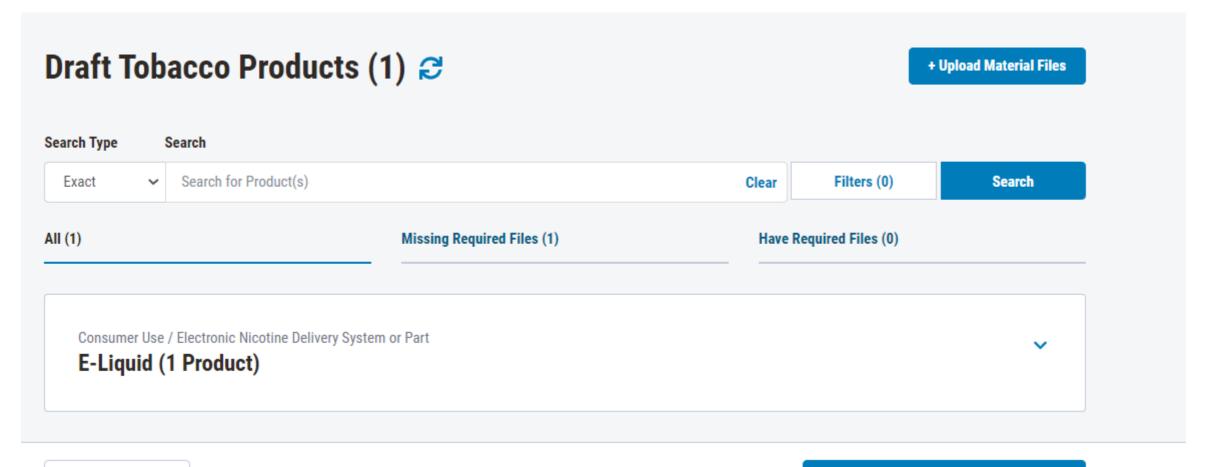




For detailed instructions on how to add your products, visit the Need Help? page. Tobacco Products (1) € + Add Product Search Type Search Search for Product(s) Filters (0) Search Exact Clear Draft (1) Trash Consumer Use / Electronic Nicotine Delivery System or Part E-Liquid (1 Product)

**Back to Establishments** 

I'm Done Adding Products, Continue



**Back to Products** 

I'm Done Adding Material Files, Continue

For detailed instructions on how to add your products, visit the  $\bf Need\ Help?$  page.

## Tobacco Products (1) €

+ Add Product

Search Type	9 5	Search						
Exact	~	Search for Product(s)			Clear	Filters (0)		Search
Draft (1)				Trash				
		/ Electronic Nicotine Delivery System or Part <b>1 Product)</b>						^
S	elect All	(Or Check all that apply using the box on the left o	f each product rov		fd Dodget - ham	a ta Dassa I	Ch 40	
Prod	duct (Bran	d / Name / Attributes)	Product ID			p to Page 1 Go	Show 10 ✓	Actions
		/ BAHAMA MAMA 0mg / Pods, 5mL, 6mg, PG 2%, VG	MTBM1001	1			None	•
				1 to 1 c	of 1 Products Jum	p to Page 1 Go	Show 10 🗸	< <b>1</b> >

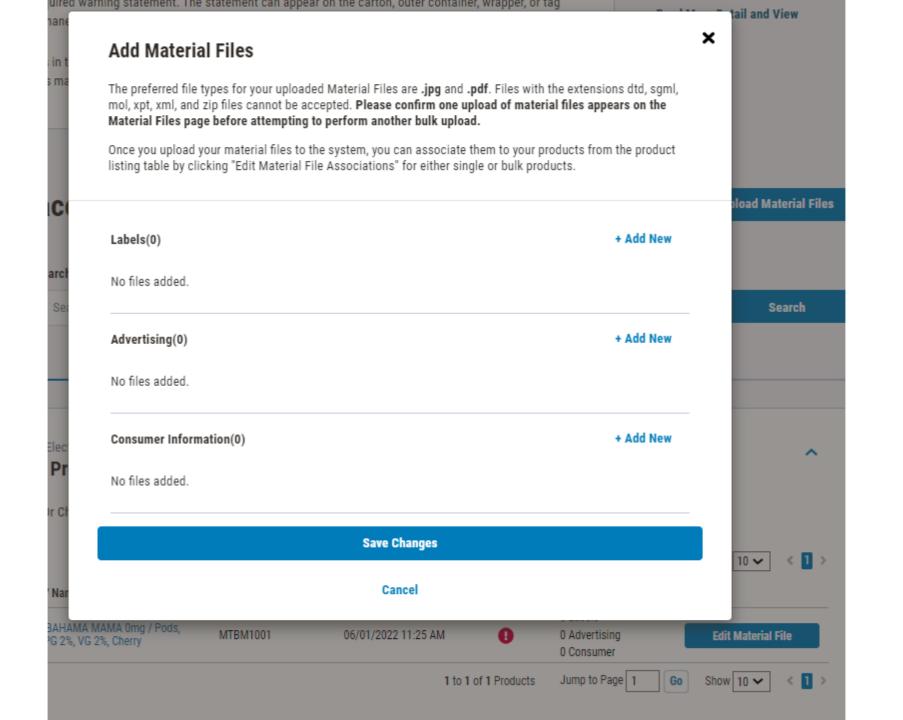
## Draft Tobacco Products (1) €

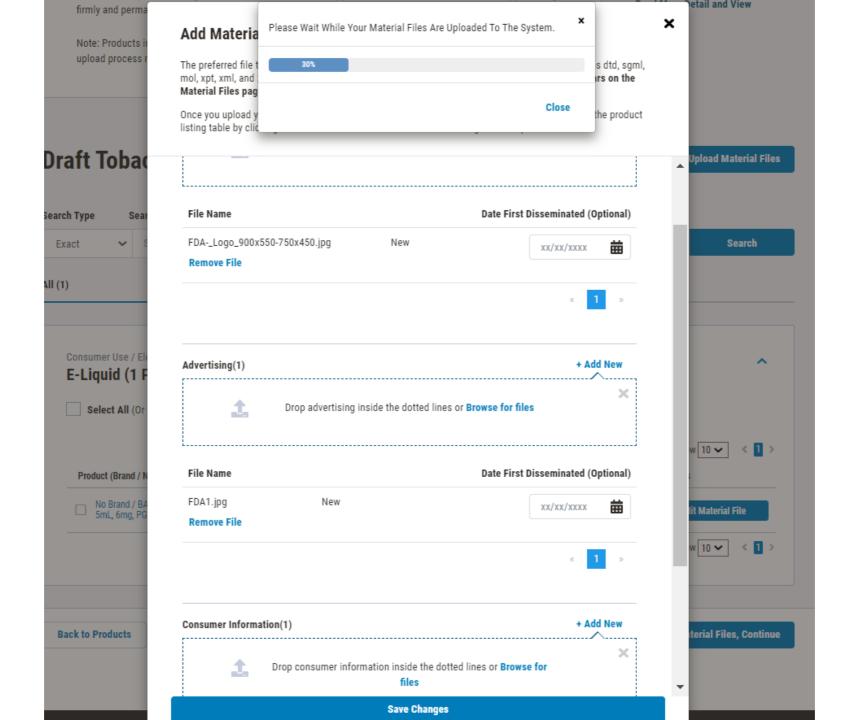
+ Upload Material Files

act 🗸	Search for Product(s)				Clear	Filters (0)	Search
)		Missing Red	uired Files (1)		Have R	equired Files (0)	
E-Liquid (	/ Electronic Nicotine Delivery S <b>1 Product)</b> (Or Check all that apply using t		each product row)				^
			1 to 1	of 1 Products	Jump to	Page 1 Go Sho	ow 10 <b>✓</b>
Product (Bran	d / Name / Attributes)	Product ID	1 to 1  Last Edited	of 1 Products	Jump to		

**Back to Products** 

I'm Done Adding Material Files, Continue





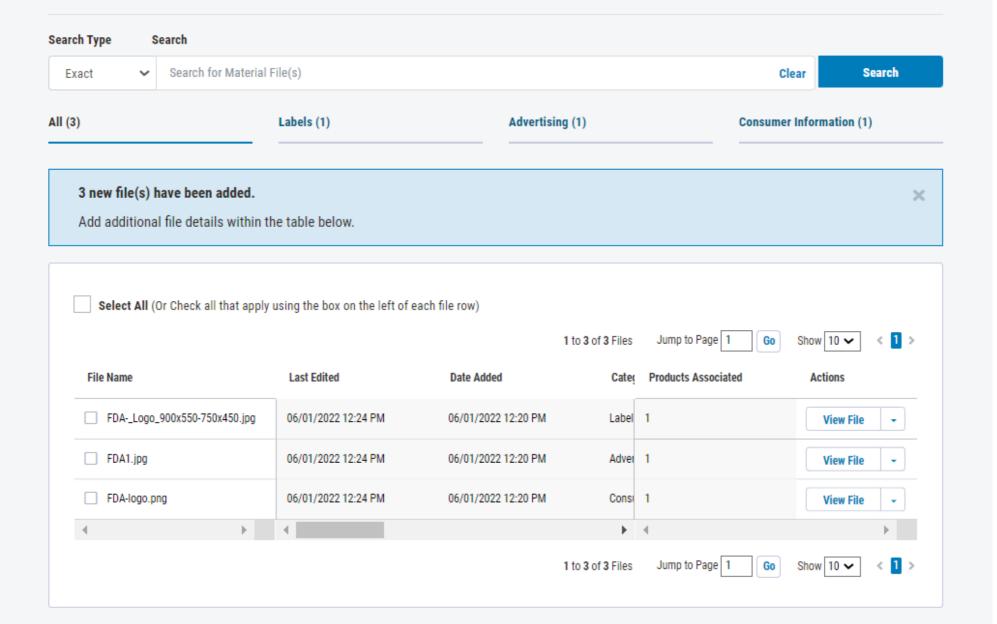
## Draft Tobacco Products (1) €

+ Upload Material Files

Search Type	Search						
Exact	Search for Product(s)				Clear	Filters (0)	Search
All (1)		Missing Red	quired Files (0)		Have Re	quired Files (1)	
	lse / Electronic Nicotine Delivery S	ystem or Part					^
Select	<b>All</b> (Or Check all that apply using t	he box on the left of		of 1 Products	Jump to P	age 1 Go Sh	iow 10 ✓
Product (B	erand / Name / Attributes)	Product ID	Last Edited	Issue?	Material I		_
□ No Br.	and / BAHAMA MAMA 0mg / Pods, 6mg, PG 2%, VG 2%, Cherry	MTBM1001	06/01/2022 12:24 PM	None	1 Labels 1 Advertis 1 Consum		Edit Material File
			1 to 1	of 1 Products	Jump to P	age 1 Go Sh	ow 10 🗸 🔞 1

**Back to Products** 

I'm Done Adding Material Files, Continue





## **Brand Owners** Enter the details of the business which has ownership interest in the brand(s) entered on Step 4. This may be the same or different to the business(es) that own or operates the manufacturing establishment(s). You may add more Brand Owners after this step. Business Name & Address Owner Name (Name of the Corporation/Partnership or Individual Owner) If the owner does business by any other name, please list all such names. + Does the Brand Owner do business by another name? Address or Mailing Address (Optional) Begin typing an address Address or Mailing Address, Line 2 (Optional) Owner Headquarters D&S DUNS Number (Optional) Associated Brands (Optional) Select the brands that are owned by this company. All brands from your product listing are displayed below. Brand Names No Brand Business Structure (Optional) What type of business is this? Sole Proprietorship: An incorporated business with a single owner. Partnership: A business or firm owned and run by two or more partners. Corporation: A company or group of people authorized to act as a single entity. Points of Contact (Optional) Please select a business structure to add contacts.

Back To Material File Info

Save & Add Another Brand Owner

Save Brand Owner & Continue

#### **Brand Owners**

Enter the details of the business which has ownership interest in the brand(s) entered on Step 4. This may be the same or different to the business(es) that own or operates the manufacturing establishment(s). You may add more Brand Owners after this step.

#### Business Name & Address

Miller	Vape				
+ Does	s the Brand Owne	r do business t	by another nan	16?	
lddress (	or Mailing Addres	s (Optional)			
87200	Carland Road, Dall	as, TX, USA			
Uddress (	or Mailing Addres	s, Line 2 (Opti	onal)		
Owner Ho	eadquarters D&B	DUNS Number	(Optional)		

#### Associated Brands (Optional)

Select the brands that are owned by this company. All brands from your product listing are displayed below.



#### Business Structure (Optional)



#### Points of Contact (Optional)

Please add the contact information for the individual who owns this business. You may also add other contacts for this business.



#### Buildance

Primary Contact: The person responsible for this business account may be contacted ... Read more

If the owner does business by any other name, please list all such names.

Back To Material File Info

Save & Add Another Brand Owner

Save Brand Owner & Continue

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## Review Brand Owner(s)

Review the details of the owners of the products' brands.

### Miller Vape

8720 Garland Road, Dallas, TX 75218, US Sole Proprietor 0 Point(s) of Contact

Brand(s): No Brand

Edit

Delete





## **Review and Submit**

**Submit Registration** 

(Section VI: Confirmation Statement from FDA Form 3741/3741a)

### 1. Owner Information

Return to Step 1

### Jane Miller

8720 Garland Road, Dallas, TX 75218, US Corporation 2 Point(s) of Contact

## 2. Operator Information

Return to Step 2

### **Jane Miller**

8720 Garland Road, Dallas, TX 75218, US Corporation 2 Point(s) of Contact

## 3. Establishment Information Return to Step 3 Miller Vape 8720 Garland Road, Dallas, TX 75218, US Blending, Labeling, Manufacturing 2 Point(s) of Contact Operated by Jane Miller **Edit this Establishment** 4. Tobacco Products Return to Step 4 Total Products to Submit (1) Product Category, Intent of Use **Total Products** E-Liquid, Consumer Use Trash (Not included in submission) 0 5. Material File Associations Return to Step 5 Total Material Files to Submit (3) **Total Files** 1 label(s) 1 advertising file(s)

1 consumer information file(s)

### 6. Material File Information

Return to Step 6

## Information provided for 3 material files

3 files do not have additional information

7. Brand Owner(s)

Return to Step 7

## Miller Vape

8720 Garland Road, Dallas, TX 75218, US Sole Proprietor 0 Point(s) of Contact

Brand(s): No Brand

# 8. Confirmation Statement

The data and information in this submission has been reviewed and, to the best of my knowledge, certified to be true and accurate. I agree to report changes to this information as required under Section 905(i)(3) of the Federal Food, Drug, and Cosmetic Act. WARNING: A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001. ✓ Agree Signature of Responsible Person or Agent Jane Miller Title Name Date Jane Miller 06/01/2022 12:46 PM  $\sim$ **Identity of Signatory** Owner Operator Authorized Agent

**Back To Brand Owners** 

**Submit Registration**