



# TTB Boot Camp for Distillers: Formulas & Labels

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ACSA DISTILLERS' CONVENTION  
AND VENDOR TRADE SHOW 2022

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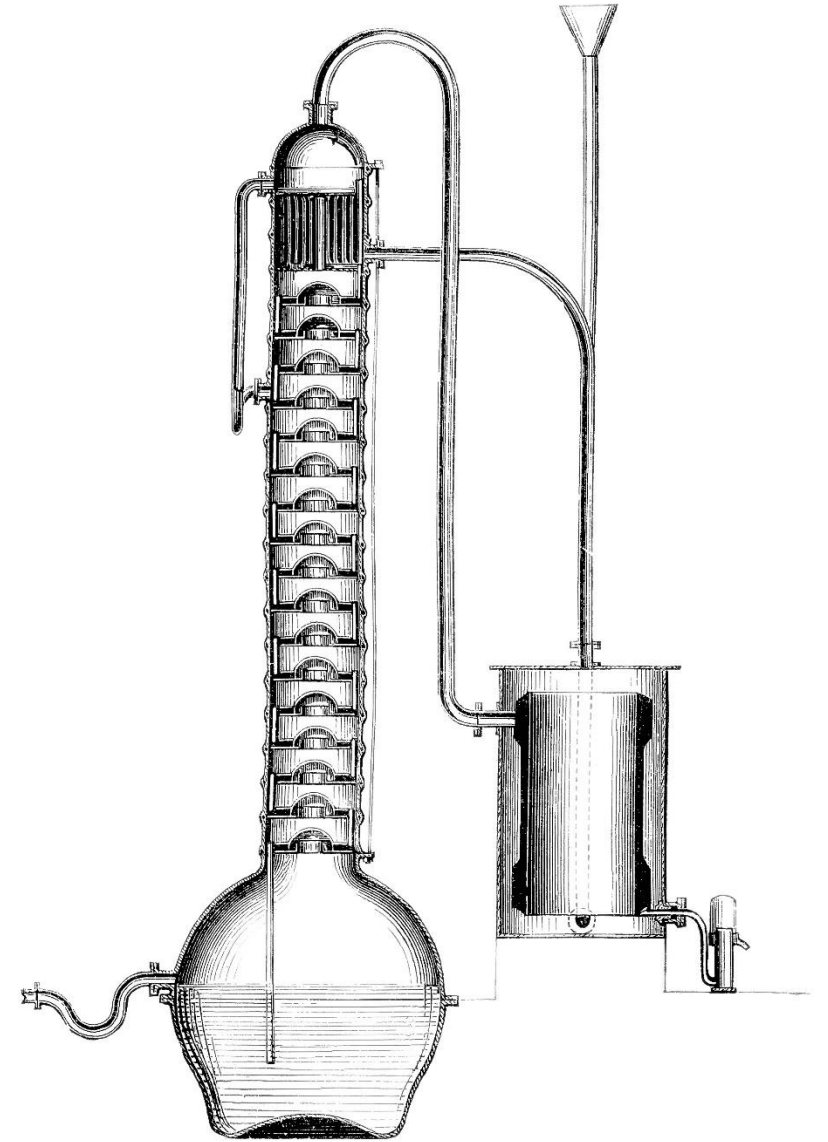
# TTB Disclaimer

## Notice:

- This information is being presented to help the public to understand and comply with the laws and regulations that the Alcohol and Tobacco Tax and Trade Bureau administers
- It is not intended to establish any new, or change any existing, definitions, interpretations, standards, or procedures regarding those laws and regulations
- In addition, this presentation may be made obsolete by changes in laws and regulations - please consult the regulations for the most current regulatory requirements
- Sample documents (such as records, returns, and labels) are for illustrative purposes only and contain fictitious data

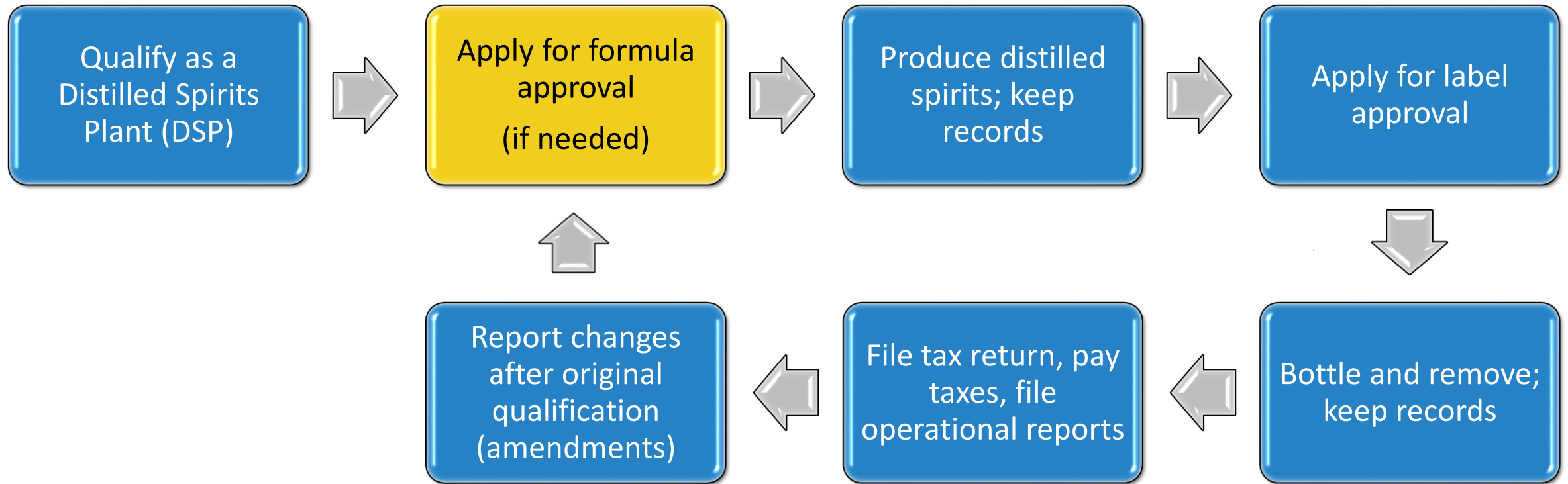
# Formulas

NAME: MICHAEL WARREN  
TITLE: ASSISTANT DIRECTOR, FORMULATION  
ALCOHOL LABELING AND FORMULATION DIVISION





# Typical TTB Touchpoints for Beverage Distilled Spirits Industry Members





# Common Formula Questions

- What is a formula?
- Why is a formula required?
- When is a formula required?
- Which distilled spirits require formula approval?
- How do I apply for formula approval?



# What is a Formula?

- A formula is the recipe for your distilled spirit product
- It must include:
  - a total yield, or batch size
  - a list of all ingredients by quantity
  - a description of how the product is made
- In some instances a sample of the product must also be submitted to TTB for laboratory analysis
- See [Formula Basics](#) page on TTB.gov



# Why is a Formula Required?

## **We use the information found in the formula to:**

- Classify the product for tax and labeling purposes
- Ensure that the product does not contain any prohibited ingredients
- Determine if limited ingredients are used within prescribed limitations or if they will impact labeling
- Provide a suggested statement of composition for labeling purposes



# When is a Formula Required?

**Generally, formula approval is required when a distilled spirit contains:**

- Artificial sweeteners
- Carbonation
- Compounded/artificial/imitation flavors
- Ingredients derived from hemp
  - See webinar presentation: [Using Hemp and Hemp Derivatives in Alcohol Beverages](#)

In addition, certain classes/types of distilled spirits always require formula approval





# Which Distilled Spirits Require Formula Approval?

Use our online tool [Which Alcohol Beverages Require Formula Approval?](#) or check the list in [TTB G 2016-3](#) to learn which products require formula approval

## Which Alcohol Beverages Require Formula Approval?

For certain distilled spirits, beers/malt beverages, and wines, TTB must evaluate the ingredients and production process before the product can be made or imported, and before you can submit your labels to TTB (if required). In some cases we also analyze a sample of the product in our laboratory while reviewing the formula.

Select your commodity, then answer a few questions about your product and we'll tell you whether it needs formula approval:



Distilled Spirits

Start



Malt Beverage (Beer)

Start



Wine/Cider

Start



# How to Apply for Formula Approval

## Formulas Online

- Step-by-step guidance
- Data validation checks along the way
- Application status updates via email



## Formulas Online Customer Page

See webinar presentation: [How to Register and Submit Formulas through Formulas Online](#)



# What TTB Looks For

- Class and Type – Is the base produced according to the stated standard for the specified class and type?
- Flavors and Flavor Ingredient Data (FID) sheets
- Food safe ingredients under FDA regulations (including Generally Recognized As Safe or GRAS ingredients)
- Restricted and prohibited ingredients
- Colors



# FDA Requirements

## **FDA has authority over food and ingredient safety**

- Approved Food Additives
  - 21 CFR parts 170-186
- Generally Recognized as Safe
  - Traditional use in food prior to 1958
  - Scientific determination
- Traditional medicines/dietary supplements are not necessarily GRAS
- Importer/producer is responsible for proving that an ingredient is GRAS or otherwise approved for use in alcohol beverages





# TTB Limited Ingredients

There are **4** artificial flavoring materials that are TTB limited ingredients:

- Synthetic maltol
- Ethyl maltol
- Synthetic vanillin
- Ethyl vanillin

If the limits for these ingredients are exceeded, a **natural flavor** is treated as an **artificial flavor** in the product



# Additional Information to Submit with Application

- Flavor Ingredient Data Sheet (FIDS) when the product is made with compounded flavors
- Limited Ingredient Calculation Worksheet when the product is made with **more than 1 compounded flavor**
- Ingredient Specification Sheet (Spec Sheet) when the product is made with ingredients composed of **more than 1 component** (e.g., a sweetener made with honey and sucralose)



# Compounded Flavors

**A compounded flavor is one you purchase from a flavor manufacturer**

- Types:
  - All natural
  - Natural and artificial containing less than or equal to 0.1% artificial content topnote
  - Natural and artificial containing greater than 0.1% artificial content topnote
  - All artificial
  - Non-flavor: product is not a flavor (e.g., Cloud Emulsion)
- Flavor manufacturer submits to TTB's Nonbeverage Products Lab for review
- May contain coloring materials



# Flavor Ingredient Data Sheet (FID Sheet)

A FID Sheet is a document that includes information about certain ingredients used to make a compounded flavor

**Submit 1 FID sheet for each compounded flavor used in your product!**

The FID Sheet allows TTB to ensure:

- Compounded flavor has been evaluated by TTB
- Beverage does not contain any ingredients in excess of the limits prescribed by TTB or by FDA
- Appropriate labeling of your product
- Product complies with TTB restrictions governing how much of the alcohol in your beverage may be derived from flavors and other nonbeverage ingredients containing alcohol

See [TTB G 2017-4](#) for additional information and examples





# Flavor Ingredient Data Sheet (FID Sheet)

- Flavor manufacturer supplies form to the producer
- It lists concentration of limited ingredients in PPM
- Lists any colors used in flavor
- States alcohol content of flavor
- This information, combined with the use rate, determines classification of flavor

Flavor Ingredient Data Sheet				
Flavor Producer Information				
TTB Co. Code: <u>FLRUS</u>		Date: <u>1/1/2017</u>		
Company Name: <u>Flavors-R-Us LLC</u>		Contact Person: <u>Jane Q. Flavor</u>		
Address: <u>123 Nonexistent Street</u>		Phone: <u>202-555-5555</u>		
<u>Any City, State USA 00000</u>		Fax: <u>202-555-5554</u>		
<b>Check Appropriate Box:</b>				
Flavor Name: <u>Natural Poppin' Pecan Supreme</u>		Approved for Drawback (DrB) <input type="checkbox"/>		
TTB Drawback Number: <u>123456</u>		Approved as No Action (N/A) <input checked="" type="checkbox"/>		
Alcohol Range by Volume: <u>50.0 - 54.0</u>		Fit for Beverage Purposes (Fit) <input type="checkbox"/>		
Flavor Product Number: <u>7891011</u>		Submitted for TTB Approval <input type="checkbox"/>		
		Not Yet Submitted for TTB Approval <input type="checkbox"/>		
Classification				
Natural <input checked="" type="checkbox"/>	N&A ≤ 0.1% Topnote <input type="checkbox"/>	N&A > 0.1% Topnote <input type="checkbox"/>	Artificial <input type="checkbox"/>	Non-Flavor <input type="checkbox"/>
Total Artificial Flavor Content: _____ ppm (Excluding Synthetic Vanillin, Ethyl Vanillin, Synthetic Maltol, and Ethyl Maltol)				
Flavor Components				
TTB/FDA Limited Ingredients	TTB/FDA Limitation in Finished Product	Amount of Additive or Agent Present in Flavor	Maximum Use Rate	Coloring Additives and Other Additives that Affect the Beverage Label (check or list label ingredients that affect the beverage label)
1. Synthetic Vanillin	40.0 ppm	_____ ppm	- %	1. FD&C Yellow #5 <input type="checkbox"/>
2. Ethyl Vanillin	16.0 ppm	_____ ppm	- %	2. FD&C Yellow #6 <input type="checkbox"/>
3. Synthetic Maltol	250.0 ppm	_____ ppm	- %	3. FD&C Blue #1 <input type="checkbox"/>
4. Ethyl Maltol	100.0 ppm	_____ ppm	- %	4. FD&C Blue #2 <input type="checkbox"/>
5. Ester Gum	100.0 ppm	_____ ppm	- %	5. FD&C Green #3 <input type="checkbox"/>
6. BVO	15.0 ppm	_____ ppm	- %	6. FD&C Red #40 <input type="checkbox"/>
7. Sodium Benzoate	1,000.0 ppm	5,000 ppm	20.00 %	7. Grapeskin Extract <input type="checkbox"/>
8. Gum Arabic/Acacia	200,000.0 ppm	_____ ppm	- %	8. Caramel Color <input checked="" type="checkbox"/>
9. Propylene Glycol	50,000.0 ppm	10,000 ppm	NO LIMIT %	9. Annatto <input type="checkbox"/>
10. BHA	(≤0.5% Essential Oil)	<input type="checkbox"/> check if contained	- %	10. Elderberry Extract <input type="checkbox"/>
11. Acetic Acid	1,500.0 ppm	_____ ppm	- %	11. Beet Extract <input type="checkbox"/>
12. _____	_____ ppm	_____ ppm	- %	12. Oak Extract <input type="checkbox"/>
13. _____	_____ ppm	_____ ppm	- %	13. Carmine/ <input type="checkbox"/>
14. _____	_____ ppm	_____ ppm	- %	14. Cochineal Extract <input type="checkbox"/>
15. Total Vanillin	40.0 ppm	- ppm	- %	15. _____ <input type="checkbox"/>
16. Total Maltol	250.0 ppm	- ppm	- %	
Confidential Limited Ingredients Not Shown (CLI)				
Check if contained in formula <input type="checkbox"/> Check if CLI was previously submitted <input type="checkbox"/>				
Beverage Manufacturer / Importer: _____				
Formula # / Serial #: _____				
_____ Title: <u>Supervisory Chemist</u> Date: <u>30-Sep-17</u>				
Flavor Company Representative Signature				



# FID Sheet Header

## Flavor Ingredient Data Sheet

### Flavor Producer Information

TTB Co. Code: FLRUS  
Company Name: Flavors-R-Us LLC  
Address: 123 Nonexistant Street  
Any City, State USA 00000

Date: 1/1/2017  
Contact Person: Jane Q. Flavor  
Phone: 202-555-5555  
Fax: 202-555-5554

Flavor Name: Natural Poppin' Pecan Supreme  
TTB Drawback Number: 123456  
Alcohol Range by Volume: 50.0 - 54.0  
Flavor Product Number: 7891011

### Check Appropriate Box:

Approved for Drawback (DrB) ☐  
Approved as No Action (N/A) ☒  
Fit for Beverage Purposes (Fit) ☐  
Submitted for TTB Approval ☐  
Not Yet Submitted for TTB Approval ☐

### Classification

Natural ☒ N&A  $\leq$  0.1% Topnote ☐ N&A  $>$  0.1% Topnote ☐ Artificial ☐ Non-Flavor ☐

Total Artificial Flavor Content: \_\_\_\_\_ ppm (Excluding Synthetic Vanillin, Ethyl Vanillin, Synthetic Maltol, and Ethyl Maltol)



# FID Sheet Limited Ingredients Section

Flavor Components				
TTB/FDA Limited Ingredients	TTB/FDA Limitation in Finished Product	Amount of Additive or Agent Present in Flavor	Maximum Use Rate	Coloring Additives and Other Additives that Affect the Beverage Label (check or list label ingredients that affect the beverage label)
1. Synthetic Vanillin	40.0 ppm	_____ ppm	- %	1. FD&C Yellow #5 <input type="checkbox"/>
2. Ethyl Vanillin	16.0 ppm	_____ ppm	- %	2. FD&C Yellow #6 <input type="checkbox"/>
3. Synthetic Maltol	250.0 ppm	_____ ppm	- %	3. FD&C Blue #1 <input type="checkbox"/>
4. Ethyl Maltol	100.0 ppm	_____ ppm	- %	4. FD&C Blue #2 <input type="checkbox"/>
5. Ester Gum	100.0 ppm	_____ ppm	- %	5. FD&C Green #3 <input type="checkbox"/>
6. BVO	15.0 ppm	_____ ppm	- %	6. FD&C Red #40 <input type="checkbox"/>
7. Sodium Benzoate	1,000.0 ppm	5,000 ppm	20.00 %	7. Grapeskin Extract <input type="checkbox"/>
8. Gum Arabic/Acacia	200,000.0 ppm	_____ ppm	- %	8. Caramel Color <input checked="" type="checkbox"/>
9. Propylene Glycol	50,000.0 ppm	10,000 ppm	NO LIMIT %	9. Annatto <input type="checkbox"/>
10. BHA	(<0.5% Essential Oil)	<input type="checkbox"/> check if contained		10. Elderberry Extract <input type="checkbox"/>
11. Acetic Acid	1,500.0 ppm	_____ ppm	- %	11. Beet Extract <input type="checkbox"/>
12. _____	_____ ppm	_____ ppm	- %	12. Oak Extract <input type="checkbox"/>
13. _____	_____ ppm	_____ ppm	- %	13. Carmine/ Cochineal Extract <input type="checkbox"/>
14. _____	_____ ppm	_____ ppm	- %	14. _____ <input type="checkbox"/>
15. Total Vanillin	40.0 ppm	- ppm	- %	15. _____ <input type="checkbox"/>
16. Total Maltol	250.0 ppm	- ppm	- %	



# Limited Ingredient Calculation Worksheet

## Submit worksheet when using compounded flavors

- Use worksheet to:
  - Calculate total volume or percent of TTB and FDA limited ingredients in product
  - Determine whether product contains an artificial flavor for labeling purposes
- Also useful as product development tool
- Worksheets available on TTB.gov in percent-based or volume-based formats

ALCOHOL AND TOBACCO TAX AND TRADE BUREAU | TTB





# Ingredient Specification Sheet

## (Spec Sheet or Technical Data Sheet)

- A spec sheet is a document or label that lists or describes the contents of an ingredient that is made from more than 1 component



### Specification Sheet

**Product Name:** St. Johnathan's® **Variety Number:** 8675456

St. Johnathan's® is a proprietary blend of two sweeteners. The sweetness of honey is enhanced by the addition of purified sucrose, resulting in a syrup that is 5 times sweeter than honey. Ideal for mouthfeel and improved overall sweetness in baked goods, beverages, dressing, sauces, jams and fillings.

Parameters	Specifications	Methods
Assay: Honey	≥ 90%	Internal Method
Assay: Sucrose	≤ 10%	Internal Method
Appearance	Viscous liquid	Visual inspection
Color	Caramel	Visual inspection

**Composition:** Honey, Sucrose

**Country of Origin:** USA

Grateful Heart Ingredients, Inc | 86408 N Heritage Highway, Sweet Home, AL 36858 | 333.333.3333  
The information contained in this bulletin should not be construed as recommending the use of our product in violation of any patent, or as warranties (expressed or implied) of non-infringement or its fitness for any particular purpose.



# Ingredient Specification Sheet

## (Spec Sheet or Technical Data Sheet)

- Submit a spec sheet for each ingredient that is made from more than 1 component, e.g., a fruit juice made from water, apples, and sugar
- Should not be used for compounded flavors (use FID Sheet)
- See [TTB G 2017-3](#) for additional information and examples



# Helpful Hints

- Supply a quantitative list of ingredients
- Provide a complete method of manufacture
- Indicate at what stage flavors are added to the product
- Flavor Ingredient Data Sheets (FIDS) should include a TTB number, a Flavor Product Number, and the TTB Approval status (Nonbeverage Products Lab Approval)
- Provide the common name and scientific name (genus and species) for any unusual herbal ingredients
- Ensure that ingredients are considered GRAS or otherwise approved by the FDA





# Formula Resources

- [Formula Approval guidance pages on TTB.gov](#)
- [Distilled Spirits Beverage Alcohol Manual \(BAM\)](#)
  - [BAM Chapter 1](#): Commodity Statements
  - [BAM Chapter 4](#): Quick product reference guide stating basic technical requirements
  - [BAM Chapter 7](#): Provides chart listing limitations placed on harmless coloring blending and flavoring materials (HCBFM)



# Example in Formulas Online

**TTBONLINE.GOV**  
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU  
U.S. DEPARTMENT OF THE TREASURY

**Formulas Online**  
COLAS Home Text Menu My Profile Help Contact Us Log Off

new View Company

**Beverage**

Main Formula Samples Results Company Comments Docs/Links Workflow Needs Correction History

[Print](#) | [Comment](#) | [Upload](#) | [Close Historical](#)

☐ Expedite ☒ Paper Submission [Note:](#)

**Product Information** Class: IMITATION DISTILLED SPIRITS Type: Product Name: DS Example #1 [Change Product Information](#)

[Definition](#)

[What does TTB look for?](#)

**1 Measurement**

Type: ☒ Percentage ☐ Volume/Weight [i](#)

**2 Yield Summary**

Total Yield:   [i](#)

Low High Unit

Alcohol Content of Finished Product:  -   [i](#)

### 3 Ingredients List

List ALL ingredients to be used in formulating a batch of the product. Please enter the ingredients in production order.

[Ingredient List Examples](#)

▶ Vodka	98.0 - 99.0 Percentage AbV: 45% - 45% PaD: 191 - 195 Proof TTB Formula ID: <Not Entered>	Finished Alcohol	
▶ Artificial Rock-Lemon flavor	1.0 - 2.0 Percentage TTB Company Code: WL5 TTB Drawback #: 100	Flavor (Compounded)	
▶ Water	1.0 - 4.0 Percentage	Other	
▶ St. Johnathan's - The Sweetener with Heart	0.75 - 1.2 Percentage	Other	

[+Add Ingredient...](#)

[Which category should I choose?](#)

### 4 Method of Manufacture

Describe in sequence each step used to produce this product.

This can be done in a format similar to a recipe, for instance providing the sequence of steps in either a list or paragraph format to describe how your product is made.

See [Method of Manufacture Examples](#) for some indications of the level of detail that TTB looks for when evaluating formula submissions.

Description:

1.) Transfer finished Vodka to plant.  
2.) Add Artificial Lemon Flavor and natural sweetener.  
3.) Test alcohol level, adjust for added alcohol from flavors, add water to adjust bottling proof and bottle.

Method of Manufacture Documents

TYPE	NAME	DATE	ACTION
------	------	------	--------

[Add Attachment](#)

[« Previous](#)

[Save as Draft](#)

[Validate](#)

[Cancel](#)

[Next »](#)

We collect this information to verify your compliance with Federal laws and regulations that TTB administers. The information collected on this form must be considered confidential tax information under 26 U.S.C. 6103, and must not be disclosed to any unauthorized party under 26 U.S.C. 7213.



# Common Reasons Formulas Are Returned for Correction

**To speed up the formula approval process, don't forget:**

Ingredient Specification Sheet (Spec Sheet) for ingredients composed of more than 1 component

Limited Ingredient Calculation Worksheet when compounded flavors are used

Flavor Ingredient Data (FID) when compounded flavors are used



Please take a few minutes to  
provide feedback on this session:

<https://www.ttb.gov/survey>

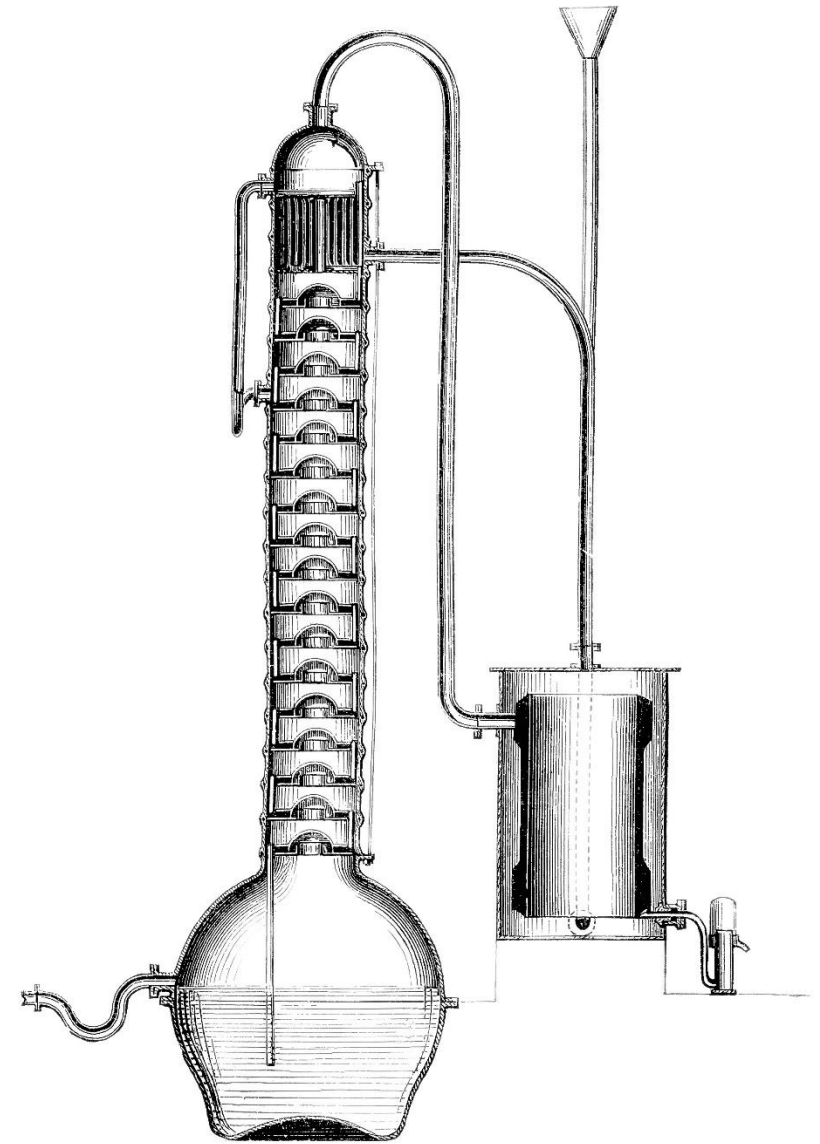


# Labeling

NAME: IAN BUCHANAN

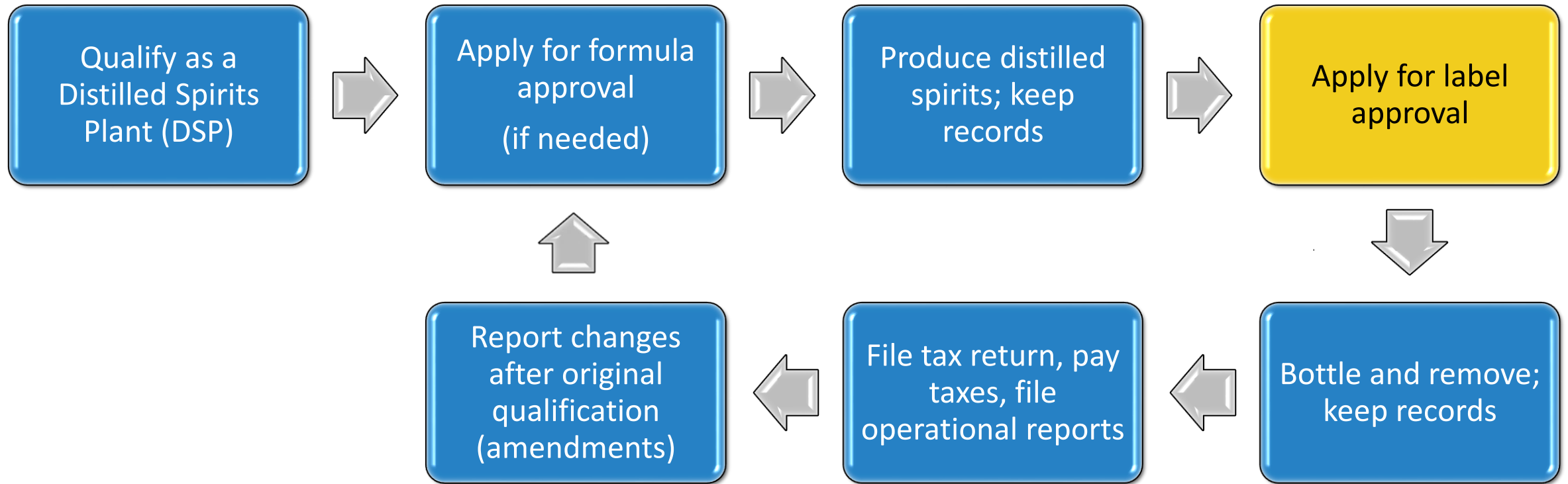
TITLE: LABELING SPECIALIST

ALCOHOL LABELING AND FORMULATION DIVISION





# Typical TTB Touchpoints for Beverage Distilled Spirits Industry Members





# Mandatory Information

## In the Same Field of Vision

- Brand Name
- Class/Type
- Alcohol Content

## Anywhere on the Label

- Bottler's or Importer's Name and Address
- Net Contents
- Health Warning Statement
- Country of Origin (if imported)

27 CFR 5.63





# Mandatory Information (if applicable)

## May appear anywhere on the label:

- Sulfite declaration
- Coloring or flavoring material
- FD&C yellow #5
- Cochineal extract or carmine
- Treatment with wood
- Percentage of neutral spirits
- Commodity statement
- Statements of age
- State of distillation

27 CFR 5.63



# Brand Name

- Name under which the product is sold
- May not create a misleading impression about the age, origin, identity, or other characteristics of the product

27 CFR 5.64

# Brand Name



Imported by XYZ Company

Pittsburgh, PA 15122

750 ml

**PRODUCT OF THE DOMINICAN REPUBLIC**



## **GOVERNMENT WARNING:**

(1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.



# Class and Type

**There are 12 standards of identity:**

1. Neutral Spirits (Vodka)
2. Whisky
3. Gin
4. Brandy
5. Blended Applejack
6. Rum
7. Agave Spirits (e.g., Tequila)
8. Cordials and Liqueurs
9. Flavored Spirits
10. Imitations
11. Geographical Designations
12. Distilled Spirits Specialty Products

27 CFR 5.141



# Class and Type (Continued)

- If product does not fall under one of the other standards of identity, it is a distilled spirits specialty product and must be designated in accordance with trade and consumer understanding, or, if no such understanding exists, with a distinctive or fanciful name appearing in the same field of vision as the statement of composition.
- For cocktails, a statement of added colors and the class/type of the spirits is sufficient:
  - e.g., Margarita made with tequila, triple sec liqueur, and FD&C Yellow #5

27 CFR 5.156

# Class and Type



Imported by XYZ Company

Pittsburgh, PA 15122

750 ml

**PRODUCT OF THE DOMINICAN REPUBLIC**



## **GOVERNMENT WARNING:**

(1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.



# Alcohol Content

- \_\_\_\_% Alcohol (ALC) by Volume (VOL)
- Bottled at \_\_\_\_% Alcohol (ALC) by volume (VOL) (for products with significant amount of solid material)
- Proof (optional, additional statement)
- Tolerances

27 CFR 5.65



# Alcohol Content



Imported by XYZ Company

Pittsburgh, PA 15122

750 ml

**PRODUCT OF THE DOMINICAN REPUBLIC**



## **GOVERNMENT WARNING:**

(1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.





# Bottler/Importer Name and Address

- Name or trade name of bottler/importer as listed on permit
- Address (City, State) of bottler/importer as listed on permit
- **Bottled by, Distilled by, Produced by**, etc. for domestic spirits
- **Imported by** or similar phrase for imported spirits
- May appear on any label

27 CFR 5.66-5.67

# Name and Address





# Net Contents

- You must use the standards of fill (essentially the container sizes) authorized in 27 CFR 5.203
- May be on label or etched/blown into the container
- You may use the following abbreviations
  - Containers of less than 1 liter: ml for milliliters
  - Containers of 1 liter or more: L for liters

27 CFR 5.61, 5.70, 5.203



# Standards of Fill

For containers other than cans:

- 1.8 Liters
- 1.75 Liters
- 1 Liter
- 900 mL
- 750 mL
- 720 mL
- 700 mL
- 375 mL
- 200 mL
- 100 mL
- 50 mL

27 CFR 5.203



# Standards of Fill (Cont.)

For metal containers which have the general shape and design of a can, which have a closure which is an integral part of the container, and which cannot be readily reclosed after opening:

- 355 mL
- 200 mL
- 100 mL
- 50 mL

27 CFR 5.203

# Net Contents





# Health Warning Statement

May appear on any label

**GOVERNMENT WARNING:** (1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.

27 CFR 16





# Health Warning Statement (Continued)

- The words **GOVERNMENT WARNING** must be in CAPITAL LETTERS and **bold type**
- The **S** in *Surgeon* and **G** in *General* must be capitalized
- Continuous statement (no intervening info)
- Legible on contrasting background
- Separate and apart

27 CFR 16.21, 27 CFR 16.22



# Heath Warning Statement



Imported by XYZ Company

Pittsburgh, PA 15122

750 ml

**PRODUCT OF THE DOMINICAN REPUBLIC**



## **GOVERNMENT WARNING:**

(1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.



# Country of Origin

Imported distilled spirits labels **must** display the product's country of origin

- See U.S. Customs and Border Protection requirements (19 CFR 134)

# Country of Origin



Imported by XYZ Company

Pittsburgh, PA 15122

750 ml

**PRODUCT OF THE DOMINICAN REPUBLIC**



## GOVERNMENT WARNING:

(1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.



# Coloring Materials

- Only allowed in certain products
- The coloring material must be stated on the label
- For example:
  - Colored with Caramel
  - Certified Color Added
  - Artificially Colored

27 CFR 5.72



# Coloring Materials

If FD&C Yellow #5 is added, the label must state:

- **Contains FD&C Yellow #5**

If cochineal extract or carmine is added, the label must include a statement to that effect, such as:

- **Contains Cochineal Extract or**
- **Contains Carmine or**
- **Contains Cochineal Extract and Carmine**

27 CFR 5.72, 27 CFR 5.63



# Commodity Statement

For spirits manufactured by blending or other processing, if neutral spirits were used in the production of spirits:

- \_\_\_\_\_% Neutral Spirits Distilled from \_\_\_\_\_
- \_\_\_\_\_% Neutral Spirits

For gin manufactured by a process of continuous distillation or in the case of neutral spirits:

- Distilled from \_\_\_\_\_

27 CFR 5.71, 27 CFR 5.63



# Statements of Age

## Required for:

- Whisky aged less than 4 years
- Certain brandies not stored in oak barrels for a period of at least two years
- Distilled spirits labeled with a distillation date
- Allowed on all distilled spirits except neutral spirits (vodka)

27 CFR 5.74





# Organic Labeling

- Must comply with U.S. Department of Agriculture National Organic Program (NOP) rules (7 CFR part 205)
- For certain organic claims, must obtain USDA-accredited certifying agent's (ACA) preview and approval of organic labels prior to submission to TTB
- [TTBGov - Alcohol Beverages Labeled with Organic Claims](#)

27 CFR 5.84





# Additional Information

## **The label may contain information other than the mandatory information**

- Must be truthful, accurate, and specific
- May not conflict with or qualify mandatory information
- Must comply with the corresponding sections of the regulations

27 CFR 5.56



# Label Approval – What is a COLA?

A **C**ertificate **o**f **L**abel **A**pproval signifies that a product label that was submitted to TTB complies with the applicable labeling requirements found in TTB regulations and policy

A COLA is required for each product sold in interstate commerce (product = distinct brand/distinct product designation/distinct label)

COLAs must be obtained by:

- importers of bottled products, i.e., products imported in consumer containers
- U.S. bottlers of domestic products and products imported in bulk and bottled in the U.S.



# At What Stage do I Apply for Label Approval?

**Domestically bottled** – COLA must be obtained prior to bottling/canning the distilled spirit

**Imported in bottles** – COLA must be obtained prior to removal from Customs custody



# Is a COLA Always Required?

- COLAs are required for each product that will be sold or otherwise introduced into interstate commerce, or that is imported in bottles
- If a distilled spirit product will only be sold in the state where it is bottled, the bottler may instead obtain a Certificate of Exemption from Label Approval
- Label must include statement, **For sale in [name of state where bottled] only**

27 CFR 5.23



# How Do I Apply for Label Approval?

## COLAs Online

- Step-by-step guidance
- Validation checks along the way
- Application status updates via email



## [COLAs Online Customer Page](#)

See webinar presentation for information on how to register for an account: [COLAs Online Workshop](#)



# Tips for Speedy Label Approval

- Know when you need to obtain formula approval, which is required prior to submitting your labels (see [Which Alcohol Beverages Require Formula Approval?](#))
- Be sure to accurately enter the brand name or fanciful name just as it appears on label
- Don't enter anything in the brand name or fanciful name fields except the brand name or fanciful name (e.g., do not enter the class/type designation in either of those fields)
- Take a look at your labels after you upload the files – if they are skewed or distorted remove them and upload images that accurately depict the real label



# COLAs Online

## Conditionally Approved Status

- Under limited circumstances, TTB may propose changes to the information you entered in the application to make it match the label you submitted
- After the specialist proposes the changes, the status is **Conditionally Approved**



# COLAs Online

## Conditionally Approved Status (Cont.)

You must review proposed changes, and then either—

- Accept for immediate approval of COLA **or**
- Decline and make necessary changes before returning

Which application fields are involved?

- Brand name
- Fanciful name





# Can I Change My Approved Label Without Getting a New COLA?

Review [List of Allowable COLA Revisions](#)

- Once a label receives TTB approval, you can make certain changes to that label without obtaining a new COLA
- Any revisions you make to your approved labels must be in compliance with the applicable regulations

You must be able to identify the COLA you are relying on to bottle a distilled spirit in the event that TTB asks you to provide evidence that the label is covered by a COLA

YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
1. Delete any non-mandatory label information, including text, illustrations, graphics, etc.	YES	YES	YES	

### Approved COLA



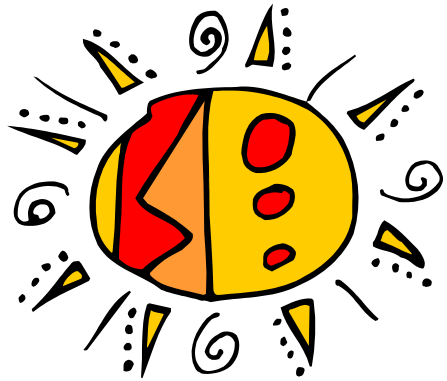
### Allowable revision



YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
2. Reposition any label information, including text, illustrations, graphics, etc.	YES	YES	YES	The repositioning must comply with any placement requirements applicable to mandatory information. For example, some types of mandatory information must appear on the brand label or must appear together with other label information.

### Approved COLA

**SUNNYSIDE Distillery**  
**Springfield, Oregon**



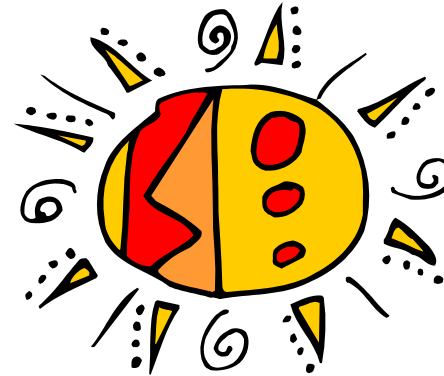
**Vodka**

**40% Alc/Vol**

**750ml**

### Allowable revision

**Vodka**



**750ml**

**40% Alc/Vol**

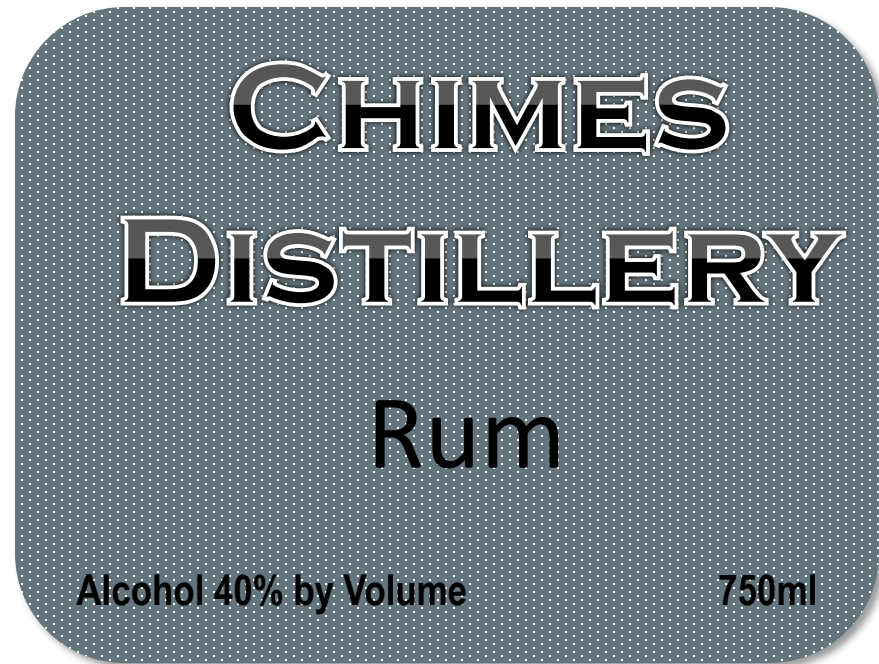
**SUNNYSIDE Distillery**  
**Springfield, Oregon**

YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
3. Change the color(s) (background and text), shape and proportionate size of labels. Change the type size and font, and make appropriate changes to the spelling (including punctuation marks and abbreviations) of words, in compliance with the regulations. Change from an adhesive label to one where label information is etched, painted or printed directly on the container and vice versa.	YES	YES	YES	All mandatory information must be readily legible and appear on a contrasting background. If you received approval for a single label then you may not divide the label into multiple labels without re-approval. All changes must comply with applicable regulations, and changes in spelling must not change the meaning of the previously approved information.

### Approved COLA



### Allowable revision



YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
10. Change the net contents statement.	YES	YES	YES	Revisions must comply with all applicable regulations governing net content statements and standards of fill. Please ensure that all applicable type size requirements are met for each container size.

### Approved COLA

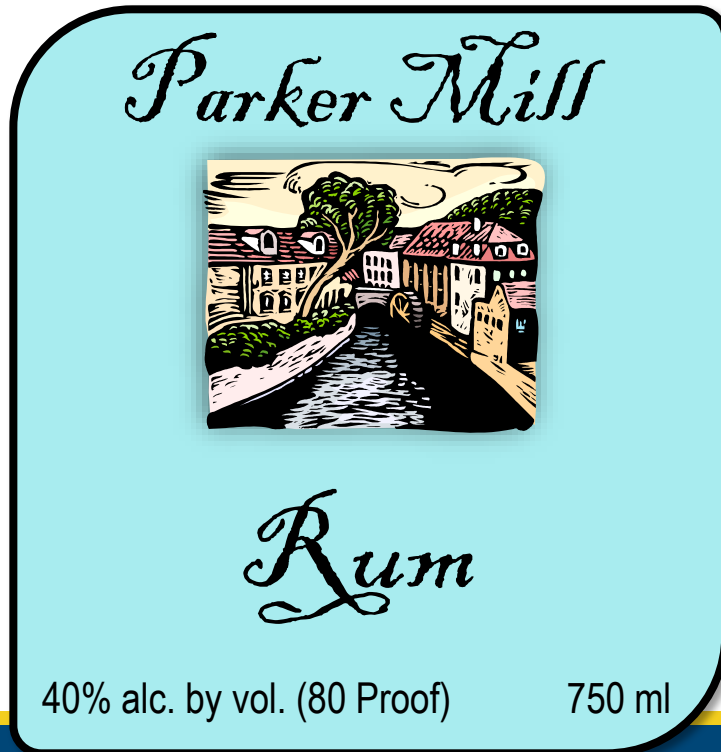


### Allowable revision

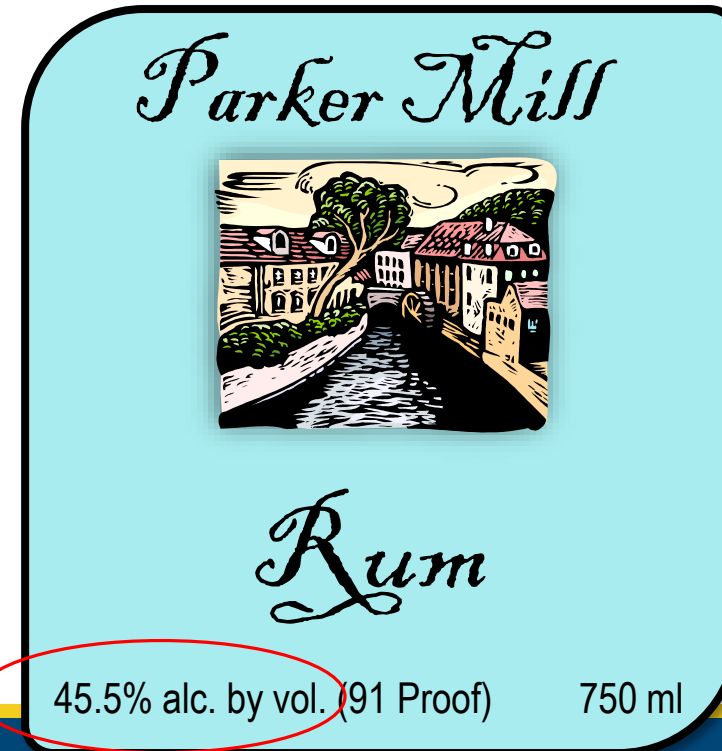


YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
11. Change the mandatory statement of alcohol content, where such change is not inconsistent with the labeled class and type designation, or with any other labeling statements.	YES	YES	YES (Flavored Malt Beverages Only)	The change must not result in a change to the labeled class or type designation of the product. For example, a label bearing a "table wine" designation may not be changed to state an alcohol content above 14 percent alcohol by volume, and a label bearing a "rum" designation may not be changed to state an alcohol content statement of less than 40 percent alcohol by volume. The change may not be inconsistent with any other mandatory or optional labeling statements.

### Approved COLA



### Allowable revision



YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
13. Change the statement of percentage of neutral spirits and the name of the commodity from which a distilled spirit is produced.	N/A	YES	N/A	These changes must not result in a change to the class or type designation of the distilled spirits product.

### Approved COLA



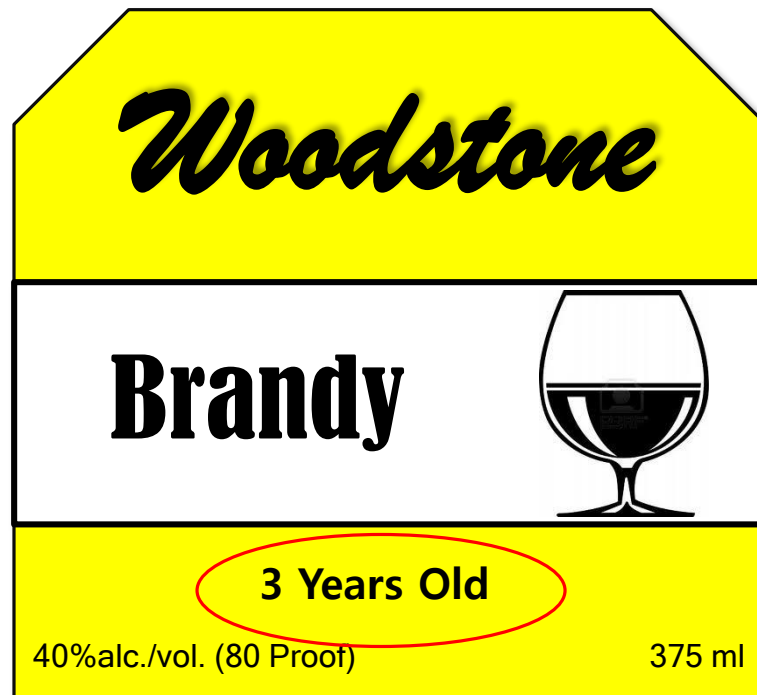
### Allowable revision





YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
14. Change the mandatory age statement, or delete or change an optional age statement for distilled spirits labels.	N/A	YES	N/A	These changes must not result in a change to the class or type designation. See 27 CFR 5.22 and 5.40 for further information about age statements and minimum aging requirements applicable to certain classes and types of spirits.

### Approved COLA



### Allowable revision





YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
22. Add, delete, or change bottle deposit information.	YES	YES	YES	

Approved COLA

**GOVERNMENT WARNING:** (1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.

Bottled by:  
 Jim’s, Chicago IL

Allowable revision

**GOVERNMENT WARNING:** (1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.

**CA REDEMPTION VALUE  
OR 5¢ IA 5¢ MI 10¢ REF**

Bottled by:  
 Jim’s, Chicago IL


YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
23. Add, delete, or change UPC barcodes and/or 2D mobile barcodes, e.g., QR codes or Microsoft Tags.	YES	YES	YES	Addition or change of UPC Code must be in compliance with Industry Circular 77-23. Any information retrieved from 2D barcodes must be in compliance with all applicable advertising regulations.

Approved COLA

Allowable revision

Bottled by: Our Distillery  
Ft. Mill, SC

**GOVERNMENT WARNING:** (1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.



88334 00140

Bottled by: Our Distillery  
Ft. Mill, SC

**GOVERNMENT WARNING:** (1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.



88334 00140



YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
25. Add, delete, or change a lot or batch identification number or other serial numbers.	YES	YES	YES	

### Approved COLA

## Greenfield Vodka

**Bottled by: Greenfield Vodka Company, Pittsburgh, PA**

**GOVERNMENT WARNING:** (1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.

BT 568799043

### Allowable revision

## Greenfield Vodka

**Bottled by: Greenfield Vodka Company, Pittsburgh, PA**

**GOVERNMENT WARNING:** (1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.

BT 7553025

YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
26. Add, delete, or change trademark, copyright symbols (e.g., TM, ©, ®), kosher symbols, company logos, and/or social media icons.	YES	YES	YES	Symbols, logos and icons may not violate TTB regulations. Advertisements on social media sites must be in compliance with all applicable advertising regulations.

### Approved COLA

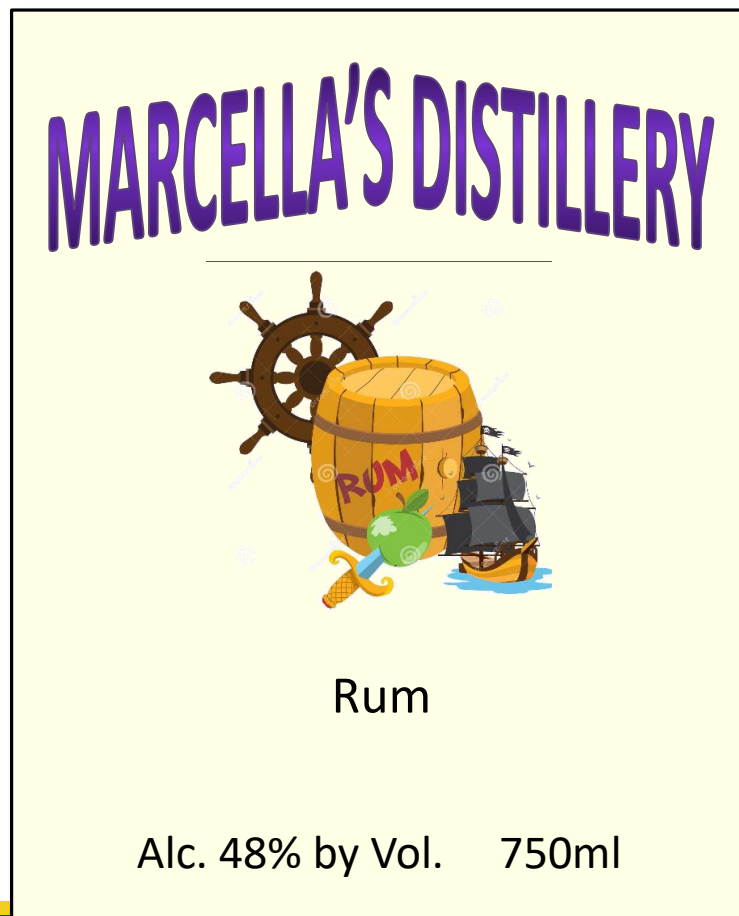


### Allowable revision

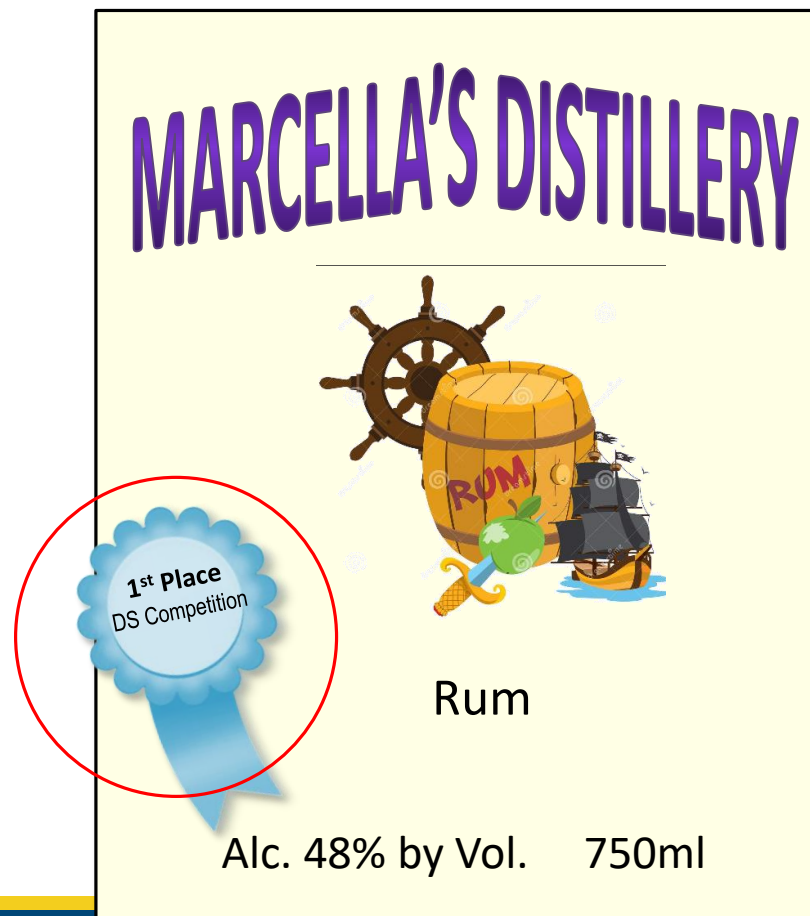


YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
27. Add, delete, or change optional information about awards or medals.	YES	YES	YES	

### Approved COLA



### Allowable revision



YOU MAY...	REVISION APPLIES TO			COMMENTS
	WINE	DISTILLED SPIRITS	MALT BEVERAGE	
28. Add, delete, or change holiday- and/or seasonal-themed graphics, artwork and/or salutations.	YES	YES	YES	Holiday/seasonal-themed information or graphics must not conflict with or qualify the mandatory information and must comply with all applicable regulations, including the rules governing prohibited practices.

### Approved COLA



### Allowable revision





# Examples of Changes that CANNOT be Made

## **A new COLA is required if you:**

- Change the class/type(all commodities)
- Change the brand name
- Add any graphics that are not specifically authorized
- Add or change wording that is not specifically authorized



# Contact Information

## **Alcohol, Labeling and Formulation Division, Customer Service:**

- Phone: 1-866-927-2533 or 202-453-2250
- Option 2 – COLAs Online technical assistance
- Option 3 – COLAs Online registration
- Option 4 – Distilled Spirits Questions
- Online: <https://www.ttb.gov/contact-alfd>





# New Distilled Spirits Labeling Pages

TTB.gov distilled spirits labeling pages updated July 2021

New [distilled spirits labeling homepage](#) makes it easy to find and access distilled spirits labeling information

We also created handy reference materials, including a [Mandatory Information Checklist](#) and the [Anatomy of a Distilled Spirits Label](#) interactive tool

# Mandatory Information Checklist

## CHECKLIST OF MANDATORY LABEL INFORMATION | DISTILLED SPIRITS

This guidance lists the mandatory information that TTB reviews on every distilled spirits label and certificate of label approval application and includes a checklist to help prevent common errors. This document does not provide comprehensive labeling guidance. Distilled spirits for which a certificate of label approval is required must be labeled in compliance with **all** applicable requirements in 27 CFR part 5 and 27 CFR part 16.

### **Mandatory Information that Must Appear on the Brand Label**

*The brand label is the label or labels bearing the brand name, alcohol content, and class/type designation in the same field of vision. The same field of vision means a single side of a container (bottle) where all of the pieces of information can be viewed simultaneously without the need to turn the container (for a cylindrical container, a side is 40 percent of the circumference). (See full definition in 27 CFR 5.11.)*

<b>Mandatory Item and Description</b>	<b>Regulatory Citation</b>	<b>Checklist</b>
<b>Brand Name</b> Name under which the product will be sold.	<a href="#">27 CFR 5.34</a>	<ul style="list-style-type: none"><li><input type="checkbox"/> Does the brand name appear on the brand label?</li><li><input type="checkbox"/> Does it match the entry in the "Brand Name" field on the application?</li></ul>



# Anatomy of a Distilled Spirits Label Tool

## Anatomy of a Distilled Spirits Label Tool

The **Anatomy of a Distilled spirits Label** tool is an interactive tool that can help you learn more about how to create a distilled spirits label.



Brand  
Label



Other  
Label



### BRAND NAME

Mandatory?	Placement Requirement?
Yes	Required to appear on the BRAND LABEL

### Description

The brand name is the name under which a distilled spirits product or line of distilled spirits products are marketed.

See [Brand Name](#) for complete requirements.

### TIPS

- The brand name must appear on the brand label.
- The brand name may not mislead the consumer about the age, origin, identity, or other characteristics of the product.
- The class/type designation (e.g., "Rum", "Bourbon" "Spiced Rum, Rum with natural flavors"), standing alone, may not be used as the brand name. However, if no other brand name appears on the label, the name of the bottler, packer, or importer will be treated as the brand name.



Please take a few minutes to  
provide feedback on this session:

<https://www.ttb.gov/survey>

