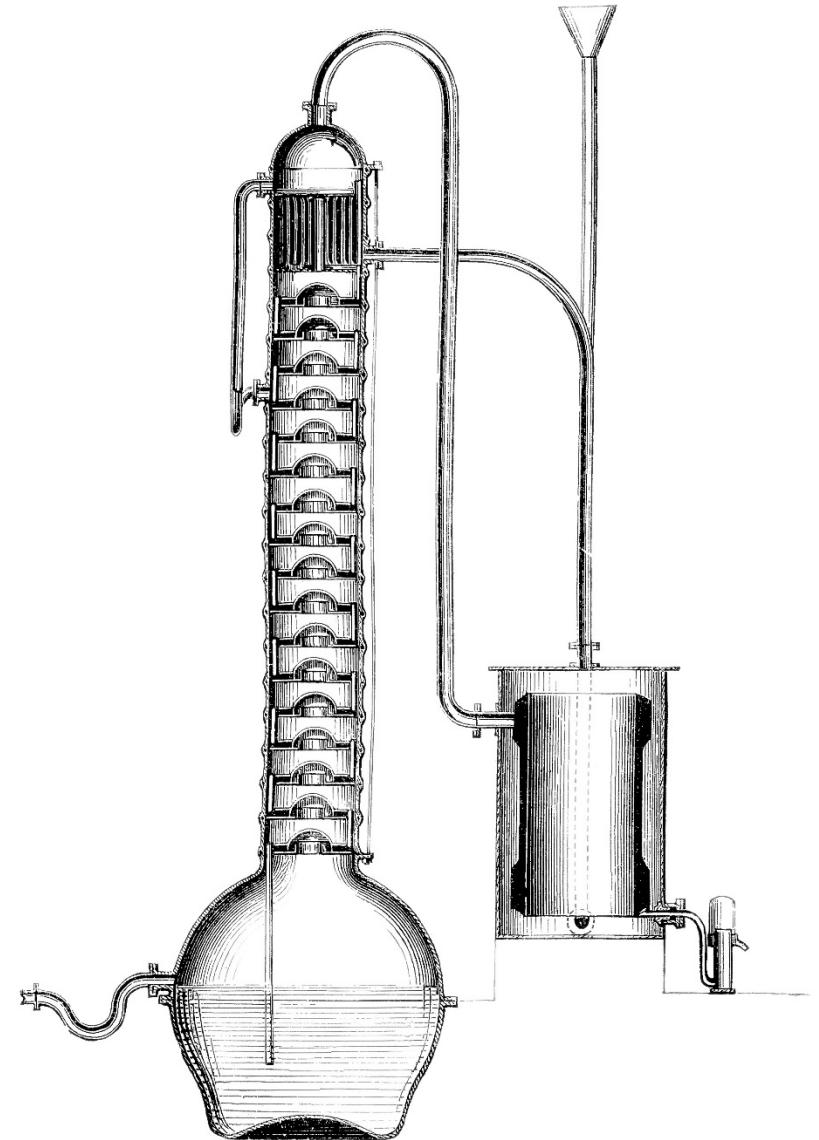




TTB Boot Camp Webinar Series for Distillers

FORMULAS

Formulas





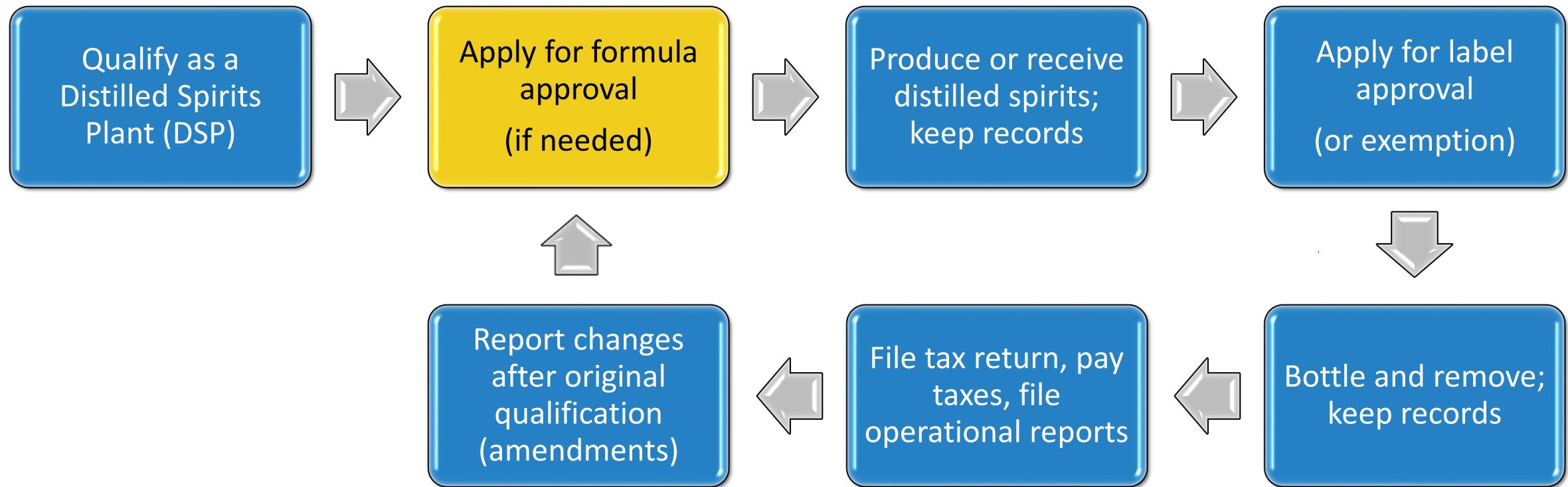
TTB Disclaimer

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



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

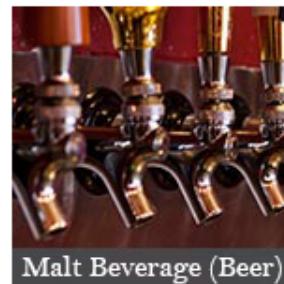
Which Alcohol Beverages Require Formula Approval?

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



Malt Beverage (Beer)



Wine/Cider

Start

Start

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



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 and/or artificial sweeteners



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

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>	Company Name: <u>Flavors-R-Us LLC</u>	Address: <u>123 Nonexistent Street</u>	<u>Any City, State USA 00000</u>	Date: <u>1/1/2017</u>	Contact Person: <u>Jane Q. Flavor</u>	Phone: <u>202-555-5555</u>
Flavor Name: <u>Natural Poppin' Pecan Supreme</u>				Fax: <u>202-555-5554</u>		
TTB Drawback Number: <u>123456</u>				Check Appropriate Box:		
Alcohol Range by Volume: <u>50.0 - 54.0</u>				<input type="checkbox"/> Approved for Drawback (DrB)	<input checked="" type="checkbox"/> Approved as No Action (N/A)	<input type="checkbox"/> Fit for Beverage Purposes (Fit)
Flavor Product Number: <u>7891011</u>				<input type="checkbox"/> Submitted for TTB Approval	<input type="checkbox"/> Not Yet Submitted for TTB Approval	
Classification						
Natural <input checked="" type="checkbox"/>	N&A \leq 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	5,000.0 ppm	20.00 %	7. Grapesein 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	10,000.0 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 #: _____						
Jane Q. Flavor Flavor Company Representative Signature				Title: Supervisory Chemist		Date: 30-Sep-17



FID Sheet Header

Flavor Ingredient Data Sheet

Flavor Producer Information

TTB Co. Code: FLRUS

Company Name: Flavors-R-Us LLC

Address: 123 Nonexistent 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

TTB/FDA Limited Ingredients	TTB/FDA Limitation in Finished Product	Flavor Components			Coloring Additives and Other Additives that Affect the Beverage Label (check or list label ingredients that affect the beverage label)
		Amount of Additive or Agent Present in Flavor	Maximum Use Rate		
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/
14. _____	_____ ppm	_____ ppm	_____	- %	Cochineal Extract 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



Limited Ingredient Calculation Worksheet



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



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

View Company

Submissions Search Advanced Search

Formulas Online

COLAS Home Text Menu My Profile Help Contact Us Log Off

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: Percentage [i](#)

* Low High *Unit [i](#)

* Alcohol Content of Finished Product: - % by Volume [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.

FORM 55



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



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>



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

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

