



TTB Wine Boot Camp

FORMULAS



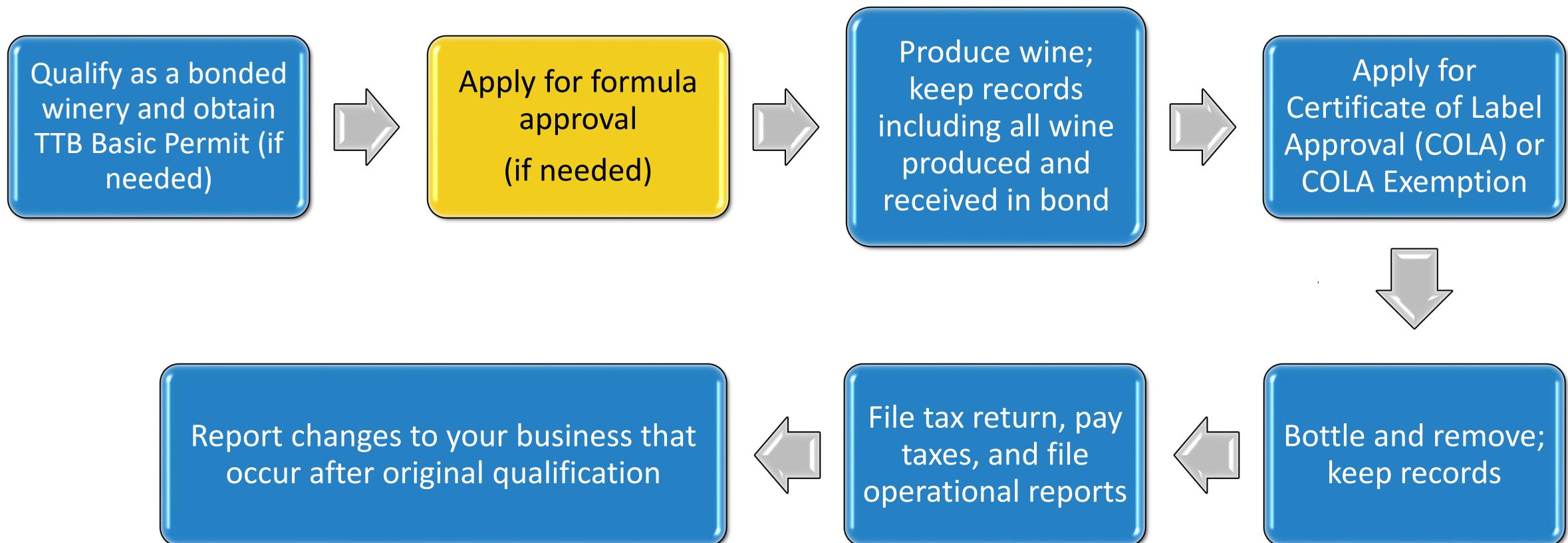
TTB Disclaimer

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 Bonded Wineries





Agenda

In this session we will go over the following topics:

- Formula Basics
- Wines That Need Formulas
- Applying for a Formula
 - Formulas Online
 - Supporting Documents
 - Formula Approval
- Resources

Formula Basics





Formula Basics

Not all wine products require formula approval.

- Whether or not you need formula approval is based on:
 - Ingredients
 - Manufacturing methods
- Formula requirements are NOT connected to:
 - Alcohol content
 - Eligibility for certain tax rates
 - Whether or not the product will require TTB label approval



What Is a Formula?

A formula is required for certain types of alcoholic beverages before they can be legally manufactured, imported, or sold. Your formula submissions must have:

- A complete, quantitative list of all ingredients used to make the product
- Method of manufacture:
 - Describes the steps you take to create your product
 - Must include each ingredient mentioned on the ingredients list
- Total yield or batch size

See [Formula Basics](#) page on TTB.gov



Where Are the Wine Formula Requirements?

- TTB regulations under the Internal Revenue Code (IRC) require formulas for certain types of domestic wine (27 CFR 24.80)
- TTB regulations under the Federal Alcohol Administration Act (FAA Act) authorize TTB to require formulas for certain domestic and imported wines (27 CFR 4.38(h))



Why Is a Formula Required?

TTB uses 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 (SOC) for labeling purposes



Who Applies for Formula Approval and When?

Who: When required, formulas are submitted by:

- *Domestic*: the producer (BW proprietor)
- *Imported**: U.S. importer (holder of an Importer's Basic Permit)

When: Formulas must be obtained:

- *Domestic*: before product is produced and before applying for label approval (if needed)
- *Imported**: before applying for label approval and before product is removed from customs custody

* Formula requirements do not apply to imported wine with under 7% ABV

Wines That Need Formulas





When Is a Wine Formula Required?

In general, formula approval is required if a wine is made with:

- Flavors (with or without alcohol), including compounded flavors, essences, and extracts
- Coloring materials
- Excess sugar or water
- Agricultural products other than fruit
- A blend of wines produced from different kinds of fruit



Common Wines That Need Formulas*

- Fruit Wine:
 - A formula **is** required when **blending** two or more kinds of Fruit Wine, e.g., Apple Wine and Cherry Wine.
 - A formula **is not** required when **fermenting** two or more kinds of fruit juice together.
- Aperitif Wine or Vermouth:
 - Formula approval not required for Italian Vermouth
- Retsina Wine flavored with pine resin
- Imported Saké

* Formula requirements do not apply to imported wine with under 7% ABV



Which Wines Require Formula Approval?

Use our online tool [Which Alcohol Beverages Require Formula Approval?](#) or check the list in [TTB G 2016-2a](#) to learn which products require formula approval.

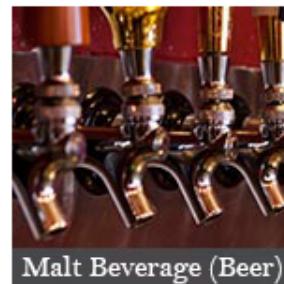
Which Alcohol Beverages Require Formula Approval?

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

Applying for Formulas





How to Apply for Formula Approval

Formulas Online

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



Resources:

- [Formulas Online Customer Page](#)
- [How to Register and Submit Formulas through Formulas Online](#)



Formulas Online Submitter Tips

Before submitting a formula, you should:

- Ensure that formula approval is required for your wine product.
 - Using the [Formula Tool](#) on TTB's website will help.
- Gather all pertinent information and documents about each ingredient used and your method of manufacture.



What TTB Looks For

- Class and Type: Is the base alcohol produced according to the TTB regulatory standard for the specified class and type?
- Supporting documentation: e.g., FID Sheets, Specification Sheets, Labels (e.g., labels for store-bought items added as flavors)
- Prohibited or limited ingredients
- Colors
- Ingredients considered food safe by FDA (including Generally Recognized as Safe or GRAS ingredients)



Example in Formulas Online

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

COLAS Home Text Menu My Profile Help Contact Us Log Off

New View Company Submissions Search Advanced Search

Beverage

Informational Messages

- Your submission was successfully saved as a draft. It will not be forwarded to TTB for review until you submit. If it remains a draft for over 30 days, it will be automatically deleted.

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

[Copy as New](#) | [Print](#) | [Comment](#) | [Upload](#) | [Close Historical](#)

Expedite Paper Submission ? Note:
Submission ID: 1234924 Date Submitted:
Status: Draft Attachment ID: 1536531 Disposition:

Product Information Class: OTHER THAN STANDARD WINE Type: WINE SPECIALTY Product Name: WN Example # 2 [Change Product Information](#)

1 Measurement

Type: Percentage Volume/Weight i Units: English Metric i

2 Yield Summary

Total Yield: x Gallons i

Low High i Unit % by Volume 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](#)

► Grape juice	950.0 - 975.0 gal.	Fermentable Ingredient	
► Pure dry sugar	150.0 - 225.0 lb.	Fermentable Ingredient	
► Group 1: Nutmeg	2.0 - 2.5 c.	Flavor (Natural)	
► Group 1: Fresh cut mint	1.0 - 1.25 c.	Flavor (Natural)	
► Group 2: Natural Jablanica Mint flavor	1.0 - 5.0 gal. TTB Company Code: WL6 TTB Drawback #: 3	Flavor (Compounded)	
► Group 2: Natural and Artificial Pineapple Flavor	0.5 - 2.0 gal. TTB Company Code: WL6 TTB Drawback #: 55	Flavor (Compounded)	
► Yeast EC 1118	60.0 - 70.0 oz.	Other	
► Magnesium sulfate	30.0 - 50.0 oz.	Other	
► Chitosan	10.0 - 15.0 oz.	Other	
► Potassium meta-bisulfite	10.0 - 35.0 oz.	Other	
► St. Johnathan's - The Sweetener with Heart	1.0 - 5.0 gal.	Other	
► FD&C Blue #1	5.0 - 8.0 oz.	Color	
► FD&C Green #3	5.0 - 10.0 oz.	Color	
► Water	10.0 - 150.0 gal.	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.) Mix grape juice, pure dry sugar, and water to a sugar density of 23 degrees Brix.
2.) Add Yeast and begin fermentation. Add Magnesium sulfate as yeast nutrient.
3.) Measure post fermentation Brix level. Planned target range between 1.5 and 3.0 degrees Brix.
4.) Blend either group 1 or group 2 flavors into wine. Only one group will be used at a time. Product will be seasonal and will be interchanged as needed. Separate COLAS reflecting the flavor groups will be used.
5.) Add St. Jonathan's sweetener.
6.) Add certified colors FD&C Blue #1 and FD&C Green #3.
7.) Treat wine with Chitosan as fining agent. The amount used will not exceed 10 grams per 100 liters of wine.

Method of Manufacture Documents

TYPE	NAME	DATE	ACTION
Add Attachment			

[Add Attachment](#)

[« Previous](#)

[Save as Draft](#)

[Validate](#)

[Next »](#)

Supporting Documents





Supporting Documents That May Be Required

Submit the following with your formula application if:

- Flavor Ingredient Data Sheet (FID Sheet) if the product is made with **compounded flavors** (1 FID Sheet for each flavor)
- Limited Ingredient Calculation Worksheet if the product is made with **1 or more compounded flavors**
- Ingredient Specification Sheet (Spec Sheet) if the product is made with **ingredients composed of more than 1 component** (1 Spec Sheet for each ingredient)



Compounded Flavors

What is a compounded flavor?

A compounded flavor is one you purchase from a flavor manufacturer

- Types of compounded flavors:
 - 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: Cloudifier or blender
- Compounded flavor manufacturer submits their flavor formula to TTB's Nonbeverage Products Lab for review
- **Compounded flavors require supporting documentation!**



Flavor Ingredient Data Sheet (FID Sheet)

What is a FID Sheet?

A Flavor Ingredient Data Sheet (FID Sheet or FIDS) is a spreadsheet that includes information about certain ingredients in compounded flavors.

The FID Sheet allows TTB to ensure:

- The compounded flavor has been evaluated by TTB
- Ingredients in the beverage will not exceed limitations prescribed by TTB or by FDA
- Appropriate labeling of your product

Submit 1 FID Sheet for each compounded flavor in your formula!



Flavor Ingredient Data Sheet (FID Sheet)

How do I get it?

- Obtain a copy of the FID Sheet from the flavor manufacturer(s) from whom you purchased the flavor(s)
 - The FID sheet is filled out and signed by the flavor manufacturer
- It includes:
 - Concentration of **limited ingredients** in parts per million (ppm)
 - Any **colors** used in flavor
 - **Alcohol content** of flavor

Flavor Ingredient Data Sheet					
Flavor Producer Information					
TTB Co. Code: WL5 Company Name: We Love Flavors Inc. Address: 123 Nonexistent Street Any City, State 00000					
Date: 1-Apr-15 Contact Person: J. Jones Phone: 202-555-5555 Fax: 202-555-5554					
Check Appropriate Box: Approved for Drawback (DrB) <input type="checkbox"/> Approved as No Action (N/A) <input type="checkbox"/> Fit for Beverage Purposes (Fit) <input type="checkbox"/> Submitted for TTB Approval <input type="checkbox"/> Not Yet Submitted for TTB Approval <input type="checkbox"/>					
Flavor Name: Natural and Artificial Pineapple flavor TTB Drawback Number: 55 Alcohol Range by Volume: 67% Flavor Product Number: 106					
Classification Natural <input type="checkbox"/> N&A ≤ 0.1% Topnote <input checked="" type="checkbox"/> N&A > 0.1% Topnote <input type="checkbox"/> Artificial <input type="checkbox"/> Non-Flavor <input type="checkbox"/> Total Artificial Flavor Content: 0 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	2,000 ppm	2.00 %	1. FD&C Yellow #5	<input type="checkbox"/>
2. Ethyl Vanillin	16.0 ppm	500 ppm	3.20 %	2. FD&C Yellow #6	<input type="checkbox"/>
3. Synthetic Maltol	250.0 ppm	175 ppm	NO LIMIT %	3. FD&C Blue #1	<input type="checkbox"/>
4. Ethyl Maltol	100.0 ppm	10 ppm	NO LIMIT %	4. FD&C Blue #2	<input type="checkbox"/>
5. Ester Gum	100.0 ppm	68 ppm	NO LIMIT %	5. FD&C Green #3	<input type="checkbox"/>
6. BVO	15.0 ppm	10 ppm	NO LIMIT %	6. FD&C Red #40	<input type="checkbox"/>
7. Sodium Benzoate	1,000.0 ppm	12 ppm	NO LIMIT %	7. Grapeskin Extract	<input type="checkbox"/>
8. Gum Arabic/Acacia	200,000.0 ppm	1,500 ppm	NO LIMIT %	8. Caramel Color	<input type="checkbox"/>
9. Propylene Glycol	50,000.0 ppm	12,000 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	3250 ppm	1.23 %	15. _____	<input type="checkbox"/>
16. Total Maltol	250.0 ppm	200 ppm	NO LIMIT %		
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 #: _____					
J. Jones Flavor Company Representative Signature					
Title: Flavor Chemist					
Date: 1-Apr-15					

* nothing below this line will print *



Limited Ingredient Calculation Worksheet

What is a Limited Ingredient Calculation Worksheet?

A Limited Ingredient Calculation Worksheet is a spreadsheet used to calculate the total amounts of ingredients in compounded flavors that have limits on their use per TTB and FDA requirements.

- You will need a FID Sheet for each compounded flavor to complete the worksheet
- Worksheets can be completed based on volume or percentage—use the worksheet that matches your formula format

Submit a Limited Ingredient Calculation Worksheet for formulas containing 1 or more compounded flavors!



Limited Ingredient Calculation Worksheet

How Do I Get It?

- Blank worksheets and examples are available at: Formulation – Alcohol Beverage Formula Approval in the Supporting Documentation, Blank Worksheets, and Examples section
- See TTB G 2017-6 for more information, including examples

Volume Based Beverage Alcohol Limited Components Calculation Sheet



Ingredient Specification Sheet (Spec Sheet)

What is an Ingredient Specification Sheet?

An Ingredient Specification Sheet (Spec Sheet) is a document that lists or describes the contents of an ingredient used to make your alcohol beverage product.

- Can be a technical data sheet or a product label (e.g., for marshmallows or chocolate syrup)

Include a Spec Sheet for each ingredient that is made from more than one component (excluding compounded flavors)!



Ingredient Specification Sheet

(Spec Sheet or Technical Data Sheet)

How Do I Get It?

- There are several ways to obtain a specification sheet for the ingredient used in your alcohol beverage product, including:
 - Shipment documentation for the product
 - Manufacturer's website
 - Ingredient listing on the product's label
- See [TTB G 2017-3](#) for more information, including examples



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.



Top 5 Reasons Wine Formulas are Returned for Correction

1. Ingredient Spec Sheet* is missing
2. FID Sheet* is missing
3. Clarification needed on a specific ingredient
4. Ingredient quantity information is missing
5. Limited Ingredient Calculation Worksheet* is missing

*when required



Formula Processing Times

- Our Current Processing Times charts show up-to-date processing information for submissions in calendar days.
 - [TTB Processing Times | TTB: Alcohol and Tobacco Tax and Trade Bureau](#)
- Use this information to estimate when your submission is likely to be processed.
- Incomplete applications, errors, or insufficient documentation may delay the processing time for your application.
- Check the status of your submission in Formulas Online.

Your Formula
is Approved,
Now What?





What Should I Do After My Formula is Approved?

Determine whether your product requires a Certificate of Label Approval (COLA)

- **YES:** If wine product contains **at least 7% alcohol by volume** and will be **sold in interstate commerce**
- **NO:** If it contains at least 7% alcohol by volume and will not be sold in interstate commerce
 - You can apply for a Certificate of Exemption instead of a COLA
- **NO:** If it contains less than 7% alcohol by volume
 - See FDA labeling requirements for wine containing under 7% alcohol by volume and TTB requirements that apply regardless of alcohol content, such as the Health Warning Statement

If your product requires a COLA, find a general statement of composition in the RESULTS tab of your approved formula



What Should I Do After My Formula is Approved?

Create a statement of composition for your label that is consistent with your approved formula

- On the approved formula, TTB will provide a simple, **general** statement of composition for the product label, such as:

Honey Wine with Natural Flavors

- You can either use this general statement of composition to meet the requirement for the class/type statement on the label, or create a **more specific** labeling statement that discloses the specific flavors as well as the coloring agent (if applicable), such as:

Mead with cherries, cinnamon, and vanilla

- See [TTB G 2017-8](#) for more information on wine statements of composition, including examples

If a COLA is required, list your formula ID on your label application!



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 6 – Wine Questions
- Online: <https://www.ttb.gov/contact-alfd>

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