

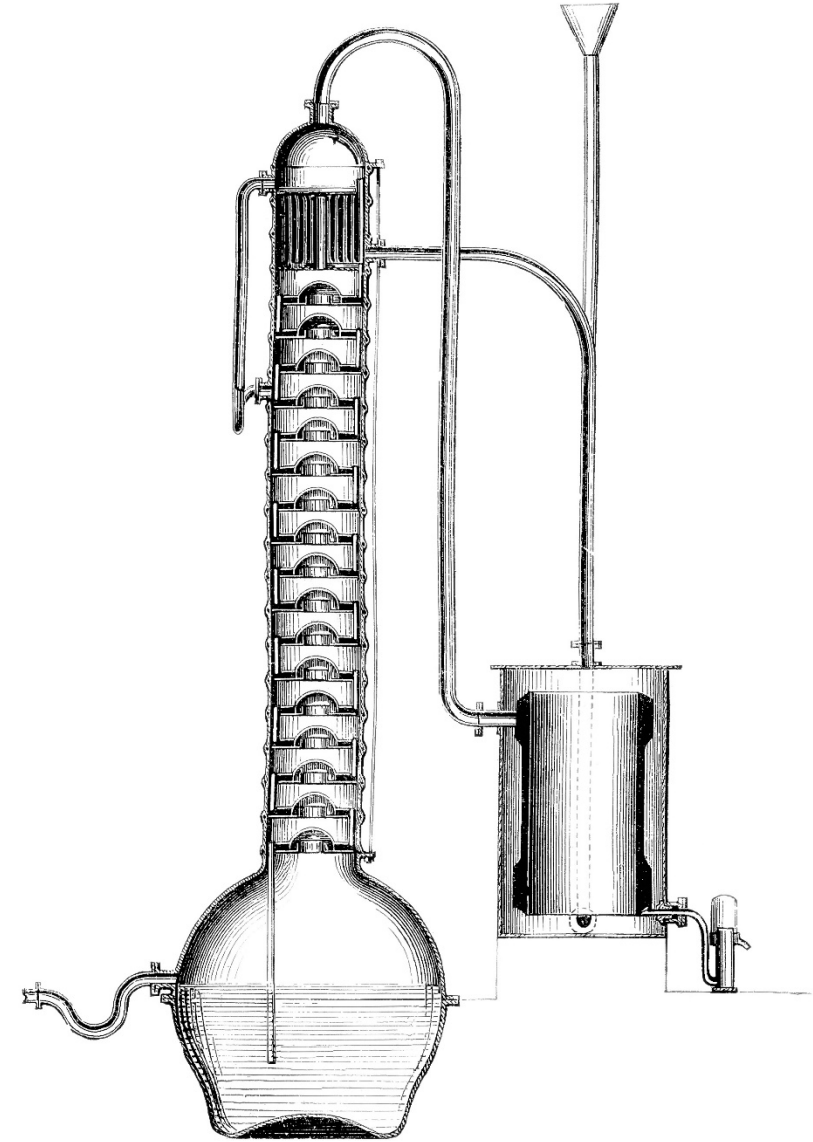


TTB Bootcamp for Distillers

2020 ADI Virtual Craft Spirits Conference

Formulas

Vonzella C. Johnson
Formula Specialist
Alcohol Labeling and Formulation Division





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 (TTB) 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.
- The examples in this presentation are for purposes of illustration only and do not represent actual products.
- Please consult the applicable laws and regulations for the most current requirements.



Common Formula Questions

- What is a formula?
- Why is a formula required?
- What types of distilled spirits require formula review?
- How is a formula submitted?



What is a Formula - A Basic Definition

- A formula is a recipe
- It must indicate a total yield, or batch size
- It must have a quantitative list of ingredients
- It must include a description of how the product is produced



Why is a Formula Required?

- It's required per TTB regulations. (27 CFR 5.27)
- **Generally, an approved formula is required to:**
 - Blend
 - Mix
 - Purify
 - Refine
 - Compound
 - Or treat spirits in a manner which results in a change of:
 - Character
 - Composition
 - Class or type of the spirits



Why is a Formula Required?

- [27 CFR 5.22](#) contains the 12 Standards of Identity
 - Some classes are straightforward, for example, Rum, while other products have more working parts that require label disclosure
 - A product may have a particular requirement to satisfy in order to belong to a given class
- Formula review finds a “home” for a product and describes its working parts
- A class, type, or statement of composition represents the outcome of this process
 - Additional information may be added for labeling reasons
- Not all products will require a formula



When is a Formula Required?

- The use (except as authorized for production or storage operations as provided by 27 CFR part 19) of any physical or chemical process or any apparatus which accelerates the maturing of the spirits
- The steeping or soaking of fruits, berries, aromatic herbs, roots, seeds, etc., in spirits.
- The artificial carbonation of spirits
- The blending in Puerto Rico of spirits with any liquors manufactured outside of Puerto Rico
- (See 27 CFR 5.27 for additional processes that require formula approval)

[Which Alcohol Beverages Require Formula Approval Tool](#)



Are Formulas Required for all Products?

- **Not** all products require formula review
- Time saving resources:
 - [Which Alcohol Beverages Require Formula Approval Tool](#)
 - [TTB G 2016-3 - Pre-COLA Product Evaluations for Distilled Spirits Products](#)
 - [TTB G 2017-5 - Alcohol Beverage Formula Approval with Lab Sample Analysis](#)
 - [TTB Ruling 2016-3 - TTB Approves General-Use Formulas for Certain Distilled Spirits Produced Using Harmless Coloring, Flavoring, or Blending Materials](#)



How to Submit a Formula

- **Formulas Online** is part of the TTB electronic storefront on www.ttbonline.gov
- You must register for an account before you can use 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



Flavors



Compounded Flavors

- 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)
- Submitted to TTB Nonbeverage Lab for Review
- May contain coloring materials



Flavor Ingredient Data Sheet (FID Sheet or FIDS)

- A FID Sheet is a document that includes information about certain ingredients used to make a compounded flavor
- Submit one for each compounded flavor used in your product
- The FID Sheet allows TTB to:
 - Ensure that the compounded flavor has been evaluated by the TTB Nonbeverage Products Laboratory (NPL)
 - Verify that your beverage does not contain any ingredients in excess of the limits prescribed by TTB or by FDA
 - Ensure the appropriate labeling of your product.
 - Ensure your 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 or FIDS)

- Flavor manufacturer supplies form to the Producer.
- FID based on exchange between flavor producer and TTB Nonbeverage Laboratory
- 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>		
Check Appropriate Box:				
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	<u>5,000</u> ppm	<u>20.00</u> %	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	<u>10,000</u> ppm	<u>NO LIMIT</u> %	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. _____ <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 #: _____				
_____ Flavor Company Representative Signature		Title: <u>Supervisory Chemist</u>		Date: <u>30-Sep-17</u>



FID 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 ≤ 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)



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	- %	



TTB Limited Ingredients

- There are four 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



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 one component
- Submit a spec sheet for each ingredient that is made from more than one 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



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.





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 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)



Benefits of Using Formulas Online

- Secure method for drafting, submitting, and tracking your formula applications electronically
- Includes:
 - Step-by-step guidance
 - Data validation checks along the way
 - Application status updates via email
 - Facilitates record keeping
 - Approved formulas are stored online
 - Copies of approved formulas can be printed if needed



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

Submissions

Search

Advanced Search

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



2 Yield Summary

* Total Yield:



* Low High *Unit

* Alcohol Content of Finished Product: -



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 Must be Returned for Correction

- [Ingredient Specification Sheet \(Spec Sheet\)](#) is missing for ingredients composed of more than one component
- [Limited Ingredient Calculation Worksheet](#) is missing when compounded flavors are used
- [Flavor Ingredient Data \(FID\)](#) is missing when compounded flavors are used