



# **TTB Webinar: Domestic Distilled Spirits Formulas**

Presented December 2017



# TTB Disclaimer

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## 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.
- Please consult the applicable laws and regulations for the most current requirements.



# Common Formula Questions

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



# A Basic Definition

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- 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 are Formulas required?

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- In 27 CFR 5.22, twelve Standards of Identity exist. Some classes are straightforward, for example, Rum, while other products have more working parts that require label disclosure.
- Formula review finds a “home” for a product and describes its working parts. A product may have a particular requirement to satisfy in order to belong to a given class.
- 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?

27 CFR 5.26

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- *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



# When is a Formula Required?

27 CFR 5.27

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- 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 and wines.
- The artificial carbonating of spirits.
- The blending in Puerto Rico of spirits with any liquors manufactured outside of Puerto Rico.



# Are Formulas required for all products?

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- No, not all products require formula review.
- Time Saving Resources:
  - *TTB Industry Circular 2007-4*
  - *TTB Industry Circular 2016-1*
  - *TTB Ruling 2016-3*
  - *TTB Guidance No. 2016-3*





# How to Submit a Formula

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- Electronic Submission - *Formulas Online* ([www.ttbonline.gov](http://www.ttbonline.gov))
- Paper Submissions - use *TTB F 5100.51* and mail to TTB.



# What TTB Looks For

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- Correct designation (Class and Type) – Is the base produced according to the stated standard?
- Colors.
- Flavors and Flavor Ingredient Data (FID) sheets.
- GRAS (generally recognized as safe) ingredients.
- Restricted and Prohibited Ingredient.



# Certified Colors – 21 CFR Part 74 Subpart A

<b>FD&amp;C Blue #1</b>	<b>(Brilliant Blue FGF)</b>	<b>(E 133)</b>
<b>FD&amp;C Blue #2</b>	<b>(Indigotine)</b>	<b>(E 132)</b>
<b>FD&amp;C Green #3</b>	<b>(Fast Green FCF)</b>	<b>(E 143)</b>
<b>FD&amp;C Red #40</b>	<b>(Allura Red AC)</b>	<b>(E 129)</b>
<b>FD&amp;C Red #3</b>	<b>(Erythosine lake only)</b>	<b>(E 127)</b>
<b>FD&amp;C Yellow #5*</b>	<b>(Tartrazine)</b>	<b>(E 102)</b>
<b>FD&amp;C Yellow #6</b>	<b>(Sunset Yellow FCF)</b>	<b>(E 110)</b>

\*Requires specific declaration on labels for finished alcohol beverages.



21 CFR part 74 subpart A

## Non-Certified Colors 21 CFR part 73 subpart A

- Annatto Extract
- Dehydrated beets (beet powder)
- Canthaxanthin
- Caramel Color
- Carmine (Cochineal Extract)\*
- Carrot oil
- $\beta$ -Apo-8'-carotenal
- $\beta$ -Carotene
- Fruit Juice
- Grape color extract
- Grapeskin Extract (Enocianina)



\*Requires specific declaration on labels for finished alcohol beverages

# Compounded Flavors

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- Are classified as:
  - All natural
  - Natural and artificial containing not more than 0.1% artificial content topnote
  - Natural and artificial containing greater than 0.1% artificial content topnote
  - All artificial
  - Non-flavor: product is not flavor (e.g., Cloud Emulsion)
- Submitted to TTB Nonbeverage Lab for Review
- May contain colors



# Flavor Ingredient Data Sheet (FIDS)

- Flavor Manufacturer usually supplies form to the Producer.
- Based on Exchange between Flavor Producer and TTB Non-Beverage Laboratory.
- Lists concentration of Limited Ingredients in PPM and Colors.
- This information, combined with the use rate, determines classification or flavor disclosure. (Example: Class 9 Flavored Spirit; Liqueur; or Specialty)

Flavor Ingredient Data Sheet				
Flavor Producer Information				
TTB Co. Code: <u>WLOVE</u>	Date: <u>5/28/2014</u>			
Company Name: <u>We Love Flavors</u>	Contact Person: <u>Martha Washington</u>			
Address: <u>6000 Ammendale Rd</u>	Phone: <u>240-555-1212</u>			
<u>Beltsville, MD 20705</u>	Fax: <u>240-5551213</u>			
<b>Check Appropriate Box:</b>				
Flavor Name: <u>Nat. Chocolate WONF</u>	Approved for Drawback (DrB)	<input type="checkbox"/>		
TTB Drawback Number: <u>1510</u>	Approved as No Action (N/A)	<input checked="" type="checkbox"/>		
Alcohol Range by Volume: <u>63.5 +/- 3.5%</u>	Fit for Beverage Purposes (Fit)	<input type="checkbox"/>		
Flavor Product Number: <u>X1257</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: _____ 0 ppm (Excluding Synthetic Vanillin, Ethyl Vanillin, Synthetic Maltol, and Ethyl Maltol)				
Flavor Components				
Additive	TTB Limitation in Finished Product	Amount of Additive or Agent Present in Flavor	Maximum Use Rate	Beverage Label Information based of functionality (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	1000.0 ppm	_____ ppm	- %	7. Grapeskin Extract <input type="checkbox"/>
8. Gum Arabic/Acacia	200000.0 ppm	_____ ppm	- %	8. Caramel Color <input type="checkbox"/>
9. Propylene Glycol	50000.0 ppm	<u>30,000</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	1500.0 ppm	_____ ppm	- %	11. Beet Extract <input type="checkbox"/>
12. _____	_____ ppm	_____ ppm	- %	12. Oak Extract <input type="checkbox"/>
13. _____	_____ ppm	_____ ppm	- %	13. _____ <input type="checkbox"/>
14. _____	_____ ppm	_____ ppm	- %	14. _____ <input type="checkbox"/>
15. Total Vanillin	40.0 ppm	- ppm	- %	
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: _____ Date: _____				
Flavor Company Representative Signature				
Beverage Alcohol Manufacturer / Importer				
Beverage Manufacturer / Importer: _____ Formula # / Serial #: _____				
Flavor Approved on: _____ Notified by: _____ As: <input type="checkbox"/> Approved				
<input type="checkbox"/> No Action				
<input type="checkbox"/> Export Only				
Signature of Alcohol Beverage Representative: _____				



# Flavor Ingredient Datasheet

**Flavor Ingredient Data Sheet**

**Flavor Producer Information**

TTB Co. Code: WLOVE Date: 5/28/2014  
 Company Name: We Love Flavors Contact Person: Martha Washington  
 Address: 6000 Ammendale Rd Phone: 240-555-1212  
Beltsville, MD 20705 Fax: 240-5551213

Flavor Name: Nat. Chocolate WONF  
 TTB Drawback Number: 1510  
 Alcohol Range by Volume: 63.5 +/- 3.5%  
 Flavor Product Number: X1257

**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: 0 ppm (Excluding Synthetic Vanillin, Ethyl Vanillin, Synthetic Maltol, and Ethyl Maltol)

**Flavor Components**

Additive	TTB Limitation in Finished Product	Amount of Additive or Agent Present in Flavor	Maximum Use Rate	Beverage Label Information based on functionality (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	1000.0 ppm	_____ ppm	- %	7. Grapeskin Extract <input type="checkbox"/>
8. Gum Arabic/Acacia	200000.0 ppm	_____ ppm	- %	8. Caramel Color <input type="checkbox"/>
9. Propylene Glycol	50000.0 ppm	<u>30,000</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	1500.0 ppm	_____ ppm	- %	11. Beet Extract <input type="checkbox"/>
12. _____	_____ ppm	_____ ppm	- %	12. Oak Extract <input type="checkbox"/>
13. _____	_____ ppm	_____ ppm	- %	13. _____ <input type="checkbox"/>
14. _____	_____ ppm	_____ ppm	- %	14. _____ <input type="checkbox"/>
15. Total Vanillin	40.0 ppm	- ppm	- %	
16. Total Maltol	250.0 ppm	- ppm	- %	

**Confidential Limited Ingredients Not Shown (CLI)**

Check if contained in formula  Check if CLI was previously submitted   
 Beverage Manufacturer / Importer: \_\_\_\_\_  
 Formula # / Serial #: \_\_\_\_\_

\_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_  
Flavor Company Representative Signature

**Beverage Alcohol Manufacturer / Importer**

Beverage Manufacturer / Importer: \_\_\_\_\_ Formula # / Serial #: \_\_\_\_\_  
 Flavor Approved on: \_\_\_\_\_ Notified by: \_\_\_\_\_ As:  Approved  No Action  Export Only   
 Signature of Alcohol Beverage Representative: \_\_\_\_\_



# FID Header

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## Flavor Ingredient Data Sheet

### Flavor Producer Information

TTB Co. Code: WLOVE  
Company Name: We Love Flavors  
Address: 6000 Ammendale Rd  
Beltsville, MD 20705

Date: 5/28/2014  
Contact Person: Martha Washington  
Phone: 240-555-1212  
Fax: 240-5551213

Flavor Name: Nat. Chocolate WONF  
TTB Drawback Number: 1510  
Alcohol Range by Volume: 63.5 +/- 3.5%  
Flavor Product Number: X1257

#### 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: \_\_\_\_\_ 0 ppm (Excluding Synthetic Vanillin, Ethyl Vanillin, Synthetic Maltol, and Ethyl Maltol)





# Limited Ingredients Section

Additive	TTB Limitation in Finished Product	Amount of Additive or Agent Present in Flavor	Maximum Use Rate	Beverage Label Information based of functionality <small>(check or list label ingredients that affect the beverage label)</small>
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	1000.0 ppm	_____ ppm	- %	7. Grapeskin Extract <input type="checkbox"/>
8. Gum Arabic/Acacia	200000.0 ppm	_____ ppm	- %	8. Caramel Color <input type="checkbox"/>
9. Propylene Glycol	50000.0 ppm	30,000 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	1500.0 ppm	_____ ppm	- %	11. Beet Extract <input type="checkbox"/>
12. _____	_____ ppm	_____ ppm	- %	12. Oak Extract <input type="checkbox"/>
13. _____	_____ ppm	_____ ppm	- %	13. _____ <input type="checkbox"/>
14. _____	_____ ppm	_____ ppm	- %	14. _____ <input type="checkbox"/>
15. Total Vanillin	40.0 ppm	- ppm	- %	
16. Total Maltol	250.0 ppm	- ppm	- %	



# GRAS and Restricted Ingredients

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- U.S. Food and Drug Administration

- GRAS – Generally Recognized as Safe

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

- Restricted ingredients



# Vodka

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- Neutral Spirits distilled or treated after distillation with charcoal or other materials so as to be without distinctive character, aroma, taste, or color.
- Must be distilled at or above 95% ABV (190 proof) and bottled at not less than 40% ABV (80 proof).
- Per TTB Ruling 2016-3, Vodka produced in accordance with the standards of identity defined under 27 CFR 5.22(a)(1) no longer requires formula review. Such Vodka may be treated with sugar, in an amount not to exceed 2 grams per liter and citric acid in an amount not to exceed 1 gram per liter. No other harmless coloring, flavoring, or blending materials are permissible for Vodka.



# Whisky

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- Whisky is an alcoholic distillate from a fermented mash of grain produced at less than 190 proof in such manner that the distillate possesses the taste, aroma, and characteristic generally attribute to whisky, stored in oak containers and bottled at not less that 80 proof.
- Per TTB Ruling 2016-3, Whisky produced in accordance with the standards of identity defined under 27 CFR 5.22(b), in most circumstances, no longer requires formula review. The TTB IC 2007-4 distilled spirits chart is the best guide to confirm when required.



# Gin

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- *Distilled Gin* is produced from original distillation from mash with or over juniper berries and other aromatics or their extracts, essences, or flavors.  
Per TTB Industry Circular 2007-04:
  - Domestic- No Formula requirement.
  - Imported – Pre-import review required.
- *Redistilled Gin* is produced by redistillation of distilled spirits with or over juniper berries and other aromatics or their extracts, essences, or flavors.
  - Domestic–Formula required.
  - Imported – Pre-import review required.
- *Compounded Gin* is produced by mixing neutral spirits with juniper berries and other aromatics or their extracts, essences, or flavors.
  - Domestic – Formula Required.
  - Imported – Pre-import review required.



# Rum

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- Spirits distilled from fermented juice of sugar cane, sugar cane syrup, sugar cane molasses, or other sugar cane by-products.
- Distilled at less than 95% ABV, or 190 proof, and bottled at not less than 40% ABV, or 80 proof, having the taste, aroma, and characteristics generally attributed to rum.
- Per TTB Ruling 2016-3, Rum produced in accordance with the standards of identity defined under 27 CFR 5.22(f), containing no HCFBM *other than* sugar, brown sugar, molasses, or caramel, singly or in combination, not exceeding 2 ½ % by volume of the finished product, does *not* require formula review.



# Liqueur

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- Flavored spirits product containing not less than 2½% by weight sugar, dextrose, levulose or a combination thereof.
- Made by mixing or redistilling any class or type of spirits with or over fruits, flowers, plants or pure juices therefrom or other natural flavoring materials or with extracts derived from infusions, percolation or maceration of such materials.
- Domestic or Imported –Formula or Pre-import approval required.



# Flavored Brandy, Rum, Gin, Vodka, Whisky

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Spirits flavored with *natural* flavoring materials, with or without the addition of sugar, bottled at not less than 30% alcohol by volume (60 proof).

- Domestic or Imported – Formula or Pre-import review required.





# Imitation Products

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When flavored products use an artificial flavoring material, it is changed to “imitation flavored” products.

- Domestic or Imported – Formula or Pre-import review required.
- The use of an artificial flavor will also cause a liqueur to become an “imitation” liqueur.
- Use Rate combined with Limited Ingredients in a flavor can become artificial if either or both are high.



# Distilled Spirits Specialty Products

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Distilled Spirits not defined under any other class.

- Generally, any class and/or type of distilled spirits that contains or are treated with flavoring and/or coloring materials and/or nonstandard blending or treating materials or processes.
- Domestic or Imported – Formula or Pre-import review required.





New View Company

Submissions

## 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   
Submission ID: 1234691 Date Submitted:  
Status: Draft Attachment ID: 1535398 Disposition:

### Product Information

Class: DISTILLED SPIRITS SPECIALTY Type: Product Name: Distilled Spirits Speciality Base

[Change Product Information](#)

### Definition

### 1 Measurement

Type:  Percentage  Volume/Weight  Units:  English  Metric

### 2 Yield Summary

\* Total Yield:  Gallons   
\* Alcohol Content of Finished Product:  Low  High \*Unit  % by Volume

### 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](#)

Corn	500.0 - 750.0 lb.	Fermentable Ingredient	<input type="button" value="trash"/>
Cane sugar	250.0 - 375.0 lb.	Fermentable Ingredient	<input type="button" value="trash"/>
Water	450.0 - 550.0 gal.	Other	<input type="button" value="trash"/>
Dry yeast	15.0 - 25.0 lb.	Other	<input type="button" value="trash"/>
Caramel	0.05 - 0.25 gal.	Color	<input type="button" value="trash"/>

[Which category should I choose?](#)

### Method of Manufacture

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Describe in sequence each step used to produce this product. Be sure to include a description of how and when each ingredient you have listed will be added.

(For Malt Beverages) Describe in detail each special process used to produce a beer product. Omit processes customarily used in brewing such as pasteurization or ordinary filtration.

Method of Manufacture Examples

**Description:**

"Moonshine" Base Product

- 1.) Malt corn, prepare, rinse, and crush.
- 2.) Add boiling water and cane sugar.
- 3.) Cool and pitch yeast to ferment. Keep mash warm.
- 4.) Strain and transfer to still.
- 5.) Distill to 100 proof. Discard unwanted products and redistill to 140 proof.
- 6.) Adjust proof with additional water.
- 7.) Add caramel color and bottle.

Plan to use product as future base, Statement of Composition - "Spirits distilled from Corn and Cane Sugar with caramel color added."

« Previous

Save as Draft

Validate

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.

FONL 2.4.15

# Fast Resources

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- **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).
- **Industry Circular 2007-4:** Useful reference chart stating when formula or preimport review is required.



# Common Return Reasons

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- *Submitter did not provide an approved FID sheet.*
- *Please upload a specification sheet or an image of the label clearly showing the list of ingredients for the following item(s).*
- *Please provide the proof at distillation of the base spirit when it comes off the still, before the addition of water.*
- *Quantities were not provided for all ingredients. Please update the list of ingredients to specify the amount of each.*
- *Provide a more detailed method of manufacture.*
- *Compounded flavors cannot be used until they have been approved by TTB's Nonbeverage Products Laboratory.*



# Helpful Hints

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- Supply a quantitative list of ingredients.
- Provide a complete method of manufacture.
- Indicate proof at distillation.
- 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 GRAS (generally recognized as safe).



**Questions?**

