

Malt Beverage Formulas

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Common Formula Questions

- What is a formula?
- Why is a formula required?
- When is a formula required?
- How is a formula submitted?



What is a Formula?

- A formula is the recipe for your beer/malt beverage
- It must include a quantitative list of ingredients
- It must include a description of how the product is produced
- It must indicate a total yield or batch size
- In some instances a sample of the product must also be submitted to TTB for laboratory analysis
- See Formula Basics page on TTB.gov
 - https://www.ttb.gov/formulation/pre_cola.shtml



Why is a Formula Required?

- It's required by TTB regulations
 - Domestic (27 CFR 25.55)
 - Imported (27 CFR 7.31(d))
- 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



At What Stage do I Apply for Formula Approval?

- **Domestic** - Formula approval is required prior to producing certain types of beer
- **Imported** - Certain malt beverages are required to undergo formula review prior to issuance of a certificate of label approval



When is a Formula Required?

- Formula approval is required if the brewer uses any of the following ingredients/processes*:
 - Flavors with alcohol
 - Compounded flavors
 - Colors (unless exempted by TTB Ruling 2015-1)
 - Artificial sweeteners
 - Flavors or other agricultural ingredients (unless exempted by TTB Ruling 2015-1)
 - The beverage is frozen and ice crystals are removed (e.g., ice beer)

*Not a complete list



When is a Formula Required?

FAQ B13: Am I Exempt from Formula Requirements if I Sell my Malt Beverage only at my Brewpub or only within my State?

- No
- If a brewer is required to obtain formula approval for a product then approval of the formula must be obtained prior to production, even if the product will be sold only at the brewer's brewpub or otherwise sold only within the state in which it is produced
- Formula requirements also apply regardless of whether the product is sold on tap at the brewer's brewpub or is bottled, canned, or kegged



Which Beers Require Formula Approval?

- Use our online formula tool or check the list in TTB G 2016-1A to determine which kinds of beer require formula approval
 - Tool: https://www.ttb.gov/formulation/formula_approval_tool_mb.shtml
 - List: <https://www.ttb.gov/public-guidance/TTB-G-2016-1A.shtml>

27 CFR 25.53, 25.55 & 7.31(d)



Which Beers Require Formula Approval?

Products that Require Formula Approval

- Ice beer
- Kombucha (when regulated by TTB)
- Malt beverage specialty products, such as flavored beer or beer made with non-traditional processes (unless exempted by [TTB Ruling 2015-1](#))
- Saké

Products that Require Formula with Laboratory Sample Analysis

- “Alcohol Free” malt beverages (0.0 percent alcohol by volume)

See TTB G 2016-1A for additional information

<https://www.ttb.gov/public-guidance/TTB-G-2016-1A.shtml>

27 CFR 25.53, 25.55 & 27 CFR 7.31(d)



Ingredients and Processes that are Exempt from Formula Requirements

- [TTB Ruling 2015-1](#) exempts certain traditional ingredients and processes
- [Attachment 1](#) specifies which ingredients and processes are exempt, for example:
 - Honey, vanilla beans
 - Barrel-aging
- The ruling **does not** exempt flavors containing alcohol or extracts, for example:
 - Vanilla beans are exempt, but vanilla extract is not exempt
- Please note that exempt ingredients cannot comprise more than 49 percent of the fermentables
- TTB can still request a formula and samples for analysis at any time, even when exempt ingredients are used



TTB Ruling 2015-1 | Attachment 1

Exempt Ingredients and Processes Determined to be Traditional Under TTB Ruling 2015-1

TTB Ruling 2015-1
Attachment 1

Exempt Ingredients Under the Conditions of TTB Ruling 2015-1

Industry members are responsible for ensuring that all ingredients, including any parts of fruit, used in the production of malt beverages or beer are wholesome products suitable for human food consumption and comply with applicable ingredient safety regulations of the Food and Drug Administration.

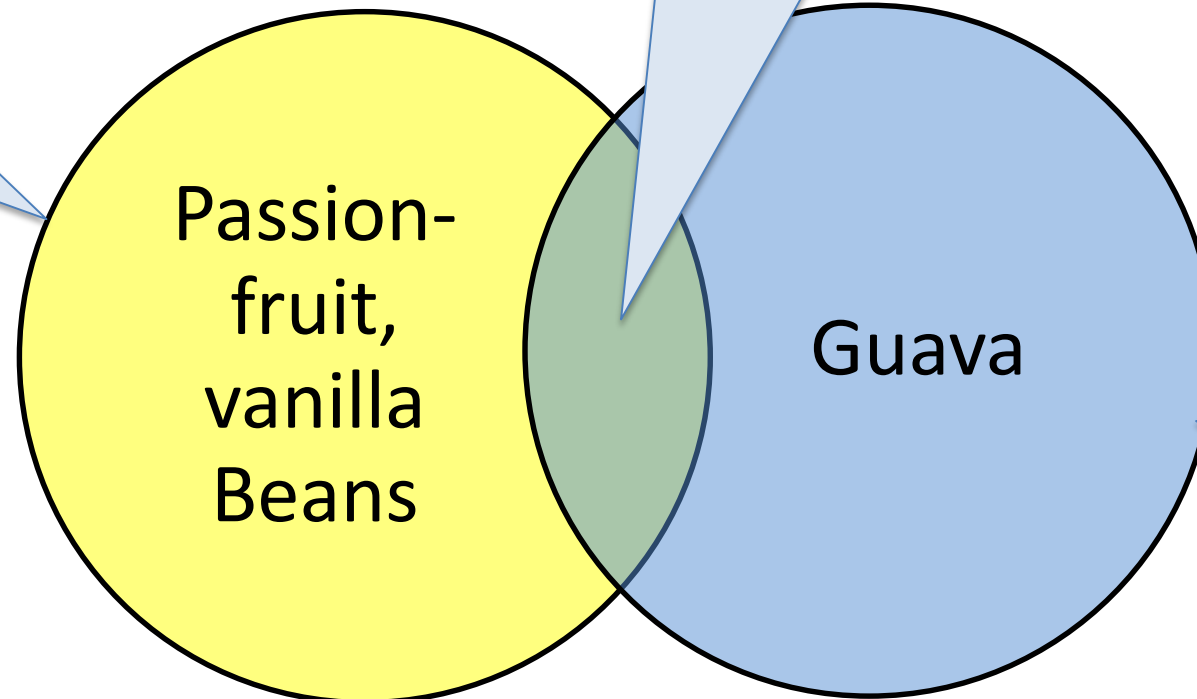
INGREDIENT	DESCRIPTION/LIMITATION
AGAVE	Whole, juice, puree, or concentrate. Does not include extracts, essential oils, or syrups.
ALLSPICE	As outlined in FDA's GRAS listing at 21 CFR 182.10 . Spices may be whole or ground. Does not include extracts, essential oils, or syrups.
ANISE	As outlined in FDA's GRAS listing at 21 CFR 182.10 . Spices may be whole or ground. Does not include extracts, essential oils, or syrups.
APPLES	Whole, juice, puree, or concentrate. Does not include extracts, essential oils, or syrups.
APRICOTS	Whole, juice, puree, or concentrate. Does not include extracts, essential oils, or syrups.



Combinations of Exempt and Non Exempt Ingredients

If you use both exempt and non exempt ingredients, formula is required

Passionfruit and vanilla beans are exempt



Guava is not exempt



What TTB Looks For When Reviewing Formulas

- Correct designation (Class and Type) – Is the base produced according to the stated standard?
- GRAS (**G**enerally **R**ecognized **A**s **S**afe) status of certain ingredients
- Any limited or prohibited ingredients used
- Correct supporting documentation for certain ingredients
 - Ingredient Specification Sheet (Spec Sheet)
 - Flavor Ingredient Data Sheets
 - Limited Ingredient Calculation Worksheet



Compounded Flavors

- Are one of the following:
 - All natural
 - Natural and artificial containing up to 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 (FID Sheet or FIDS)

- A FID Sheet is a spreadsheet 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 brewer
- 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	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 #: _____				
_____ Flavor Company Representative Signature		Title: <u>Supervisory Chemist</u>		Date: <u>30-Sep-17</u>



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

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

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

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)



FID Sheet: Limited Ingredients Section

Flavor Components					Coloring Additives and Other Additives that Affect the Beverage Label (check or list label ingredients that affect the beverage label)	
TTB/FDA Limited Ingredients	TTB/FDA Limitation in Finished Product	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/ 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 Worksheets

- Used to calculate the total amounts of ingredients that have limits on their use per TTB and FDA requirements
- Complete and submit one for each malt beverage made with one or more compounded flavors
- Also useful as a product development tool
 - Allows you to confirm that new product formulas are in compliance with limited ingredient requirements, and whether a flavor will be labeled as artificial prior to submitting the formula
- See [TTB G 2017-6](#) for additional information and examples



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



Certified Colors

21 CFR part 74, Subpart A*

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

*Regulations of the U.S. Food and Drug Administration (FDA)

**Requires specific declaration on labels for finished alcohol beverages



Non-Certified Colors*

21 CFR part 73, subpart A

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

*This is a partial list. See 21 CFR part 73, Subpart A for a complete list of FDA regulations

**Requires specific declaration on labels of finished alcohol beverages



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





GRAS and Restricted Ingredients

- GRAS – **G**enerally **R**ecognized **A**s **S**afe
 - 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
- Having GRAS status does not impact formula requirements
- FDA maintains a list of prohibited ingredients at 21 CFR part 189
- Certain non-prohibited ingredients may be used within limits
 - http://www.ttb.gov/ssd/limited_ingredients.shtml



TTB Limited Ingredients

- There are 4 artificial flavor materials that TTB allows to be present at certain levels in alcohol beverages without affecting the label declaration:
 - Synthetic maltol
 - Ethyl maltol
 - Synthetic vanillin
 - Ethyl vanillin
- If these limits are exceeded, a “natural flavor” is treated as an “artificial flavor” in the product



Beer/Malt Beverages with Flavors that Contain Alcohol*

- **Final ABV is less than or equal to 6 percent:**
 - at least 51 percent of the alcohol in the final product must come from the malt base
 - no more than 49 percent of the alcohol in the final product can come from the flavor and other nonbeverage materials
- **Final ABV is greater than 6 percent:**
 - no more than 1.5 percent of the volume of the malt beverage can consist of alcohol from flavors and other nonbeverage ingredients containing alcohol
- An alcohol content statement must appear on the label if any alcohol in the malt beverage was derived from added flavors

27 CFR 7.11 & 22(a)(5), 27 CFR 25.15



How to Submit a Formula

- The recommended method is completing the full application electronically using [Formulas Online](#)
 - See webinar handout: [How to Register and Submit Formulas through Formulas Online \(July 2018\)](#)
- Although TTB strongly encourages you to use Formulas Online, a paper alternative is also available
 - [TTB Form 5100.51](#) mailed to TTB (use address on the form)



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




1 Measurement

Type: Percentage Volume/Weight 

Units: English Metric 

2 Yield Summary

Total Yield: × 

	Low	High	Unit	
* Alcohol Content of Finished Product:	<input type="text" value="6.1"/>	<input type="text" value="6.45"/>	<input type="text" value="% by Volume"/>	
Alcohol From Flavors:	<input type="text" value="0.5"/>	<input type="text" value="0.85"/>	<input type="text" value="% by Volume"/>	
Alcohol From Base:	<input type="text" value="5.6"/>	<input type="text" value="5.6"/>	<input type="text" value="% 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](#)

▶ Draft Lemon Pale Ale	990.0 - 995.0 l.	AbV: 5.5% - 5.6%	PaD: <Not Entered>	TTB Formula ID: <Not Entered>	Finished Alcohol	
▶ Flavor Group 1: Natural Mango flavor	1.2 - 5.0 l.	TTB Company Code: WL5	TTB Drawback #: 25		Flavor (Compounded)	 
▶ Flavor Group 1: Natural Jablanica Mint flavor	4.0 - 5.0 l.	TTB Company Code: WL5	TTB Drawback #: 3		Flavor (Compounded)	 
▶ Flavor Group 2: Natural and Artificial Pineapple flavor	3.5 - 5.0 l.	TTB Company Code: WL5	TTB Drawback #: 55		Flavor (Compounded)	 



Method of Manufacture

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:

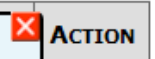
- 1.) Mash at 65 C malted barley, flaked oats, and honey malt. Lactose may be used as an optional ingredient.
- 2.) Bring to boil and add hops and hops extract.
- 3.) Whirlpool for 20 minutes and then chill.
- 4.) Pitch yeast and ferment.
- 5.) Add hops after fermentation.
- 6.) Add listed flavors after fermentation is complete.
- 8.) Add preservative-Sodium benzoate at use rate no greater than .1%
- 8.) Add Caramel Color.
- 8.) Bottle/ Keg with Carbon Dioxide under pressure.

Method of Manufacture Documents

Be sure to include:

- All of the ingredients identified in the list above, including when each ingredient is added.
- The agricultural source of the alcohol.
- The proof at distillation (Distilled Spirits products only).

In most circumstances, we do not require details such as temperature or pressure conditions during manufacture or how long ingredients were fermented. For Malt Beverage products, you may omit processes customarily used in brewing such as pasteurization or ordinary filtration.



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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 (generally recognized as safe) by the FDA



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
- **Formula approval is not required** for this product because it is composed of exempt ingredients or processes (See [TTB Ruling 2015-1](#))



Summary & Questions