

FORMULAS  
ONLINE:  
REDUCING RETURNS



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# REDUCING RETURNS

- FONL
- Guidelines
- Errors / Mistakes
- Paper → Electronic Submissions
- Questions



FONL



# REDUCING RETURNS - FONL

- Basic questions – read through New Users Webinar
  - Available on [TTB.gov](http://TTB.gov)
- If just starting – submit 1 formula and see how it goes.
- Complex submission – may want to submit by paper.



# REDUCING RETURNS - FONL

- Alcohol Beverage Use Box
  - If used, it must be filled out completely.

## Alcoholic Beverage Use

- Is Finished Product to be Used In Alcohol Beverages?
- Product Contains Natural Flavoring
- Product Contains > 0.1% Artificial Flavoring *(excludes Vanillin, Ethyl Vanillin, Maltol, Ethyl Maltol)*
- Product Contains Color Additive
- All FDA Approved Ingredients Are Without Limitation

TTB LIMITED INGREDIENT	PARTS PER MILLION
Synthetic Vanillin:	<input type="text"/>
Ethyl Vanillin:	<input type="text"/>
Synthetic Maltol:	<input type="text"/>
Ethyl Maltol:	<input type="text"/>



# REDUCING RETURNS - FONL

- Limited Ingredients
  - All must be disclosed.
  - Cannot be included in a group.
  - If an ingredient contains any limited ingredient, 'Yes' must be chosen and quantities included.
- Even if spec sheet states the amount.

Ingredient

Simple Mix or Filtration - Disapproved Intermediates

\* Ingredient Name: Nat Raspberry Flavor

\* Weight (LB): 4.1

\* Volume (GAL): 0.51

\* Eligible Alcohol (%): 5

\* Total Alcohol (%): 5

TTB Formula ID:

Company Code: WLF

Company Formula #: 12

\* Contains Colors: No

\* Limited Ingredients: Yes

\* Names and % by Weight:

OK Cancel



# REDUCING RETURNS - FONL

- Grouping Ingredients
  - TTB and FDA limited ingredients must be listed separately.
  - Provide weight of predominant ingredients in group, not %.

## Nonalcoholic Components

Does product contain ingredients by group?

### INGREDIENTS BY GROUP

-----CHEMICAL CLASS-----		-----PREDOMINANT CHEMICALS-----	
<input type="checkbox"/> NAME	TOTAL WEIGHT (LB)	NATURAL / ARTIFICIAL	NAME, FEMA #, WEIGHT (LB)
<input type="checkbox"/> Esters	.09	Natural	Ethyl Butyrate, FEMA #2427, 0.05lbs



# REDUCING RETURNS - FONL

- Intermediates
  - All information must match technical data sheet or TTB's records.
    - Name, alcohol content (by volume), limited ingredients, etc.
  - Mid-point of total alcohol value should be used.
    - Exception – 1% solutions where the actual alcohol content is known.





# REDUCING RETURNS - FONL

\* Process Type:

- Process Types

Simple Mixture
Filtration
Washed Extracts
Other

- Simple Mixture

- Theoretical and Actual Yields are the same (no loss of materials).

- Filtration

- A small loss during manufacturing is expected.

- Washed Extract

- Soluble check box must be checked for soluble ingredients otherwise the system cannot calculate the total alcohol content.
    - Volume of liquid components is required.



# REDUCING RETURNS - FONL

\* Process Type:

- Process Types

Simple Mixture
Filtration
Washed Extracts
Other

- Other

- Should only be used if the product does not fit under the other process type options.
    - Must fill in all information (yields, density, alcohol, etc).
    - Yield Calculations
      - Actual and theoretical should not be the same.
    - Be sure the theoretical yield matches the sum of ingredients.



# REDUCING RETURNS - FONL

- Manufacturing Process
  - If using the process type of Filtration, Washed Extract, or Other...
    - Manufacturing information must be included in the Formula Information and Process field (on the Formula tab).

Formula Information and Process:

Unlimited



# REDUCING RETURNS - FONL

- Density

- Be sure the densities of intermediates and the final product are correct.

Ingredient	Pounds/gallon	grams/milliliter (also kilograms/liter)
Water	8.3282	1.0000
200 proof Ethanol	6.6097	0.7936
190 Proof Ethanol	6.7943	0.8141
Propylene Glycol	8.6300	1.0360

\* All density values are at 60° F



# REDUCING RETURNS - FONL

- Botanicals
  - Dry or wet?
  - Provide moisture content
  - Include volume of water in alcohol calculations (may have to use 'Other' process type).



# GUIDELINES



# REDUCING RETURNS – GUIDELINES

- Technical Data Sheets / Spec Sheets / FIDs
  - Ingredients that do not require extra documentation:
    - Ingredients derived from a single source that do not contain limited or prohibited ingredients, added colors, nor alcohol.
    - Examples: Cinnamon, juniper berries, vanilla beans, parsley, lemon peel, orange oil, cherry juice, etc.



# REDUCING RETURNS – GUIDELINES

- Technical Data Sheets / Spec Sheets / FIDs
  - Ingredients that require a technical data sheet:
    - Ingredients derived from a single natural source that may contain limited ingredients, colors, and/or alcohol.
    - Includes extracts, essences with high alcohol content (above 7% v/v)\*, distillates and solid extracts.
    - Examples: apple essence, cherry distillate, alcohol extract of lemon peels, fenugreek solid extract (with PG and caramel color)
    - Compounded flavor with no TTB#.

*\* If the essence (regardless of alcohol content) is the only natural source of the naming flavor, we reserve the right to request a spec sheet.*





# REDUCING RETURNS – GUIDELINES

- Technical Data Sheets / Spec Sheets / FIDs
  - Documentation Required:
    - Technical data sheet that lists the ingredients and describes production.
    - Must disclose the solvent, limited ingredients with quantities, and any coloring materials.
    - Must be from manufacturing company.

## TECHNICAL DATA SHEET

# Manufacturing Company Letterhead

Name of Product: **St. John's Bread Solid Extract**

### IDENTIFICATION

Description:	Solid Extraction of St. John's Bread
Botanical Source (if applicable):	
FEMA # (if applicable):	2243
CAS No (if applicable):	84961-45-5

### COMPONENTS

Solvent/Carrier:	Propylene Glycol, Water
Flavor:	
Other:	Corn Syrup

### SPECIFICATIONS

Alcohol by volume:	0% ABV
Density/Specific Gravity:	1.234 g/mL

### LIMITED INGREDIENTS AND COLORS

Limited Ingredients (names and quantities):	Propylene Glycol: 10 – 15%w/w
Colors (either 'none' or declared):	Caramel Color

### REGULATORY STATUS (CFR Reference or FEMA number or GRN No.)

St. John's Bread:	21 CFR 182.20
Propylene glycol:	21 CFR 184.1666
Corn Syrup:	21 CFR 184.1865

### MANUFACTURING PROCESS

St. John's Bread is mixed with propylene glycol at a ratio of 1: 5, after one week of maceration the PG is mostly removed by evaporation of the fluid part



# REDUCING RETURNS – GUIDELINES

- Technical Data Sheets / Spec Sheets / FIDs
  - Ingredients that require TTB approval
    - Compounded flavors – consists of multiple ingredients
      - Provide TTB Company Code and Company Formula Number (TTB #) or FIDs



# REDUCING RETURNS – GUIDELINES

- Ingredient Information
  - Provide all required information
    - Examples:
      - Ginseng extracts
        - » American Ginseng - GRAS up to 30% ABV
      - Bitter Almond Oil – must be prussic acid free
      - Cherry pits – prussic acid
      - Wormwood, oakmoss, cedar – thujone
      - Woodruff – coumarin



# REDUCING RETURNS – GUIDELINES

- Ingredient Information
  - Provide all required information
    - Examples:
      - Cinchona – alkaloids
      - Licorice – glycyrrhizin
      - St. Johnswort – hypericin free
      - Star Anise – provide species name
        - » Chinese star anise (*Illicium verum*) - GRAS
        - » Japanese star anise (*Illicium anisatum*) - toxic
  - Refer to the Limited Ingredient page on TTB.gov



# REDUCING RETURNS – GUIDELINES

- Naming
  - Must be N&A if it contains any artificial ingredients, even if it is considered ‘TTB Natural.’
  - WONF should not be included if the products contain any artificial ingredients.
  - If WONF is used, natural still must be included.



# REDUCING RETURNS – GUIDELINES

- Vanillin
  - Natural vs. Artificial
    - Refer to the Drawback Tutorial
    - If using a natural vanillin product listed in the Drawback Tutorial, the name of the product must be provided (or a spec sheet).



# ERRORS / MISTAKES





# REDUCING RETURNS – ERRORS / MISTAKES

- Needs Corrections changes
  - Must be recorded within the formula itself if possible



# REDUCING RETURNS – ERROR / MISTAKES

- Fitness
  - Refer to the appropriate guideline.
  - The more specific the better.
    - We can process the submission much faster if this information is correct.
  - High end of total alcohol range must be used in calculations.

Unfit for Beverage Statement:

Propylene Glycol = 56.2% v/v

971 characters left



# REDUCING RETURNS – ERROR / MISTAKES

- Neither vs Natural or Artificial
  - Neither should be used for ingredients such as PG, glycerin, water, and fixed acids.

A screenshot of an Internet Explorer browser window. The address bar shows the URL: <https://int.ttbonline.gov/?method=editIngredient&currentTab=Formula&index=&type=Nonalcoholic&tsu>. The page title is "Ingredient". The form is titled "Nonalcoholic - Solids" and contains the following fields:

- \* Natural/Artificial: A dropdown menu with options "Natural", "Artificial", and "Neither".
- \* Name: A text input field.
- FEMA #: A text input field.
- \* Weight (LB): A text input field.
- \* Additional Information: A text input field.
- Limited Ingredients: A dropdown menu with a downward arrow.

At the bottom of the form are "OK" and "Cancel" buttons. The browser's status bar at the bottom right shows "100%".



# PAPER TO ELECTRONIC SUBMISSIONS



# PAPER TO ELECTRONIC SUBMISSIONS

- Paper Submission Returned for Correction:
  - Resubmit by paper.
  - Cancel returned submission and create a new electronic submission.
    - Must reference original submission in Comments Tab and/or Docs/Links Tab.
  - Fill out Formula Tab as if an electronic submission.
    - System will not do any automatic calculations.
    - Most fields not marked as mandatory and system will not validate the submission the same way as an electronic submission.
      - Fields still must be completed (alcohol content, yields, etc.)



# PAPER TO ELECTRONIC SUBMISSIONS

- Already Approved Paper Submission:
  - Create a new electronic submission.
    - Supersede the original submission.
    - Complete as a normal electronic submission.



# QUESTIONS



# FORMULAS ONLINE – REDUCING RETURNS

- Please send any questions to [formulasonline@ttb.gov](mailto:formulasonline@ttb.gov).