

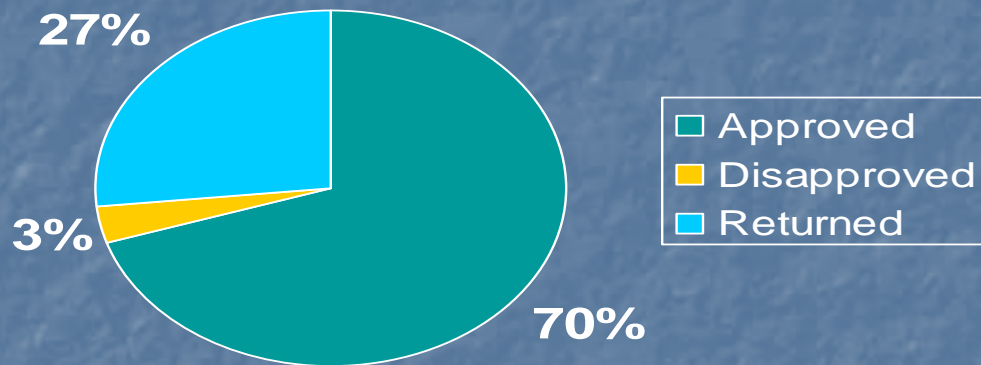
# Reducing Returns: Getting Your Formula Through the First Time

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# Past Formula Submissions

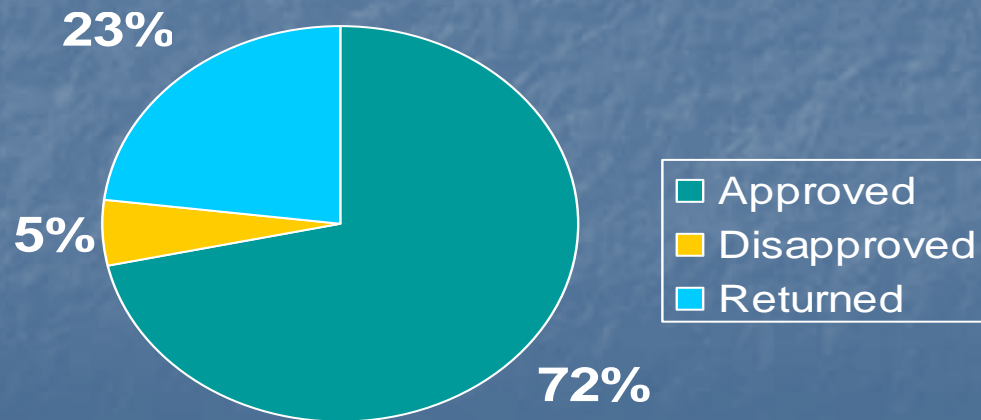
## ■ 2004

- Received 6917 Formulas
- Action Taken on 6808 Formulas



## ■ 2005

- Received 6471 Formulas
- Action Taken on 6339 Formulas





# Turnaround Time

Very Difficult to Meet 10 Day Turnaround

- High Volume of Formula Submissions
- Errors in Naming Product, Items 9 & 10
- Information Missing from Submissions
- Ambiguous Information on Submissions
- Is a Sample Required?



# FDA Naming Guidelines

- Natural Flavor: Flavor comes only from the named material (*Nat. Cherry Flavor*)
- Natural Flavor WONF: A Natural Flavor, With Other Natural Flavors Not from Named Material (*Nat. Cherry WONF*)
- Natural Type Flavors: All Natural Flavor, but No Source of the Named Material (*Nat. Cherry Type*)

# FDA Naming Guidelines

- Natural & Artificial Flavor: Natural Source of the Named Material, and Artificial Flavors  
*(N&A Cherry Flavor)*
- Natural & Artificial Type Flavors: No Source of Named Material, but Natural & Artificial Flavor  
*(N&A Cherry Type)*
- Artificial Flavors: Predominant Flavor is Artificial  
*(Art. Cherry Flavor)*

# TTB Guidelines

- N&A Flavors with Less than 0.1% Artificial Topnote
  - Should Comply with FDA Naming Guidelines (N&A)
  - Considered Natural when Used in Alcoholic Beverage
  - Calculation Does Not Include Art. Vanillin, Art. Maltol, Ethyl Vanillin, or Ethyl Maltol
- If Greater than 0.1% Artificial → Considered Artificial for Alcoholic Beverage Labeling Purposes





# Missing Information

- Disclose & Quantify All Sources of Ethanol
  - Essences, Distillates, Intermediates
  - List Each Item Separately
  - Provide Percent Alcohol by Volume and Total Volume Used
- Disclose & Quantify All Limited Ingredients
  - Solid Extracts (Commonly Propylene Glycol, Caramel)
  - Intermediates (Commonly Propylene Glycol, Art. Vanillin)
- Grouping of Chemicals
  - List and Quantify Predominant Ingredient
  - Separate Natural from Artificial Flavor Chemicals
  - Group by Chemical Class (Aldehydes, Esters, Ketones)

# Essences, Distillates, & Aromas

- List Each Product Containing Ethanol as a Separate Line Item
- State the Percent Ethanol by Volume and the Volume Used
- If the Product is Water-Based, Please State:  
"No Alcohol. No Limited Ingredients"
- Possible Presence of Methanol in Essences
  - Please Be Aware
  - Please Screen, Quantify, and Disclose



# Limited Ingredients

- Limited Ingredients can be found in:
  - TTB Website – 21 CFR Part 184
- Common Limited Ingredients:  
Acetic Acid, Propylene Glycol, Caffeine
- TTB Limited Ingredients:

Artificial Vanillin	Ethyl Vanillin
Artificial Maltol	Ethyl Maltol

# Vanillin: Natural vs. Artificial

- TTB Only Recognizes Vanillin as Natural when Derived from Vanilla Beans
- Artificial Vanillin may be Derived from:
  - Turmeric
  - Eugenol
  - Clove
  - Lignin
- No Documentation from FDA to Show that the Process Used to Make Vanillin is Natural

# Avoiding Ambiguity

- Specify the Proof & Type of Spirit Used
- Specify Units for All Ingredients
- Avoid Abbreviations or Obscure Names
- Provide Chemical Name and FEMA Number
- Use TTB Numbers (Not Product Numbers)
- Specify Alcohol Content by Volume
- Identify the Solvent in Extracts & Essences
  - Quantify if Propylene Glycol
  - If Ethanol, Provide the Volume of the Extract & Ethanol by Volume
- State “No Alcohol, No Limited Ingredients, No Colors”





# Other Helpful Items

- Provide Yields in Both Weight and Volume
- Provide a Density or Specific Gravity for Your Product
- Provide Your Phone Number & Email Address
- Do Send Copies of :
  - Product Specification Sheets if No TTB #
    - Must State: Ethanol (v/v), Density, Limited Ingredients, Colors
  - Pre-1990 Formulas if Used as Intermediates
- Do Not Send Copies of:
  - Specification Sheets for Intermediates with TTB #s
  - Flavor Ingredient Data (FID) Sheets for the Formula You're Submitting



# Don't Send a Sample When...



- No Alcohol in Product
- More PG by Volume than Ethanol (Upper Limit) and No Masking Agents are Present in the Formula
- Formula is a Simple Mixture and Lists At Least 1% of a Chemical on the 1% List and No Masking Agents are Present in the Formula
- See Handout for Unfit Guidelines Concerning:  
Citric Acid, Salt, Vanillin, Ethyl Vanillin,  
Maltol, Ethyl Acetate, and Essential Oils

# Send a Sample When...



- Formula Does Not List Significant Amounts of Flavor Chemicals
  - Only Essences, Concentrates, Extracts are Listed
- Low Levels of Essential Oils in a Washed Extract
- Formula Contains Masking Agents
  - Sugar, High Fructose Corn Syrup, Glycerin, Juices
- Ingredient Making Formula Unfit is Not Listed on Formula
- Product is a Sauce/Syrup
  - Ethanol is Not More than 12% (v/v) and Residual Solids  $\geq$  60g/100 cc
- Vanilla Extracts
  - Less than 1 Fold
  - 1X or 2X with Ethanol Greater than 45% (v/v) in Item 10



# What Does This Mean?

“Please contact the manufacturer for status of their product”

- TTB# Listed is Invalid
- TTB# Listed was Disapproved
- Product # is Listed, Not TTB#
- TTB# and Product Description Don't Match
- Formula has been Returned to Customer



# Do I Need a New TTB Number?

- You MAY Keep Your Current TTB Number If:
  - Yield Changes Due to Processing Changes
  - Correcting an Error or Omission in an Ingredient that is NOT Limited by FDA or TTB
- You NEED a New TTB Number If:
  - Changing the Quantity of a TTB or FDA Limited Ingredient
  - Adding or Deleting a Color
  - Changing a Component that Would Affect Labeling Status of the Product
  - Changing a Component that Would Affect the Beverage Character of the Product