The Brighter Future of the TTB

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Objectives

- Discuss the need for a regulation change and outline the proposed new regulations
- Present an overview of the future formulas online system
- Suggest interim solutions
Nonbeverage Products Laboratory

- 1 Legal Instruments Examiner
  - Lakisha Bryant  240-264-1666
- 5 Chemists
  Responsibilities Include:
  - Processing NBA formulas
  - Processing SDA formulas
  - Method Development
  - Special Projects as assigned
Our Goals for the Future

- Meet the established turnaround time for formula approval
- Minimize NPL’s burden on industries’ business opportunities
- Provide better tools for industry members
The Result: New NPL Regulations

Consists of two parts:

- 0.1% and 1% Solution General Use
  Formulas
- Certification
0.1% AND 1% SOLUTIONS

- Natural and artificial flavor ingredients known to make products unfit for beverage use
- Concurrent publication of General Use Formulas (TTB Publication 5154.1)
- To be added to the formulas allowed by 27 CFR 17.132
- Solutions may be manufactured without submission of TTB Drawback Form 5154.1
- Manufacturers will be allowed to claim drawback by submitting a drawback claim to the National Revenue Center (NRC)
Certification

Three categories of certified formulas:

- Certified as unfit without a taste panel
- Certified as unfit with a taste panel
- Certified as fit for beverage use
Certified As Unfit Without a Taste Panel

- Product contains an ingredient in Pub. 5154.1 at the required level without mitigating ingredients (glycerin, high fructose corn syrup, etc.)

- Product contains an ingredient from the “guidelines for nonbeverage product formulation” at the required level without mitigating ingredients

- Product meets the standards for sauces, syrups, brandied fruits, or candies as specified in the current regulations (27 CFR 17.133)
Certified As Unfit Without a Taste Panel, Cont’d.

- Product meets the standards for vanilla extract, concentrated vanilla extract, vanilla flavoring, concentrated vanilla flavoring, vanilla-vanillin extract, or vanilla-vanillin as specified in FDA’s regulations (21 CFR)

  Exception: Vanilla extracts less than 3-fold with an alcohol content above 45% by volume

- Product contains less than 0.5% alcohol by volume, or no alcohol
Certified As Unfit With a Taste Panel

- Product does not meet TTB’s standards based on any single ingredient, but does contain one or more ingredients that the manufacturer believes makes the product unfit for beverage use.

- Product contains an ingredient that may appear to mitigate the impact of the flavoring ingredient, but the manufacturer believes that the product is unfit for beverage use.
Certified As Unfit With a Taste Panel, Cont’d.

- Manufacturer must subject product to a 6 member taste panel (parameters will be provided)
- 4 out of 6 panelists must agree that product is unfit for beverage use
- Manufacturer must submit formula with the results of taste panel results to NPL
Certified As Fit for Beverage Use

- Domestic manufacturer knows that the product is fit for beverage use and intends to use it as an intermediate product in a nonbeverage product eligible for drawback.

- Foreign manufacturer wants to use a product fit for beverage use in an alcoholic beverage manufactured outside of the U.S.
Certification Process, Cont’d.

- Appropriate canned statement will be included in item #18 on TTB Form 5154.1

- Certified formulas will be submitted to NPL at the time of sale or concurrently with drawback claim

- Applies to domestic and imported flavors as well as “No Action” formulas

- Drawback claims for domestic products will be submitted to the National Revenue Center (NRC)
Certification Process, Cont’d.

- NPL will log formulas into database and make formulas available to NRC for processing claims, but will not take any action on or mail copies to NRC or manufacturers.

- Manufacturers will be required to retain samples for a period of time.

- NPL will randomly request samples to verify that products are in agreement with the certified formulas.
The Road to the New Regulations

- Regulations are currently being drafted for a temporary rule
- Several levels of review required before final draft is submitted for publication in Federal Register
- Voluntary basis
The Road to New Regulations, Cont’d.

- 1st NPRM will be published concurrently with temporary rule in Federal Register
- Comment period
- Revision
- 2nd NPRM will be published later proposing to make the temporary rule permanent
- Final rule
NPL’s Role After New Regulations

- Enhanced NPL website, including tutorial
- Seminars
- Provide advice and training to TTB auditors and investigators
- Develop analytical methods
- Goal – To expand the guidelines so everything can be certified based on guidelines to remove subjectivity
**Formulas Online**

- Currently working on a system for online formula submission
- It will do calculations automatically for most instances of nonbeverage products
- Customers can search for status electronically
Formulas Online, Cont’d.

- Emailed questions will go directly to the chemist working on the formula
- Immediate email verification when the formula is complete
- Submitting online will not be mandatory

COMING FALL 2009!
Interim Solutions

- Provide complete information on the formula
- TTB# or ingredient data sheets for intermediate flavors
- Identify and quantify all sources of ethanol
- Identify and quantify limited ingredients

Disclose what makes a product unfit!!!
TTB Drawback Tutorial

http://www.ttb.gov/ssd/drawbacktutorial.shtml

- Link through the Laboratory’s Webpage
- Google: “Drawback Tutorial”
- Add to Your Favorites
Pay.gov

For username and password please contact: Edward Limowski
Thank You!

Questions:

Contact: Julie Arthur