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

I 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

O.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



We are providing you with this tutorial to show a more effective way to fill out <u>TTB Form 5154.1</u>. Guidelines for submissions of nonbeverage product formulas to the Nonbeverage Products Laboratory and sample calculations for items 9 & 10 are provided for the most common types of submissions. We have found that roughly 80 to 90% of the submissions fall under two categories:

- 1. Simple mixtures (with and without filtration)
- 2. Washed extracts of essential oils

Compounded flavors are the most frequently encountered by the Laboratory and will serve as examples for simple mixtures. Sample calculations for washed extracts are also included. Even if your product does not strictly adhere to these formats, please review the calculations because much of the information can be applied to other types of products.

The first twelve topics cover an array of issues that should help you better understand the requirements for approval of a nonbeverage product formula. The rest of the topics include example calculations for the scenarios discussed above.

Questions and comments regarding this tutorial can be sent to the laboratory staff at the following e-mail address drawback@ttb.gov. Please do not send status requests to this e-mail.

TTB F 5154.1

Important definitions

TTB actions on formulas

Naming nonbeverage products

Format of submissions (entries in item 13)

TTB Form 5154.1 - common mistakes

<u>Classes of ingredients</u>

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For username and password please contact: Edward Limowski



THANK YOU!

Questions:

Contact: Julie Arthur



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