

2009 TTB Expo Presentation

# **Beverage Alcohol Pre-Import Basics**

Presented by  
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and Amanda Smith, Chemist



# Overview

- Advertising, Labeling and Formulation Division (ALFD)
- Part I: The Basics for Acquiring Pre-COLA Approval for Formulated Beverage Alcohol Products (Wine, Distilled Spirits, Malt Beverage)
- Helpful Hints and Resources
- Part II: Pre-Import Product Evaluation — Laboratory Analysis

ALFD

# ALFD's Mission

- Collect the Revenue:
  - **Ensure** proper tax classification
- Protect the Public:
  - **Verify** safety of ingredients
  - **Provide** adequate consumer information
  - **Prevent** consumer deception

# Legal Authority

- Federal Alcohol Administration Act
- Alcohol Beverage Labeling Act of 1988
- Webb-Kenyon Act
- Internal Revenue Code — Chapter 51

# Regulations

## 27 CFR:

- Part 4 – Labeling and advertising of wine
- Part 5 – Labeling and advertising of distilled spirits
- Part 7 – Labeling and advertising of malt beverages
- Part 19 – Distilled Spirits
- Part 24 – Wine
- Part 25 – Beer
- § 27.58 – Labeling of imported distilled spirits
- § 27.59 – Labeling of imported wine
- § 27.60 – Labeling of imported beer

# ALFD

## Formulation Team

- Gracie Joy, Assistant Director:
  - Roberta Sanders, Program Manager
  - Shonda Geddie, Formula Specialist
  - Stephen Robey, Formula Specialist
  - Michael Warren, Formula Specialist
  - Michelle Williams-Ellerbe, Program Analyst

Part I

The Basics of Acquiring  
Pre-Import Approval  
for Formulated Beverage  
Alcohol Products

# Industry Circular 2007-4

- Pre-Cola Requirements:
  - Laboratory analysis
  - Pre-import letter
  - Label only



- About TTB
- Advertising
- Careers
- EEO
- FAQs
- FOIA
- Forms
- Formulation
- Importers
- International Trade
- Labeling
- Laboratory
- National Revenue Center
- Student Research
- Trade Practices
- Tutorials and Job Aids
- Wholesalers
- Language Links

# FORMULATION

## How Do I Obtain Formula Approval?

For many alcohol beverage products, TTB must evaluate the product and approve its formula before issuing a Certificate of Label Approval (COLA) to determine whether a proposed label identifies the product in an adequate and non-misleading way. We refer to this requirement as a [Pre-COLA Product Evaluation](#).

There are four types of pre-COLA product evaluation. The type of pre-COLA product evaluation required for a particular product depends on that product's formulation and origin.

TTB regulations require formulas most commonly when [flavoring](#) or [coloring materials](#) are added to an alcohol beverage product. Since TTB does not have access to foreign plants, some imported products are subject to laboratory analysis or pre-import formula approval. For further information, visit the [Formulation](#) page.

## Do I Need Formula Approval for My Product?

To determine if your product requires formula approval and/or laboratory analysis, please use the drop down menus to first select your industry, and then the alcohol beverage product for which you are seeking label approval. Please identify whether the product is domestic or imported, and then click on SHOW ME.

# Methods of Submission

## 1. Letterhead Approval:

- Submitted on Foreign Producer's Letterhead
- Quantitative list of ingredients and Method of Production
- Signed and dated
- Importer's Permit

## 2. TTB F 5100.51:

- One form for all alcohol beverage products
- Legal size paper
- <http://www.ttb.gov/forms/f510051.pdf>
- Will be mandatory

The image shows the form TTB F 5100.51, titled 'FORMULA AND PROCESS FOR DOMESTIC AND IMPORTED ALCOHOLIC BEVERAGES'. The form is divided into several sections:

- 1. NAME AND ADDRESS OF APPLICANT / PRODUCER:** Includes fields for name and address.
- 2. CONTACT PERSON'S PHONE NUMBER:** Includes fields for name, phone number, and email.
- 3. PLANT / INDUSTRY / BASIC PERMIT / BUSINESS NAME:** Includes fields for plant name, industry, and permit/business name.
- 4. CLASS AND TYPE OF PRODUCT:** Includes a field for product name.
- 5. QUANTITATIVE LIST OF INGREDIENTS:** A large section for listing ingredients.
- 6. METHOD OF MANUFACTURE / PROCESS OF PRODUCTION:** A large section for describing the production process.
- 7. TOTAL YIELD:** Includes fields for number of gallons from alcohol, number of gallons from alcohol, and number of gallons from base.
- 8. ALCOHOL CONTENT OF FINISHED PRODUCT:** Includes fields for alcohol content and proof.
- 9. APPLICANT'S SIGNATURE AND DATE:** Includes fields for signature and date.
- 10. APPROVED BY THE SPECIALIST FOR THE ADMINISTRATOR, ALCOHOL AND TOBACCO TAX AND TRADE BUREAU:** Includes a field for the specialist's signature and date.
- 11. NUMBER IMPORT ONLY:** Includes a field for the import number.

The form also includes a section for 'FORMULATION' and 'LABELING' with checkboxes for various options. At the bottom, there is a note: 'TTB F 5100.51 (FORM 5100.51) (FORM 5100.51) (FORM 5100.51)'. The form is dated 10/1/00.

# TTB Form 5100.51

OMB NO. 1513-0122 (05/31/2009)

**FOR TTB USE ONLY**

TTB ID

1. NAME AND ADDRESS OF APPLICANT / IMPORTER  
(See Instructions):

**DEPARTMENT OF THE TREASURY**  
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU (TTB)  
**FORMULA AND PROCESS FOR DOMESTIC  
AND IMPORTED ALCOHOL BEVERAGES**  
(See Instructions and Conditions at the end of this form)

FORMULA #:

SUPERSEDING  
FORMULA

1a. MAILING ADDRESS (If different than above) / FOREIGN  
PRODUCER'S ADDRESS:

2. CONTACT PERSON'S PHONE NUMBER / E-MAIL ADDRESS:

3. PLANT REGISTRY / BASIC PERMIT / BREWER'S NUMBER:

4. CLASS AND TYPE OF PRODUCT:

5. PRODUCT NAME:

6. QUANTITATIVE LIST OF INGREDIENTS (If more space is  
needed, use space at the top of the next page or separate sheet):

7. METHOD OF MANUFACTURE / PROCESS OF PRODUCTION (If more space is  
needed, use space at the top of the next page or separate sheet):

# TTB Form 5100.51 (Continued)

8. TOTAL YIELD:		9. ALCOHOL CONTENT OF FINISHED PRODUCT ( <i>range may be shown</i> ):									
9a. AMOUNT OF ALCOHOL FROM FLAVORS:		9b. AMOUNT OF ALCOHOL FROM BASE:									
10. PRINTED NAME OF APPLICANT / IMPORTER:	11. BY ( <i>Signature and Title</i> )	12. DATE:									
FOR TTB USE ONLY (Items 13, 14, 15, and 16)											
<p>13. <b>FORMULATION:</b></p> <p><i>WINE PRODUCTS</i></p> <p><input type="checkbox"/> Approved subject to the provisions of 27 CFR _____</p> <p><i>DISTILLED SPIRITS PRODUCTS</i></p> <p><input type="checkbox"/> Harmless coloring, flavoring, or blending materials must not total more than 2.5% by volume of the finished product.</p> <p><input type="checkbox"/> Sugar, dextrose, or levulose or a combination thereof must be used in an amount not less than 2.5% by weight of the cordial or liqueur.</p> <p><input type="checkbox"/> The use of refining agents must not alter the basic composition of the spirits.</p> <p><input type="checkbox"/> The blended whiskey must contain not less than 20% straight whiskey on a proof gallon basis.</p>		<p><b>LABELING (<i>finished product only</i>):</b></p> <p><input type="checkbox"/> The designation of the product must include a truthful and adequate statement of composition, such as _____</p> <p>_____</p> <p>_____</p> <p><input type="checkbox"/> Commodity statement _____</p> <p><input type="checkbox"/> The label must indicate the use of:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;"><input type="checkbox"/> caramel color</td> <td style="width: 50%;"><input type="checkbox"/> certified color (<i>other than FD&amp;C Yellow #5</i>)</td> </tr> <tr> <td><input type="checkbox"/> artificial flavor</td> <td><input type="checkbox"/> FD&amp;C Yellow #5</td> </tr> <tr> <td><input type="checkbox"/> allergen(s): _____</td> <td></td> </tr> <tr> <td><input type="checkbox"/></td> <td></td> </tr> </table>		<input type="checkbox"/> caramel color	<input type="checkbox"/> certified color ( <i>other than FD&amp;C Yellow #5</i> )	<input type="checkbox"/> artificial flavor	<input type="checkbox"/> FD&C Yellow #5	<input type="checkbox"/> allergen(s): _____		<input type="checkbox"/>	
<input type="checkbox"/> caramel color	<input type="checkbox"/> certified color ( <i>other than FD&amp;C Yellow #5</i> )										
<input type="checkbox"/> artificial flavor	<input type="checkbox"/> FD&C Yellow #5										
<input type="checkbox"/> allergen(s): _____											
<input type="checkbox"/>											
14. DATE:	15. APPROVED – TTB SPECIALIST FOR THE ADMINISTRATOR, ALCOHOL AND TOBACCO TAX AND TRADE BUREAU		16. EXPIRES (IMPORT ONLY):								
TTB F 5100.51 (09/2007) (TTB FORMS 5110.38, 5120.29 SUPERSEDED)											

# Pre-COLA Evaluations

## Pre-Import Approval

- Method of manufacturing must be on producer's letterhead in English, signed and dated
- Requires submission of method of manufacture
  - Specific, quantitative list of all ingredients
  - Step-by-step description of production process
- Transmittal letter

## Lab Analysis

- Method of manufacturing must be on producer's letterhead in English, signed and dated
- Requires 750 ml sample or six-pack method of manufacture
  - Specific, quantitative list of all ingredients
  - Step-by-step description of the production process
- Transmittal letter

# Important Formula Components

- Colors:
  - Certified, non-certified, prohibited colors
- Flavors
- Flavor Ingredient Data (FID) sheets
- Food additives

# Certified Colors

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)
*Requires specific declaration on labels for finished alcohol beverages.		

# Non-Certified Colors

- Annatto Extract
- Astaxanthin
- Dehydrated beets (beet powder)
- Dried algae meal
- Canthaxanthin
- Caramel color
- Carmine (Cochineal Extract)
- Carrot oil
- Corn endosperm oil
- $\beta$ -Apo-8'-carotenal
- $\beta$ -Carotene
- Elderberry Extract\*
- Ferrous gluconate
- Ferrous lactate
- Fruit Juice
- Grape color extract
- Grapeskin Extract (Enocianina)
- Haematococcus algae meal

# Non-Certified Colors (Continued)

- Paprika
- Paprika oleoresin
- Phaffia yeast
- Riboflavin
- Saffron\*
- Sodium copper chlorophyllin
- Synthetic iron oxide
- Tagetes (Aztec marigold) meal and extract
- Titanium Dioxide
- Toasted partially defatted cooked cottonseed flour
- Tomato lycopene extract; tomato lycopene concentrate
- Turmeric\*
- Turmeric oleoresin
- Ultramarine blue
- Vegetable Juice

# Flavors Classified As

- Natural:
  - All natural
  - Natural and artificial containing ***not more than*** .1% artificial content in topnote
- Artificial:
  - All artificial
  - Natural and artificial containing ***greater than*** 0.1% artificial content in topnote
- Non-Flavor (e.g., Cloud Emulsion)

# Flavor Ingredient Data Sheet

- Name of flavor company
- TTB identification number
- Name of flavor
- Classification
- Limited ingredients
- Colors

**FLAVOR INGREDIENT DATA SHEET**

**Flavor Producer Information**

(A) ATF Co. Code: \_\_\_\_\_ (B) Date: \_\_\_\_\_  
 (C) Company Name: \_\_\_\_\_ (D) Phone: \_\_\_\_\_  
 (E) ADDRESS: \_\_\_\_\_ (F) Fax: \_\_\_\_\_  
 (G) Contact Person: \_\_\_\_\_

(H) Flavor Name: \_\_\_\_\_  
 (J) ATF Number (Form 1678): \_\_\_\_\_  
 (K) Alcohol Range by Volume: \_\_\_\_\_  
 (L) Flavor Product number: \_\_\_\_\_

**(M) Check Appropriate Box:**

Approved for Drawback (DRB)   
 Approved as No Action (N/A)   
 Approved for Export Only (Exp)   
 Submitted for ATF Approval   
 Not Yet Submitted for ATF Approval

**(N) Classification**

Natural  N&A<=0.1% Topnote  N&A>0.1% Topnote  Art  Non-Flavor

Total Artificial Flavor Content: \_\_\_\_\_ ppm (Excluding Synthetic Vanillin, Ethyl Vanillin, Synthetic Maltol and Ethyl Maltol)

**(O) Flavor Components**

Additive	ATF Limitation in finished Product	Amount of additive or Agent present in flavor	Beverage label information based on functionality (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	1000.0 ppm	_____ ppm	7. Grapeskin Extract <input type="checkbox"/>
8. Gum Arabic /Acacia	10000.0 ppm	_____ ppm	8. Caramel Color <input type="checkbox"/>
9. Propylene Glycol	50000.0 ppm	_____ ppm	9. Annatto <input type="checkbox"/>
10. BHA	(<0.5% of Essential Oil)	<input type="checkbox"/> check if contained	10. Elderberry Extract <input type="checkbox"/>
11. Acetic Acid	1500.0 ppm	_____ ppm	11. Beet Extract <input type="checkbox"/>
12. _____	_____ ppm	_____ ppm	12. Oak Extract <input type="checkbox"/>
13. _____	_____ ppm	_____ ppm	13. _____ <input type="checkbox"/>
14. _____	_____ ppm	_____ ppm	14. _____ <input type="checkbox"/>

**(P) Confidential Limited Ingredients Not Shown (CLI)**

Check if contained in formula  Check if CLI was previously submitted

Beverage Manufacturer / Importer: \_\_\_\_\_ Formula # / Serial Number: \_\_\_\_\_

Flavor Company Rep Signature: \_\_\_\_\_ Title: \_\_\_\_\_ Date: 04/13/06

**(Q) Beverage Alcohol Manufacturer/Importer**

Beverage Manufacturer / Importer: \_\_\_\_\_ Formula # / Serial Number: \_\_\_\_\_

Flavor approved on: \_\_\_\_\_ Notified by: \_\_\_\_\_ As: \_\_\_\_\_

SIGNATURE OF ALCOHOL BEVERAGE REPRESENTATIVE: \_\_\_\_\_

Drawback   
 No Action   
 Export Only

6/1/98

# Food Additives

- GRAS — Generally Recognized As Safe
- Restricted Ingredients — GRAS with maximum use rate
- Prohibited ingredients

# Wine Products

# Pre-COLA Evaluation Required

- Agricultural Wine:
  - Honey Wine
  - Sake
  - Dried Fruit Wine
  - Other Agricultural Wine
- Aperitif Wine:
  - Vermouth – Italian Vermouth does not require pre-COLA approval
- Ice Wine
- Imitation Wine
- Asian Plum Wine
- Retsina Wine
- Substandard Wine
- Other Than Standard (OTS) wine

# Agricultural Wine

- Honey wine/Mead
- Sake/Rice wine
- Dried fruit wine
- Other agricultural wine

# Honey Wine/Mead

- Produced from fermented honey
- Honey-water mixture not less than 13 degrees Brix
- Up to 1 pound of hops per 1,000 pounds of honey
- Final ABV not to exceed 14%
- Final Brix content not more than 35 degrees Brix
- Sugar or honey may be added to sweeten
- Pre-import approval letter required

# Sake/Rice Wine

- Produced from rice at brewery
- Sake is taxed as malt beverage-but can also be taxed as distilled spirit when alcohol is added
- Labeled as wine
- Laboratory analysis letter is required

# Dried Fruit Wine

- May reduce to 22 degrees Brix
- Fixed acid level minimum 5 grams/liter
- Volume of ameliorating material may not exceed 35% of wine
- Example: Raisin Wine
- Pre-import approval letter is required

# Other Agricultural Wine

- Weight of sugar less than wine material
- Final alcohol content is not more than 14% alcohol by volume
- Final total solids content is not more than 35 degrees Brix
- Minimum Brix prior to fermentation is 22 degrees
- Example: Dandelion Wine, Rhubarb Wine, Agave Wine
- Pre-import approval letter is required

# Aperitif Wine

- Wine having alcohol content of not less than 15%
- Produced from grape wine, containing added brandy
- Flavored with herbs and other natural aromatic flavor materials
- With or without caramel color
- Vermouth is a type of aperitif wine
- Aperitif wine is sufficient as a class and type designation

# Wine Specialty

- Produced by:
  - Blending different types of finished fruit wine (e.g., grape wine and peach wine)
  - Flavors, fruits, oils, extracts, juices, concentrates, spices, essences, or coloring materials are added to wine
- Pre-import approval letter required

# Fortification of Imported Wine

- May be fortified with grain and/or fruit spirits provided country of origin permits process
- Documentation is required from foreign government to allow for fortification

# Distilled Spirits

# Requiring Pre-COLA Evaluation

- Vodka
- Whiskey
- Gin
- Brandy:
  - Lees
  - Marc
  - Neutral
  - Grappa
- Liqueurs/Cordials
- Flavored products
- Recognized cocktails
- Imitation products
- Distilled spirits specialty

# Vodka

- Neutral spirits produced without distinctive character, aroma, taste, or color
- Distilled at or above 95% ABV or 190 proof
- Bottled at not less than 40% ABV or 80 proof
- Citric Acid – Max 0.1% by volume
- Sugar – Max 0.2% by volume
- Laboratory analysis approval letter is required

# Whiskey

- Spirits distilled from fermented mash of grain
- Distilled at less than 95% ABV, or 190 proof and bottled at not less than 40% ABV, or 80 proof
- Formula approval required only if there is blending material
- Storage in certain types of containers requires storage proof:
  - e.g., charred or uncharred oak
  - New or used containers
- Storage proof is required
- Laboratory analysis letter is required

# Gin

- Distilled gin:
  - Mash is distilled with Juniper berries
- Redistilled gin:
  - Spirits are distilled with Juniper berries
- Compound gin:
  - Spirits are blended with Juniper berry flavor
- Pre-import approval letter is required

# Brandy

- Distilled from fermented juice, mash, or wine of fruit or from its residue
- Distilled at less than 95% ABV, or 190 proof
- Bottled at or above 40% ABV, or 80 proof
- Having general taste, aroma, and characteristics generally attributed to brandy
- Different types:
  - Lees
  - Marc
  - Neutral
  - Grappa
- Laboratory analysis letter required

# Liqueur/Cordial

- Contains spirits
- Contains flavor(s)
- Contains not less than 2.5% sugar by weight
- Up to 49% wine on a proof gallon basis
- Pre-import approval letter is required

# Flavored Products

- Includes flavored rum, gin, vodka, brandy, whiskey
- Bottled at not less than 30% ABV or 60 proof
- Predominant flavor is part of class and type designation; e.g., “Apricot Flavored Brandy”
- No minimum/maximum sugar requirements
- Up to 2.5% by volume wine
- Flavored brandy:
  - Up to 15% by volume wine, if it is same fruit as predominant flavor
- Laboratory analysis letter is required

# Recognized Cocktails

- Mixed drinks that have gained “trade” and “consumer” recognition
- Contain one or more classes and/or types of distilled spirits with flavoring and/or coloring materials
- Requires statement of composition on label:
  - May only need to state spirit and any coloring materials
  - e.g., Margarita made with tequila, triple sec liqueur, and FD&C Yellow #5
- Pre-import approval needed

# Imitation Products

- Artificial flavors
- Simulates another class and type
- Brandy with sugar added to mash
- Flavored Vodka with artificial flavoring material
- Pre-import letter is required

# Distilled Spirits Specialty

- Distilled spirits not defined under any other class
- Generally, any class and/or type of distilled spirits that contains or are treated with flavoring and/or coloring materials and/or nonstandard blending or treating materials or processes
- Requires truthful and adequate statement of composition; however, a distinctive or fanciful product name with statement reflecting composition and character of product is sufficient as class and type
- Pre-import approval letter is required

# Malt Beverage

# Class and Type Designations

- Malt Beverage Specialty:
  - Flavored malt beverages
- Ice Beer
- Alcohol-Free Malt Beverages

# Malt Beverage Specialty

- In general, any product that has:
  - Flavors, colors, spices, fruit, or honey added
  - Anything outside of standard brewing ingredients of barley (or an adjunct such as rice, corn, or wheat), hops, water, and yeast
- Any fermented product that will be treated by any processing, filtration, or other method not generally recognized as traditional process
- Pre-import approval letter is required

# Flavored Malt Beverages

- Any malt beverage product that has flavors added
- Flavors may be alcoholic or non-alcoholic
- Requires a statement of composition:
  - Description of what is in product (e.g., Malt beverage with natural flavors added)
- Pre-import approval letter is required

# Ice Beer

- Not more than 0.5% of beer can be removed as ice crystals
- ATF Ruling 94-3
- Pre-import approval letter is required

# Alcohol-Free Malt Beverages

- Must contain 0.0% alcohol by volume
- Alcohol must be produced through fermentation
- Alcohol is removed after fermentation
- Laboratory analysis letter is required

# **Helpful Hints and Resources**

# Items to Remember

- Supply a complete quantitative list of ingredients
- Supply detailed method of production
- Provide proof at distillation
- Provide name, address, and TTB number for all flavors
- Provide botanical name for herbs and plant extracts
- Be sure all documents are legible and in English
- Pre-Import Letters/Laboratory Analyses for imported beverage alcohol products expire five years after the date of approval

# Resources

- [www.ttb.gov](http://www.ttb.gov)
- TTB Industry Circular 2007-4
- TTB Industry Circular 2007-5
- Formula Approval Tool
- [www.fda.gov](http://www.fda.gov)

# ALFD Contact Information

- **Phone:**

Customer Service Desk (202) 453-2250  
or Toll Free (866) 927-ALFD (2533)

- **Mail:**

Advertising, Labeling and Formulation Division  
1310 G Street, NW, 4th Floor  
Washington, DC 20220

**Questions?**

## Part II

# Pre-Import Product Evaluation — Laboratory Analysis

# Who Handles Pre-Import Product Evaluation?

- ALFD — Formulation Team
- Scientific Services Division (SSD):
  - Beverage Alcohol Laboratory (BAL)
  - Nonbeverage Products Laboratory (NPL)
  - Compliance Laboratory (CL)
  - Tobacco Laboratory (TL)

# Beverage Alcohol Laboratory

**Jeffrey Ammann, Ph.D., Chief**

**(240) 264-1596**

**Sherrie High, Legal Instruments Examiner**

**(240) 264-1665**

**James Jaganathan, Ph.D., Senior Scientist**

**(240) 264-1586**

**Armen Mirzoian, Ph.D., Senior Chemist**

**(240) 264-1598**

**Michael Webster, Chemist**

**(240) 264-1660**

**Fan Ni, Ph.D., Chemist**

**(240) 264-1585**

**Neil Pennington, Chemist**

**(240) 264-1599**

**Jessica Gray, Chemist**

**(240) 264-1670**

**Leticia Drakeford, Chemist**

**(240) 264-1587**

**Amanda Smith, Chemist**

**(240) 264-1592**

# Pre-Import Product Evaluation

# Pre-Import Product Evaluation

- Submit only what requires evaluation
- Consult Industry Circular 2007-4 found on TTB Web site ([www.ttb.gov](http://www.ttb.gov)); click on Research Resources, then click on Industry Circulars:
  - Describes evaluations that some products must undergo
  - Sets forth TTB F 5100.51 use procedure

# Types of Pre-Import Product Evaluation

- Formula (N/A, domestic only)
- Pre-import letter — send letter to ALFD
- Laboratory analysis — send sample to laboratory
- Sulfite Analysis — send sample to laboratory

**Difference between laboratory analysis and pre-import letter approval = chemical analysis**

PRODUCT	DOMESTIC (D) OR IMPORTED (I)	LABORATORY ANALYSIS	PRE-IMPORT LETTER	FORMULA F 5100.51 or F 5110.38	COMMENT
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PRODUCT	DOMESTIC (D) OR IMPORTED (I)	LABORATORY ANALYSIS	PRE-IMPORT LETTER	FORMULA (TTB F 5100.51 or TTB F 5110.38)	COMMENT
A Blend Of Straight Bourbon Whiskies Or Blended Straight Bourbon Whiskies	D	-	-	-	PRODUCT OF U.S. ONLY
	I	-	-	-	
Amaretto	D	-	-	X	
	I	-	X	-	

Blended Straight Wheat Whiskies	I	X	-	-	
A Blend Of Straight Whiskies Or Blended Straight Whiskies	D	-	-	-	
	I	X	-	-	
Advocaat	D	-	-	X	
	I	-	X	-	
Alcohol	D	-	-	-	
	I	-	-	-	
Amaretto	D	-	-	X	
	I	-	X	-	
Anise	D	-	-	X	
	I	-	X	-	
Anisette	D	-	-	X	
	I	-	X	-	

# Submitting Samples

- If sample requires laboratory analysis, send following to laboratory:
  - 750 mL sample
  - Copy of TTB issued basic import permit (for first-time importers)
  - TTB F 5100.51, “Formula and Process for Domestic and Imported Alcoholic Beverages” (optional)
  - Statement of production on manufacturer’s official letterhead:
    - Quantitative list of all ingredients
    - Method of manufacture

# Submitting Samples (Continued)

- Statement of production **must** provide:
  - Agricultural source of alcohol
  - Proof at distillation, which is highest proof of distillate before dilution to bottling proof (for distilled products)
  - Identification and source of any flavoring material used in product (botanical names for natural flavors)
  - Specific description of when flavoring material is added in manufacture of product
  - Total volume and percent alcohol by volume of finished product

# *We Love Alcohol Distillery*

*6000 Ammendale Road  
Ammendale, MD 20705*

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Recipe for Iced Tea Flavored Vodka

April 18, 2009

## **Ingredients for 1000 L of product:**

alcohol	313.0 L (neutral alcohol distilled from wheat at a minimum of 96.0 % alc. by vol. or 192 proof)
water	428.1 L
sugar	115.0 kg
tea leaves	45.36 kg ( <i>Camellia sinensis</i> )
spearmint	22.68 kg ( <i>Mentha spicata</i> , FEMA GRAS # 3030)
artificial iced tea flavor	20 L (ATF (or TTB) # 1 - from We Love Flavors, Inc. in Ammendale, MD, approved 8/31/2007)

## **Method of Manufacture:**

1. Wheat is ground and fermented. The ferment is then distilled in a pot still. After the final distillation the alcohol is 192 proof. The distillate is filtered through charcoal filters.
2. Tea leaves and mint are steeped in the alcohol from step 1 for 2 weeks. After 2 weeks the tea leaves and mint are removed.
3. The alcohol from step 2 is then mixed with the iced tea flavor purchased from We Love Flavors. Next water is added to bring the alcohol content to 40%. The final product is aged in stainless steel tanks for 2 weeks. It is then bottled.

*Jane Doe 4/18/09*

Jane Doe, Chief Distiller

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**EXAMPLE—This is a fictional example recipe, it is not an actual product.**

# Submitting Samples (Continued)

- Visit Laboratory section on [www.ttb.gov](http://www.ttb.gov) for details
- Ensure that flavors are evaluated by NPL **before** submitting beverage to BAL
- Submit **beverage** samples to BAL and **flavor** samples to NPL at:

TTB National Laboratory Center  
Beverage Alcohol Laboratory or  
Nonbeverage Products Lab  
6000 Ammendale Road  
Beltsville, MD 20705-1250

*For Flavors: Please request “Foreign  
Flavor Producer Packet”*



The screenshot shows the TTB.gov Laboratory section. The header includes the TTB.gov logo, the text "ALCOHOL AND TOBACCO TAX AND TRADE BUREAU U.S. Department of the Treasury", and a search bar. Below the header is a navigation menu with tabs for HOME, BEER, WINE, DISTILLED SPIRITS, OTHER ALCOHOL, TOBACCO, and FIREARMS & AMMUNITION. The main content area is titled "LABORATORY" and features the "Scientific Services Division" section. This section includes a list of laboratories: Beverage Alcohol Laboratory, Nonbeverage Products Laboratory, Compliance Laboratory, Tobacco Laboratory, and SSD Quality and Safety Program. There is also a "Quick Links" sidebar with various links such as "SSD Home", "Organizational Chart", "Laboratory Forms", "Drawback Tutorial", "Chemist Certification", "Methods and Procedures", "Limited Ingredients", "A2LA Accreditation", "FAQs", "Scientific Publications", "Useful Links", and "Flavor Ingredient Data Sheet (FIDS)". At the bottom, there is a "News and Events" section with a "View Calendar" link and a "Contacts" link.

# Submitting Samples (Continued)

- Remember:
  - All of the documents must be in English!
  - If the original document is in a foreign language, submit the original along with an English translation signed by the translator.

## Submitting Samples (Continued)

- Turnaround time is 2 months
- Receipt letter sent by BAL LIE to submitter
- Laboratory analysis done by BAL
- Laboratory report sent to ALFD
- Response sent from ALFD to submitter
- Free!!!!

**LAB NUMBER LABEL DESCRIPTION**

---

**B-2009-00123**

**Tea Time**

**Please retain this form for reference. If you have any questions regarding this form, contact the Legal Instruments Examiner of the Beverage Alcohol Laboratory, (240) 264-1665.**

**The Beverage Alcohol Laboratory received your sample and the request for analysis on **April 28, 2009.****

**Sample analysis is in progress. Once analysis is completed, the lab report will be sent to the Advertising, Labeling, and Formulation Division (ALFD), where all of the paperwork will be reviewed for final classification of your product. Please allow **2 months** for this process to be completed.**

**Any inquiries concerning the status of a sample should be directed to the ALFD, (202) 435-2250.**

**LAB NUMBER LABEL DESCRIPTION**

**B-2009-00124 Mystery Hooch**  
**B-2009-00125 Shoe Shine Brandy**

**The Beverage Alcohol Laboratory received your sample and the request for analysis on April 28, 2009.**

The submitted **sample will be destroyed** without analysis after July 28, 2009 unless we received the requested information. Any inquiries concerning the status of a sample should be directed to the ALFD, (202) 435-2250.

may also request additional information.

**dated** by an official of the manufacturing company.

**Please retain this form for reference. If you have any questions regarding this form, contact the Legal Instruments Examiner of the Beverage Alcohol Laboratory, (240) 264-1665.**

**results will be sent to the ALFD, where all of the paperwork will be reviewed for final classification of your product. Please allow 2 months for this process to be completed.**

**The submitted sample will be destroyed without analysis after July 28, 2009 unless we received the requested information. Any inquiries concerning the status of a sample should be directed to the ALFD, (202) 435-2250.**

# Laboratory Analysis

# What Does Lab Analysis Involve?

- **Routine analyses** to determine class and type using AOAC methods or equivalent:
  - Alcohol by volume (density metering apparatus)
  - Specific gravity (density metering apparatus)
  - Fusel oils (gas chromatography)
  - Methanol (gas chromatography)
  - Solids (evaporation)
  - Total acids (autotitrimer)
  - Sodium and potassium (atomic absorption)

# What Does Lab Analysis Involve?

## (Continued)

- **Special analyses on case-by-case basis:**
  - Additives
    - Synthetic colors (high performance liquid chromatography)
    - Propylene glycol (gas chromatography)
  - Prohibited or limited ingredients
    - Coumarin (gas chromatography/mass spectrometry)
    - Stevioside (high performance liquid chromatography)
    - Benzoic acid (ultra performance liquid chromatography)
  - Contaminants
    - Pesticides (gas chromatography/mass spectrometry)
    - Lead (inductively coupled plasma mass spectrometry)
  - Authentication
    - Agricultural source (stable isotope ratio mass spectrometry)

# Typical Submissions for Pre-Import Laboratory Analyses

# Typical Products Submitted for Pre-Import Lab Analysis

- **Vodka:**
  - Must be distilled at or greater than 190 proof
  - Can be distilled from any agricultural source
  - Can only have small amounts of citric acid and sugar added
  - Must be without distinctive character, aroma, taste, or color
- **Rice Wine (Sake):**
  - Must derive alcohol from rice fermentation
  - Can contain added alcohol; but finished product is taxed as distilled spirit
- **Grappa (Brandy):**
  - Must be distilled at less than 190 proof
  - Must be distilled from the skin and pulp of sound, ripe grapes
  - Must contain less than 0.35% v/v methanol

# Sulfite Analysis

- Products with total sulfites between 10–350 parts per million (ppm) require sulfite warning label
- For waiver of this label, submit sample to:
  - TTB National Laboratory Center OR
  - Private laboratory certified by TTB (see [www.ttb.gov](http://www.ttb.gov))
- For waiver, product must have less than **10 ppm** total sulfites
- To be labeled “sulfite free” product must not have **ANY** detectable sulfites

# Special Cases

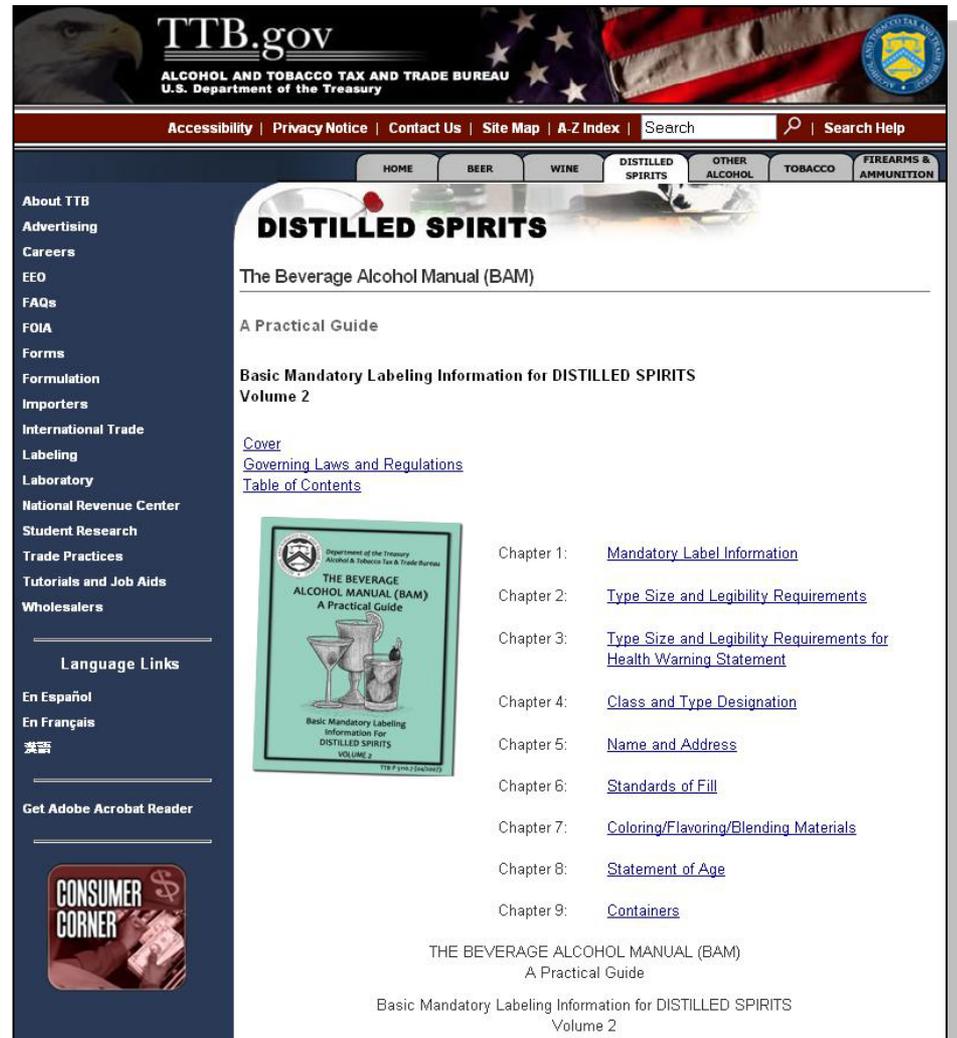
- Diluted Products — under proof:
  - Resubmit for testing **OR**
  - Label so that “Diluted” appears as part of class/type (e.g., “Diluted Rum”)
- Imitation Liqueurs — containing artificial flavors:
  - Reformulate using natural flavor(s) **OR**
  - Request product be classified as “Distilled Spirits Specialty” **OR**
  - Classify product as “Imitation Liqueur”

# Helpful Hints

- Provide quantitative list of ingredients
- Supply **complete** method of manufacture
- Include proof at distillation and final product ABV
- Provide flavor name, flavor manufacturer name and address, TTB number, and approval date for all flavors, and **ensure that flavors are approved**
- Provide botanical name for herbs and plant extracts
- Ensure all documents are legible and in English
- Expect turnaround time of 2 months

# Resources

- [www.ttb.gov](http://www.ttb.gov)
  - Industry Circular 2007-4
  - Beverage Alcohol Manual
- [www.fda.gov](http://www.fda.gov)



**TTB.gov**  
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU  
U.S. Department of the Treasury

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HOME BEER WINE DISTILLED SPIRITS OTHER ALCOHOL TOBACCO FIREARMS & AMMUNITION

**DISTILLED SPIRITS**

The Beverage Alcohol Manual (BAM)

A Practical Guide

Basic Mandatory Labeling Information for DISTILLED SPIRITS  
Volume 2

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THE BEVERAGE ALCOHOL MANUAL (BAM)  
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Basic Mandatory Labeling Information for DISTILLED SPIRITS  
Volume 2

CONSUMER CORNER

# Contact Information

- Advertising, Labeling and Formulation Division
  - **Phone:** Customer Service Desk (202) 435-2250 or Toll Free (866) 927-ALFD (2533)
  - **Mail:** Advertising, Labeling and Formulation Division  
1310 G Street, NW, 4th Floor  
Washington, DC 20220
- Beverage Alcohol Laboratory
  - Jeffrey Ammann, Chief
  - **Phone:** 240-264-1596
  - **Mail:** Beverage Alcohol Laboratory  
6000 Ammendale Rd.  
Beltsville, MD 20705-1250