



#### Agenda

#### PART I

- Advertising, Labeling and Formulation Division (ALFD)
- Basics of TTB Formulation
- Wine
- Distilled Spirits
- Malt Beverage

#### PART II

- Beverage Alcohol Laboratory, Scientific Services Division (SSD)
- Pre-Import Product Evaluation
- Laboratory Analysis
- Typical Submissions for Pre-Import Laboratory Analyses

# Advertising, Labeling and Formulation Division



#### **ALFD's Mission**

- · Collect the Revenue
  - Proper tax classification
- Protect the Public
  - Verify the safety of the 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

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## Laws and Regulations

- 27 CFR part 4, Labeling and advertising of wine
- 27 CFR part 5, Labeling and advertising of distilled spirits
- 27 CFR part 7, Labeling and advertising of malt beverages
- 27 CFR part 19, Distilled Spirits
- 27 CFR part 24, Wine
- 27 CFR part 25, Beer
- 27 CFR part 27, Importation of distilled spirits, wines, and beer



#### **ALFD Formulation Team**

- · Gracie Joy, Assistant Director
  - Roberta Sanders, Program Manager
  - Shonda Geddie, Formula Specialist
  - Michael Warren, Formula Specialist
  - Stephen Robey, Formula Specialist

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The Basics of Formulation



#### **Forms**

- Domestic Wine TTB F 5120.29
- Domestic Distilled Spirits TTB F 5110.38
- Domestic Malt Beverage Formula
- Imported Product Pre-Import Approval letter or Laboratory Analysis
- In the future, all formulas should be submitted on a single form, TTB F 5100.51

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# TTB Expo

#### **Proposed TTB F 5100.51**



- One form for all
- · Legal size paper
- http://www.ttb.gov/for ms/f510051.pdf
- Currently voluntary, but will be mandatory

TTB Expo	TTB Form	Form 5100.51			
	1	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 Instancias and Conditions at the end Offits bm)	FORMULA #:  SUPERSEDING FORMULA			
	2. CONTACT PERSON'S PHONE NUMBER / E-MAIL AD				
	3. PLANT REGISTRY / BASIC PERMIT / BREWER'S NUM	MBER:			
<ol> <li>MAILING ADDRESS (If different than above) / FOREIGN PRODUCER'S ADDRESS:</li> </ol>					
	CLASS AND TYPE OF PRODUCT:				
	5. PRODUCT NAME:				
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 PROD needed, use space at the top of the next page or separate				

D E				н	B For			
BE	xpc				(00	ont'c	1)	
8. TOTAL YIEI	.D:				DL CONTENT OF FINISHED CT (range may be shown):			
9a. AMOUNT C				9b. AMOUN	T OF ALCOHOL			
	FROM FLAVORS:  0. PRINTED NAME OF APPLICANT / IMPORTER:  11. BY (S.		11. BY (Sign	FROM E			12. DATE:	
IO. I MINIED I	WINE OF AFFE	JOSET FINI ORTER.	11. BT (Sigi	name and i	n~,		Us. Desta	
		F	OR TTB USE O	ONLY (Items	13, 14, 15, and 16)			
13. FORMU	ATION:				BELING (finished product only):			
A	RODUCTS  pproved subject  CFR  D SPIRITS PR	t to the provisions of			The designation of the product r statement of composition, such		and adequate	
□ ;	larmices colorin	g, flavoring, or blending me	terials must no	pt .				
Sugar, dextrose, or levalose or a combination thereof muse be used in an amount not less than 2.5% by weight of the cordial or fliqueur.  The use of refining agents must not alter the basic composition of the spirits.			n thereof must	must	Commodity statement  The label must indicate the use			
			basic		caramel color	olor (other than llow #5)		
		skey must contain not less on a proof gallon basis.	than 20%		artificial flavor	FD&C Yel	low #5	
14. DATE:		15. APPROVED – TTB S TOBACCO TAX AND TRA		R THE ADM	IINISTRATOR, ALCOHOL AND	16. EXPIRES	(IMPORT ONLY):	

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## TTB Industry Circular 2007-4

- Import requirements
   Domestic
  - Laboratory Analysis
  - Formula Only
  - · Label Only

- Domestic requirements
  - Laboratory Analysis
  - Formula Only
  - · Label Only

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#### What We Look For

- Colors
  - Certified, non-certified, prohibited
- Flavors and Flavor Ingredient Data (FID) sheets
- · GRAS ingredients
- Restricted and Prohibited Ingredients



#### **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.

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#### **Non-Certified Colors**

- Annatto Extract
- Astaxanthin
- Dehydrated beets (beet powder)
- Dried algae meal
- Canthaxanthin
- Caramel
- Carmine (Cochineal Extract)
- Carrot oil
- Corn endosperm oil

- β-Apo-8'-carotenal
- β-Carotene
- Elderberry Extract\*
- Ferrous gluconate
- Ferrous lactate
- Fruit Juice
- Grape color extract
- Grapeskin Extract (Enocianina)
- Haematococcus algae meal
- Paprika



## Non-Certified Colors (Cont'd)

- · 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

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#### **Flavors**

- Flavors are classified as:
  - All Natural
  - Natural and Artificial Containing Not More Than 0.1% Artificial Content in the Topnote
  - Natural and Artificial Containing Greater Than 0.1%
     Artificial Content in the Topnote
  - All Artificial
  - Non-Flavor: The product is not a flavor (e.g., Cloud Emulsion)
- Submit to our lab first
- May contain colors



## Flavors (Cont'd)

 Flavor manufacturers use FIDS to give the beverage manufacturer relevant information about their flavor

	Flavor	Producer Information			
(A) ATF Co. Code:			(B) Date:		
(C) Company Name:			(D) Phone:		
			(F) Fax:		
(E) ADDRESS:			(G) Contact Person:		
-			(M) Check Appropriate Box;		
(H) Flavor Name:			Approved for Drawback (DrB)		
(J) ATF Number (Form1678):			Approved as No Action (N/A)		
(K) Alcohol Range by Volume:			Approved for Export Only (Exp)		
(L) Flavor Product number:			Submitted for ATF Approval		
			Not Yet Submitted for ATF Approval		
		) Classification			
Natural	N&A=<0.1% Topnote	N&A>0.1% To	pnote Art Non-Flavor		
Total Artificial Flavor Content:	ppm (Exch	uding Synthetic Vanillin, Ethyl Van	ilin, Synthetic Maltol and Ethyl Maltol)		
	(O) F	lavor Components			
	ATF Limitation	Amount of additive or	Beverage label information based on functionality		
Additive	in finished Product	Agent present in flavor	(Check or list label ingredients		
			that affect the beverage label)		
Synthetic Vanillin	40.0 ppm	ppm	1. FDSC Yellow #5		
2. Ethyl Vanilin	16.0 ppm	ppm	2. FD&C Yellow # 6		
3. Synthetic Maltol	250.0 ppm	pom	3. FD&C Blue # 1		
4. Ethyl Matol	100.0 ppm	pom	4. FDSC Bue # 2		
5. Ester Gum	100.0 ppm	ppm	5. FD&C Green #3		
6. RVO	15.0 ppm	ppm	6. FDBC Red # 40		
7. Sodium Benzoste	1000.0 ppm	ppm	7. Grapeskin Extract		
8. Gum Arabic /Acacia	10000.0 ppm	ppm	8. Caramel Color		
Propylene Glycol	50000.0 ppm	ppm	9. Annatio		
10. BHA	(<0.5% of Essential OII)	check if contains			
11. Acetic Acid	1500.0 ppm	Dom Contains	11. Beet Extract		
12	ppm	ppm	12. Oak Extract		
13	pom	pom	13.		
14.	pom	pom	14.		
	- Paris		"—— F		
	(P) Confidential Lim Check if contained in form	ited Ingredients Not Shown	(CLI) Check if CLI was previously submitted		
Beverage Manufacturer /		na []	CiteOx ii CEI was previously submitted		
activity instance is		/ Serial Number:			
Flavor Company Rep S	ignature: Title:		Date: 04/13/06		
	(O) Benerana é	ücohol Manufacturer/Importer			
Beverage Manufa	cturer / Importer:		Formula # / Serial Number: Drawback		
		N-116- 41			
Flavor approved	onc	Notified by:	As: No Action [ Export Only [		
	ALCOHOL BEVERAGE REP		Espair only [		

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## **GRAS & Restricted Ingredients**

- GRAS
  - Generally Recognized as Safe
- U.S. Food and Drug Administration
- Restricted Ingredients

# Wine Formulation



# Class and Type Designations

- Agricultural Wine
  - Sake
  - Honey Wine
  - Other Agricultural Wine
  - Dried Fruit Wine
- Aperitif Wine
- Fruit Wine
- Retsina Wine
- Carbonated and Sparkling wines
- Other Than Standard (OTS) wine



# Agricultural Wine – Major Types

- · Honey Wine/Mead
- Sake/Rice Wine
- Rhubarb Wine
- Flower Wine
- Agave Wine
- Raisin Wine
- · Other Agricultural Wine

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## **Agricultural Wine**

- Approved per 27 CFR 24.200
- Grain, cereal, malt, or molasses are not allowed
- · May not be flavored or colored



## Honey Wine/Mead 27 CFR 24.203



- 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

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## **Sake/Rice Wine 27 CFR 4.21(f)(5)**

- · Produced from rice at a brewery
- Domestic Sake is taxed as malt beverage
- Imported Sake may be taxed as a distilled spirit if spirits are added
- · Labeled as a wine



## Dried Fruit Wine 27 CFR 24.202

- May reduce to 22 degrees Brix
- Fixed acid level minimum 5 grams/liter
- Volume of the ameliorating material may not exceed 35% of the wine

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## Other Agricultural Wine 27 CFR 24.204

- 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



## Aperitif Wine 27 CFR 4.21(g)

- 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

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## Special Natural Wines 27 CFR 24.195

- Flavors must be all natural
  - Herbs, Spices, Fruit Juices, Natural Aromatics, and Natural Essences may be added
- May contain caramel color, but may not contain certified color
- Requires a formula approval with a statement of composition



## Fruit Wine 27 CFR 4.21(e)

- · Wine produced by:
  - the normal alcoholic fermentation of the juice of sound, ripe fruit (other than grapes or citrus)
  - with or without added fruit brandy or alcohol
- "Fruit wine" is not a sufficient class and type designation
  - e.g., Apple Wine, Strawberry Wine, Peach Wine
- Fruit wine not derived wholly from one kind of fruit or berry may be designated as fruit wine or berry wine qualified by a truthful and adequate statement of composition

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## Retsina Wine 27 CFR 4.21(i)

- Grape table wine flavored or fermented with pine resin
- After March 10, 2006, product of Greece only



## Sparkling and Carbonated Wine 27 CFR 4.21(b) and (c); 27 CFR 24.190

- Sparkling wine occurs from secondary fermentation in a closed container
- Carbonated wine is a result of other than secondary fermentation in a closed container
- Carbonated wine has at least 0.392 grams of CO<sub>2</sub> per 100 mL
- May not contain more than 14% ABV

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## Other Than Standard Wine 27 CFR 24.218

#### Formula is required

- Made in various ways:
  - By blending different types of finished fruit wine, e.g., Grape wine and Peach wine
  - Flavors, fruits, extracts, juices, concentrates, spices, essences, or coloring materials are added to wine



## Fortification of Domestic Wine

- Domestic wines may only be fortified with fruit spirits produced in the U.S.
  - e.g., Grape brandy, citrus brandy, apple brandy
- If the wine and fruit spirit are not kind to kind, then the spirit is required in the statement of composition
  - e.g., Peach wine with grape brandy added





## Class and Type Designations

- Vodka
- Whiskey
- Gin
- Brandy
- Rum
- Liqueur
- Tequila

- Flavored Brandy
   Flavored Rum,
   Flavored Gin,
   Flavored Vodka,
   Flavored Whiskey
- Recognized Cocktails
- Imitation Products
- Distilled Spirits Specialty

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## Vodka 27 CFR 5.22(a)

- Neutral spirits without distinctive character, aroma, taste, or color
- Distilled at or above 95% ABV or 190 proof and bottled at not less than 40% ABV or 80 proof
- Citric Acid Max 0.1% by volume
- Sugar Max 0.2% by volume



## Whiskey 27 CFR 5.22(b)

- · Spirits distilled from a fermented mash of grain
- Distilled at less than 95% ABV, or 190 proof and bottled at not less than 40% ABV, or 80 proof
- Many different varieties
- Storage in certain types of containers requires storage proof
  - e.g., Charred or uncharred oak
  - New or used containers
- Storage proof is required

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#### Gin 27 CFR 5.22(c)

- 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



## Brandy 27 CFR 5.22(d)

- Distilled from the fermented juice, mash, or wine of fruit or from its residue
- Distilled at less than 95% ABV, or 190 proof, bottled at not less than 40% ABV, or 80 proof
- Having the general taste, aroma, and characteristics generally attributed to brandy
- Different Types
  - Immature Brandy
  - Grappa
  - Fruit Brandy
  - Pomace Brandy
  - Neutral Brandy

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#### Rum <u>27 CFR 5.22(f)</u>

- Distilled from fermented juice of sugar cane, sugar cane syrup, sugar cane molasses, or other sugar cane by-products
- Distilled at less than 95% ABV, or 190 proof and bottled at not less than 40% ABV, or 80 proof
- Having the taste, aroma, and characteristics generally attributed to rum
- Formula required only if harmless coloring, flavoring, or blending materials (HCFBM) are added
  - Can't exceed 2.5% of the final product
  - Doesn't need to be stated on the label



## Tequila 27 CFR 5.22(g)

- Spirits distilled in Mexico in compliance with the laws and regulations of the Mexican government
- From the Agave Tequilana Weber ("blue" variety)
- With or without additional fermentable substances
- Having the general tastes, aroma, and characteristics generally attributed to Tequila
- No blending or coloring material allowed
- Bottled at not less than 40% ABV, or 80 proof



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## Liqueur/Cordial 27 CFR 5.22(h)

- Contains spirits
- Contains natural flavor
- Contains not less than 2.5% by weight sugar
- Up to 49% wine on a proof gallon basis



#### Flavored Brandy, Rum, Gin, Vodka, Whiskey 27 CFR 5.22(i)

- · Bottled at not less than 60 proof
- The predominant flavor shall appear as part of the class and type designation, e.g., "Apricot Flavored Brandy"
- Up to 2.5% by volume wine
- Flavored brandy
  - Up to 15% by volume wine, if it is the same fruit as the predominant flavor

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#### **Recognized Cocktails**

- Mixed drinks that have gained "trade" and "consumer" recognition
- Contain one or more classes and/or type of distilled spirits with flavoring and/or coloring materials
- Requires a Statement of Composition on the label
  - May only need to state spirit and any coloring materials
- Examples: Margarita, Bloody Mary, Egg Nog





## Imitation Products 27 CFR 5.22(j)

- Artificial flavors
- Simulates another class and type
- · Brandy with sugar added to the mash
- · Brandy or rum with other spirits added

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## Distilled Spirits Specialty 27 CFR 5.35

- · 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



## Distilled Spirits Specialty (Cont'd)

- Domestic: Formula Required
- Imported: Pre-Import Approval Required
- Requires a truthful and adequate statement of composition (SOC); however, a distinctive or fanciful product name with a statement reflecting the composition and character of the product is sufficient as a class and type
  - e.g., "Fanciful name SOC = Spiced Mango, Rum with Natural Flavor"





## **Malt Beverages**

- Formula Submission and TTB F 5100.51
- Flavored Malt Beverages
- Treasury Decision 21
- Other Products



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## Class and Type Designations

- Malt Beverage Specialty
  - Flavored Malt Beverages
- Ice Beer
- Alcohol-Free Malt Beverages
- Non-Alcoholic Malt Beverages





## **Malt Beverage Specialty**

- In general, any product that has:
  - Flavors added
  - Colors added
  - Spices added
  - Fruit or honey added
  - Anything outside of the 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 the traditional process



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## Flavored Malt Beverages

- · Any malt beverage product that has flavor added
- · Flavors can be alcoholic or non-alcoholic
- Will require a statement of composition
  - Description of what is in the product
  - e.g., Malt beverage with natural flavors added



#### **Treasury Decision 21**

- Effective January 2006
- If the final ABV is less than 6%, at least 51% of the alcohol in the final product must come from the malt base, up to 49% of the alcohol in the final product can come from the flavor.
- If the final ABV is greater than 6%, no more than 1.5% of the volume of the malt beverage can consist of alcohol from flavors.
- If there is ANY alcohol in the added flavors, the alcohol content must be listed on the label unless otherwise directed by State or local law.

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#### Ice Beer

- Not more than 0.5% of the beer can be removed as ice crystals
- ATF Ruling 94-3



# Alcohol-Free Malt Beverages

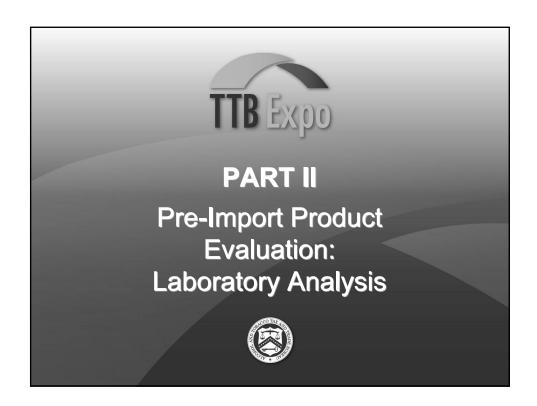
- Must contain 0.0% alcohol by volume
- Must be fermented
- Alcohol must be produced through fermentation

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## Non-Alcoholic Malt Beverages

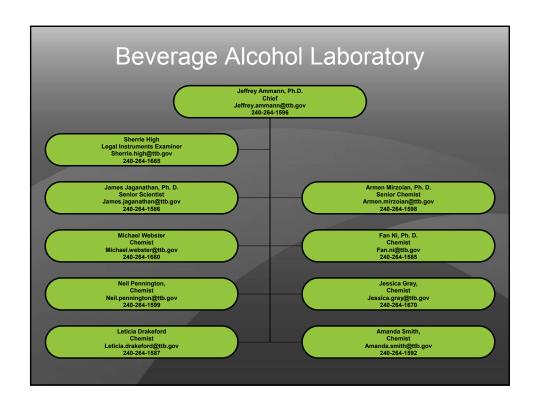
- Contains less than 0.5% alcohol by volume
- The alcohol must come from fermentation





## Who Handles Pre-Import Product Evaluation?

- Advertising Labeling and Formulation Division (ALFD)
  - Formulation Team
- Scientific Services Division (SSD)
  - Beverage Alcohol Laboratory
  - Nonbeverage Products Laboratory







## Pre-Import Product Evaluation

- Not all alcohol beverages require evaluation
- Consult TTB Industry Circular 2007-4 found on the TTB Web site, <u>www.ttb.gov</u>, and click on 'Industry Circulars' in 'Research Resources'

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## Types of Pre-Import Product Evaluation

- Laboratory Analysis
  - Sample sent to laboratory
- Pre-Import Letter
  - No need to send sample to laboratory, letter sent directly to ALFD
- Formula
- Sulfite Analysis
  - Sample sent 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 (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	Terror
A Blend Of Straight Corn Whiskies Or Blended Straight Corn Whiskies	D I	- X	•			
A Blend Of Straight Malt Whiskies Or Blended Straight Malt Whiskies	D	. Х				
A Blend Of Straight Rye Malt Whiskies Or Blended Straight Rye Malt Whiskies	D	- X	•			
A Blend Of Straight Rye Whiskies Or Blended Straight Rye Whiskies	D	- X	•			
A Blend Of Straight Wheat Whiskies Or Blended Straight Wheat Whiskies	D	- X	•			
A Blend Of Straight Whiskies Or Blended Straight Whiskies	D	- X	-			
Advocaat	D	•	- X	X		
						n



## **Submitting Samples for Pre-Import Lab Analysis**

- If sample requires laboratory analysis, send the following to the laboratory for expedited analysis:
  - A **750 ml sample** of the product
  - For first-time importers, send a copy of the TTB issued basic import permit
  - Can use TTB Form 5100.51, "Formula and Process for Domestic and Imported Alcoholic Beverages"
  - Statement of production
    - A list of ingredients used to make the product from the manufacturer
    - A method of manufacture of the product submitted by the manufacturer



## **Submitting Samples for Pre- Import Lab Analysis (Cont'd)**

- Statement of production
  - Information on the agricultural source of alcohol
  - For distilled products, information regarding the proof at distillation, which is the highest proof of the distillate before dilution to bottling proof
  - Identification and source of any flavoring material used in the product
  - A specific description of when the flavoring material is added in the manufacture of the product
  - The total volume and percent alcohol of the finished product

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## **Submitting Samples for Pre- Import Lab Analysis (Cont'd)**

- Visit the Laboratory section on <u>www.ttb.gov</u> for details
- If a beverage contains a flavor, it must be evaluated by the Nonbeverage Products Laboratory before we can analyze the beverage
- Submit <u>beverage</u> samples to: TTB National Laboratory Center

Beverage Alcohol Laboratory 6000 Ammendale Road Beltsville, MD 20705-1250

Submit flavor samples to: Nonbeverage Products Laboratory

6000 Ammendale Road Beltsville, MD 20705-1250

\*Please request "Foreign Flavor Producer Packet"



#### REMEMBER

- All 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.

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## **Submitting Samples for Pre- Import Lab Analysis (Cont'd)**

- Maximum laboratory evaluation turnaround time is 2 months
- After analysis, Lab Reports are sent to the Advertising, Labeling and Formulation Division (ALFD), not to the submitter
- Free!!!!
- Receipt letters

#### LAB NUMBER LABEL DESCRIPTION

B-2008-00123

**Tea Time** 

The Beverage Alcohol Laboratory received your sample and the request for analysis on June 21, 2008.

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

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.

Any inquiries concerning the status of a sample should be directed to the ALFD, (202) 927-8140.

#### LAB NUMBER LABEL DESCRIPTION

B-2008-00124 Mystery Hooch B-2008-00125 Shoe Shine Brandy The Beverage Alcohol Laboratory received your sample and the request for analysis on June 21. 2008.

Before analysis may begin we must receive additional information. Please provide a complete list of ingredients. The chemical analysis provided is not the same as a list of ingredients. The list should be in English or a certified translation. All information should be written on the producer's letterhead, signed and dated by an official of the manufacturing company.

Send the requested information along with a copy of this form to the attention of the Beverage Alcohol Laboratory to either the return address below or by FAX to (240) 264-1489. Please note that the Advertising Labeling and Formulation Division (ALFD) may also request additional information.

Expect sample analysis to take 2 months from the time we receive the requested information. Once analysis is completed, a lab report of the results will then be sent to the ALFD, where all of the paperwork will be reviewed and a final decision will be made regarding the classification of your product.

The submitted sample will be destroyed without analysis after September 21, 2008 unless we received the requested information. Any inquiries concerning the status of a sample should be directed to the ALFD, (202) 927-8140.

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.

# Laboratory Analysis



## What Does Laboratory Analysis Involve?

- · Samples are assigned to a chemist
- Perform analyses that determine class and type using AOAC methods or equivalent
  - Alcohol by volume (density metering apparatus)
  - Fusel oils (gas chromatography)
  - Methanol (gas chromatography)
  - Solids (evaporation)
  - Total acids (autotitrimeter)
  - Specific gravity (density metering apparatus)
  - Sodium and potassium (atomic absorption)
- Will perform special analyses on a case-by-case basis
  - Additives, prohibited ingredients, and contaminants



## Laboratory Analysis: Additives in Products

- Definition:
  - Additives are ingredients that are intentionally added to an alcohol beverage
- Examples:
  - Synthetic color
  - Propylene Glycol
  - Potassium Benzoate
- Some additives have limitations in the finished product or labeling requirements

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## **Product Evaluation: Additives in Products**

- Approval of additives and/or their established limitations in another country is not sufficient for COLA approval by TTB. All additives and ingredients must comply with U.S. laws and regulations.
- All additives and ingredients must be determined to be Generally Recognized as Safe (GRAS) or approved for food use by the U.S. Food and Drug Administration (FDA).
- The presence of any FDA limited ingredients in the finished product must not exceed the regulatory limits.



## Prohibited Ingredients & Contaminants

- Definition:
  - Prohibited Ingredients are intentionally added to the beverage product yet are not allowed to be present
  - Contaminants are extraneous substances present by accident or due to the manufacturing process
- Examples:
  - Prohibited Ingredients: Coumarin, Thujone, Calamus
  - Contaminants: Pesticides. Phthalates

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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
- 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)

- Alcohol must be derived from rice
- Addition of alcohol is allowed, but product is then taxed as a distilled spirit

#### Grappa

- Brandy distilled from the skin and pulp of sound, ripe grapes
- Ensure that the methanol content is not above 0.35% v/v

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## Sulfur Dioxide Label Waiver

- Products with total sulfites between 10–350 parts per million (ppm) require sulfite warning label
- For waiver of this label:
  - Submit sample to the TTB National Laboratory Center;
  - To a private laboratory certified by TTB (see 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
  - Either resubmit for testing or "Diluted" must appear as part of the class/type
  - e.g., "Diluted Rum"
- Imitation Liqueurs—containing artificial flavors
  - Reformulate using natural flavor(s), request product be classified as "Distilled Spirits Specialty" or product must be classified as "Imitation Liqueur"

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#### **Helpful Hints**

- Quantitative list of ingredients
- Supply a complete method of manufacture
- · Proof at distillation
- Provide name, address, and TTB number for all flavors
- Provide botanical name for herbs and plant extracts
- Please be sure all documents are legible and in English
- · Turnaround time: approximately 2 months



#### Resources

- www.ttb.gov
- Industry Circular 2007-4
- www.fda.gov

Alcohol and Tobacco Tax and Trade Bureau



#### **Contact Information**

- Advertising, Labeling and Formulation Division
  - Phone: Customer Service Desk (202) 927-8140 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

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