



# What to Expect in a Distilled Spirits Plant Product Integrity Investigation

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PRESENTER: TTB INVESTIGATOR MARK EPPS

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# TTB Disclaimer



## Notice:

This information is being presented to help the public to understand and comply with the laws and regulations that the Alcohol and Tobacco Tax and Trade Bureau administers. It is not intended to establish any new, or change any existing, definitions, interpretations, standards, or procedures regarding those laws and regulations. In addition, this presentation may be made obsolete by changes in laws and regulations. Please consult the regulations for the most current regulatory requirements.

Sample documents (such as records, returns, and labels) are for illustrative purposes only and contain fictitious data.



# Agenda



- Introduction
- Opening Conference
- Qualifying Documents
- Standards of Identity and Formula Compliance
- Label/Certificate of Label Approval (COLA) Verification
- Advertising
- Samples for TTB Lab Submission
- Closing Conference and Follow-Up
- Updates and Resources



# TTB Overview



- Bureau within the Department of the Treasury
- Currently about 480 employees
- Headquarters are in Washington, DC
- Office of Permitting and Taxation is in Cincinnati, Ohio
- Field offices located across the country and Puerto Rico
- Laboratories located in Maryland and California



# Our Mission



**COLLECT** the taxes on alcohol, tobacco, firearms, and ammunition

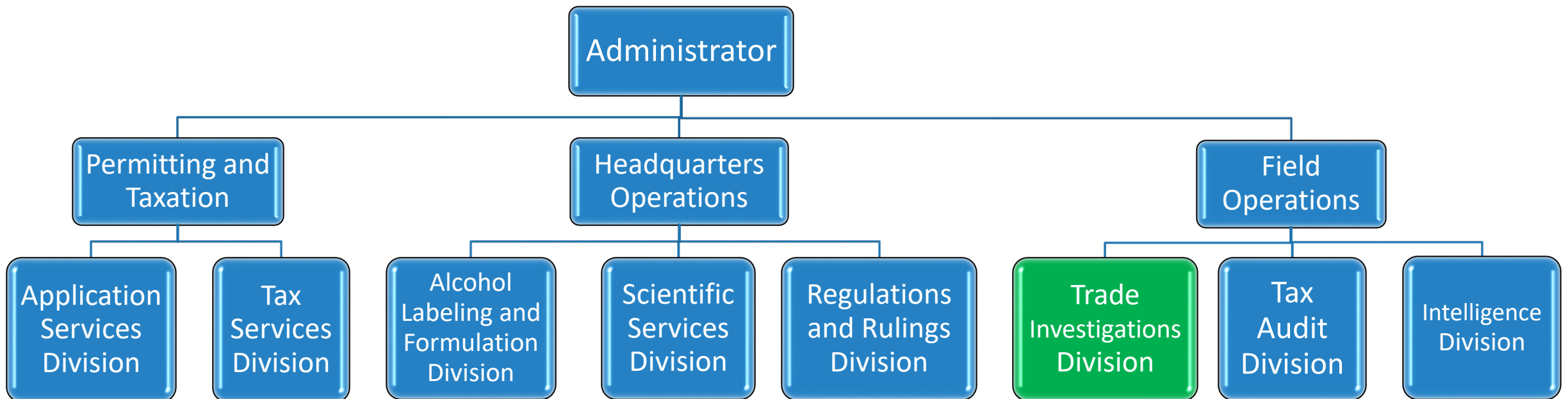
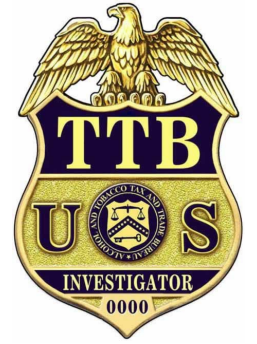
**PROTECT** the consumer by ensuring the integrity of alcohol products

**ENSURE** only qualified businesses enter the alcohol and tobacco industries

**PREVENT** unfair and unlawful market activity for alcohol and tobacco products



# TTB Organizational Chart





# Trade Investigations Division (TID)



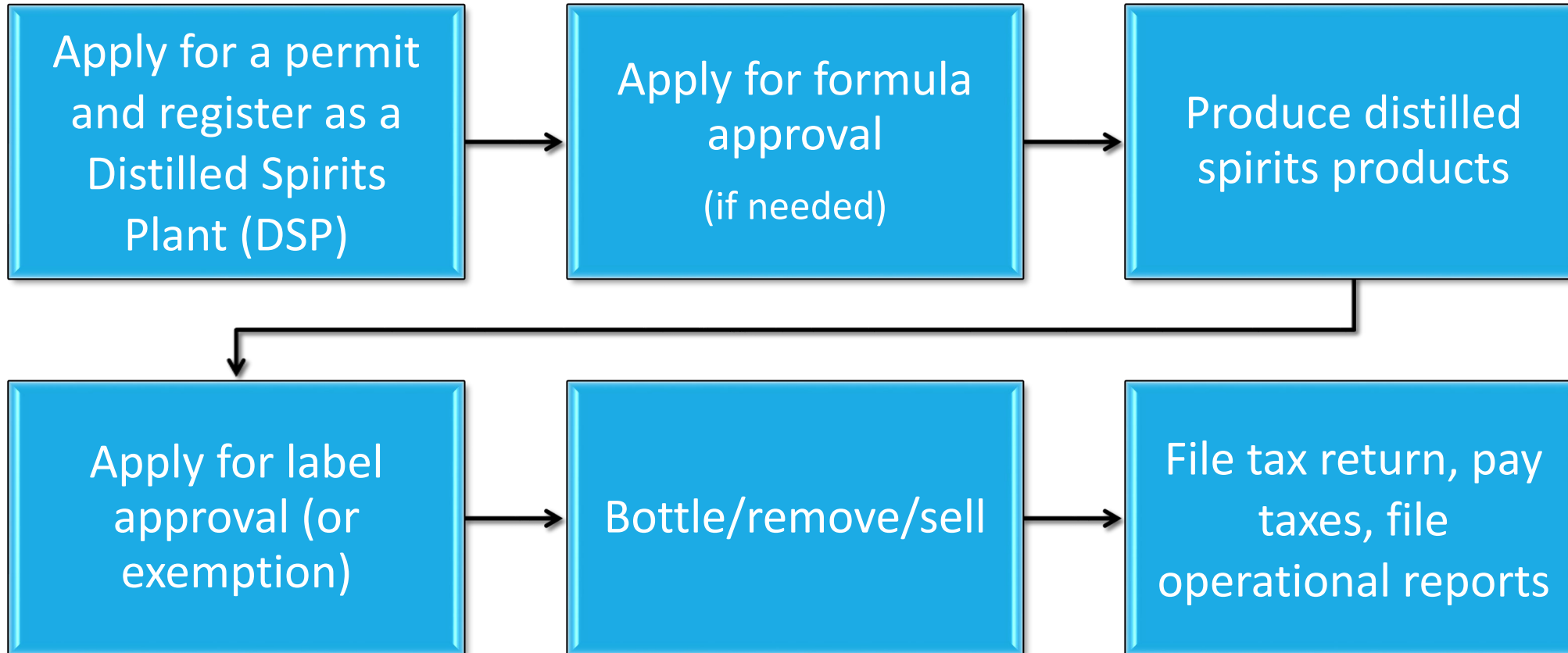
The Trade Investigations Division (TID) is responsible for ensuring industry members comply with the laws and regulations administered by TTB.

## TID investigators:

- Ensure only qualified applicants are granted permits to engage in the production and distribution of alcohol and tobacco
- Investigate allegations of trade practice violations in the marketplace
- Examine Certificates of Label Approvals (COLAs) to deter unauthorized usage
- Prevent misleading labeling and advertising of alcohol beverages
- Respond to credible information suggesting a health-related contamination or adulteration of an alcohol product



# Follow the TTB Path for Distillers



## Ongoing once your permit is approved:

- 1) Keep records of operations
- 2) Report changes to your business to TTB





# What Do We Look For?



## Product integrity (consumer protection)

- Opening Conference
- Qualifying Documents
- Standards of Identity & Formula Compliance
- Label/Certificate of Label Approval (COLA)  
Verification



# What Do We Look For?



## Product integrity (consumer protection)

- Manipulated/Altered COLAs
- Advertising
- Proof and Fill
- Samples for TTB Lab Analysis

# Opening Conference



# Opening Conference



## The TTB investigator will:

- Tour the premises
- Identify and interview key personnel responsible for production, labeling, and lab analysis including alcohol and fill tests
- Identify COLAs, formulas, records, and reports needed for the investigation
- Identify operations conducted on bonded DSP premises

# Qualifying Documents



# Qualifying Documents

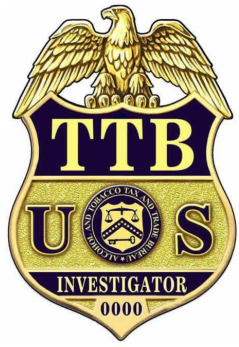


## The TTB investigator will:

- Examine qualifying documents from the original application that relate to the DSP operations
- If necessary, advise of procedures to amend your permit/registration
- Verify that only authorized persons sign documents submitted to TTB



# Qualifying Documents: Common Issues and Solutions



## **Not reporting changes in the business operations to TTB**

- Must report changes in officers / directors within 30 days
- Must report changes in control / ownership within 30 days
- New consultants / employees need Power of Attorney or Signing Authority to submit on your behalf

## **Failure to File for altered business premises**

- New buildings, tanks, rooms, labs, etc. must be reported to TTB and approved before construction or addition

# Standards of Identity and Formula Compliance





# Standards of Identity



## The TTB investigator will:

- Verify the permittee's records accurately identify the class and type of spirits produced and/or received in bond (imported and domestic)
- Determine whether the kinds of spirits are properly identified according to the materials from which they are produced
- When applicable, examine additional documents necessary to remove specific products from Customs custody
  - Certificates of origin for Scotch, Irish, and Canadian Whiskey;
  - Certificates of age for rum, brandy, and agave spirits; and
  - Certificates of authenticity for Tequila and Cognac



# Standards of Identity: Common Issues



## Proof Issues

- Vodka must be bottled at or above 80 proof
- Whisky (at the time of distillation) must be made at less than 190 proof

## Ingredient Issues

- Corn whisky must be made with not less than 80% corn
- Straight whisky may not have sugar added
- Bourbon whisky must use charred new oak barrels
- Rum must be made with sugar cane or sugar cane products



# Formula Compliance



## TTB Approved Formula

- Ensure DSP has TTB-approved formulas for all products produced and bottled that require them

## DSP Processing Batch Records

- Compare product batch records to TTB-approved formula
- Ensure ingredients match approved formula
- Ensure all quantities and ranges of ingredients are within compliance



# Formula Compliance: Common Issues



**DSPs producing products without an approved formula**

**DSPs not adhering to an approved formula:**

- Quantities and ranges must match your approved formula
- Statement of process must match your actual production process
- Must amend / resubmit formulas if you wish to change the ingredient list

# Labels/COLA Verification



# Label/COLA Verification



## The TTB investigator will:

- Verify permittee has either certificates of label approval (COLA) or exemption from label approval for labels on all bottled spirits in inventory
- Verify labels on bottled spirits include all mandatory information and avoid prohibited practices (27 CFR Parts 5 and 19)
- Verify trade names appearing on labels are identical to trade names listed on permittee's basic permit



# Label/COLA Verification



- For COLAs granted conditional or use-up approval:
  - Verify product labels comply with restrictions, including expiration date, listed in the **Qualifications** section
  - Verify adequate controls are in place to ensure new labels will be in compliance and expired COLAs are not used beyond expiration date
- Verify Government Health Warning Statement meets requirements of 27 CFR part 16
- Request DSP surrender any COLAs that are inactive, obsolete, or terminated



# COLAs: Common Issues



- No COLA
- Making unallowable change to product label without obtaining new COLA
- Incorrectly formatted Government Health Warning Statement
  - **Government Warning** is not bold and does not stand out from rest of warning
- Exceeding requirements for conditionally-approved COLA or per a TTB-approved use-up approval



# Advertising



# Advertising



## The TTB investigator will:

- Review all advertising material on the DSP website and social media accounts
- Review any point of sale (POS) materials for violations, such as:
  - Sales pamphlets
  - Posters
  - Promotional displays, or
  - Written, printed, or graphic materials in stock

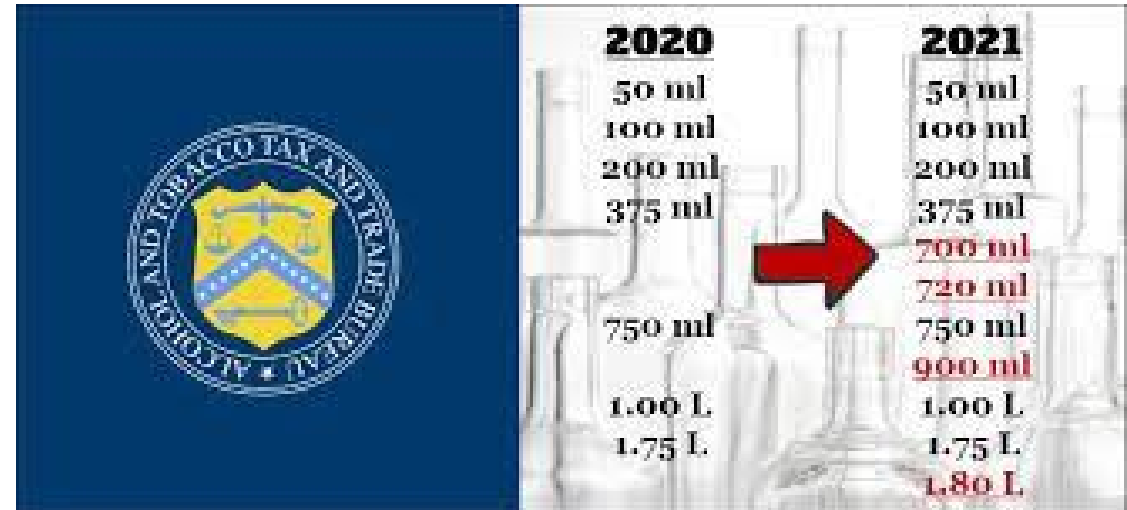


# Advertising: Common Issues



- Missing mandatory statements
- Health claims
- Advertising is inconsistent with label
- Class/Type issues

# Proof and Fill





# Proofing



## The TTB investigator will:

- Verify DSP proofing procedures
- Observe plant personnel conduct proofing test
- Verify all measuring devices used for proofing are correctly calibrated
- Review required proofing records
  - Records must include all information showing DSP is compliant with requirements/regulations at 27 CFR 19.188, 19.600, and 19.356



# Proofing: Common Issues



- Not using properly calibrated equipment
- Not distilling samples with high solids before proofing
- Not correcting for temperature
- Not following consistent steps in proofing
- Not maintaining accurate proofing logs



# Fill Testing



## The TTB investigator will:

- Verify DSP fill procedures
- Observe plant personnel conducting fill test
- Verify all measuring devices used for fill are correctly calibrated
- Review fill records required
  - Records must include all information showing DSP is compliant with requirements/regulations at 27 CFR 19.188, 19.600, and 19.356



# Fill: Common Issues



- Calibration and Testing
  - Correcting for the temperature of the liquid
  - Must use calibrated equipment (thermometer, hydrometer, graduated cylinders, etc.)
  - Not checking each fill head on bottling line and making adjustments if necessary
- Records
  - No fill test records, or corrections shown on fill test record
  - No calibration records
  - No proofing records



# Samples for TTB Lab Submission



# Samples for TTB Lab Submission



## The TTB investigator will:

- Pull several samples from bonded inventory
  - Samples will be of various sizes and products
- Send samples to TTB lab for analysis and check for proof and fill compliance (27 CFR 19.356)
- Follow up with DSP as to the results of lab analysis



# Lab Samples: Common Issues



- Product is under/over proof
  - Product is under filled
  - Headspace, more than 8% of container
- See 27 CFR 5.202(b), 19.356(c), and 19.356(b)

# Closing Conference and Follow-Up



# Closing Conference



## The TTB investigator will:

- Hold closing conference with DSP and explain results of investigation
- Advise proprietor of the results from samples submitted to the TTB lab for analysis which may require corrective action
- Issue written summary of violations and, if needed, advise proprietor of corrective action



# Adverse Action



- Violations may result in TTB taking administrative action against your permit
- Administrative action can range from a warning letter, up to and including, suspension or revocation of a permit
- Findings are made part of your official TTB file
- Additional administrative actions may be taken if violations continue



# Voluntary disclosure



## Voluntary disclosure of non-compliance

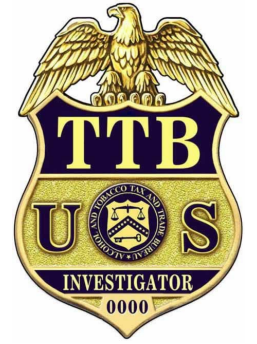
- TTB encourages industry members to voluntarily disclose violations upon discovery and take appropriate corrective action
- These disclosures may mitigate actions taken by TTB in response to violations
- See TTB Industry Circular 2004-5 for details
  - [https://www.ttb.gov/images/industry\\_circulars/archives/2004/04-05.html](https://www.ttb.gov/images/industry_circulars/archives/2004/04-05.html)
- Submit your voluntary disclosure here:
  - <https://www.ttb.gov/contact-nrc>

# Updates and Resources





# Labeling Modernization Proposed Rule



In 2018, we proposed to modernize the labeling and advertising regulations for:

- Wine (27 CFR part 4)
- Distilled spirits (CFR part 5)
- Malt beverages (CFR part 7)

## **Goals of Proposed Rule:**

- Reorganize regulations
- Simplify and clarify regulatory standards
- Incorporate guidance documents and current policy
- Reduce regulatory burden on industry members where possible



# Labeling Modernization

## Phase 1 Final Rule



On April 2, 2020, we published a rule known informally as **Phase 1**.

This rule finalized proposals that could be implemented quickly and provide industry members greater flexibility.

### **Proposals for distilled spirits:**

#### **1. Elimination of “Brand Label”**

Mandatory information may appear anywhere on the label, as long as the brand name, class or type designation, and alcohol content appear in the same field of vision.



# Labeling Modernization

## Phase 1 Final Rule (cont.)



### 2. Increased alcohol content tolerance

TTB increased the alcohol content tolerance for distilled spirits to +/- 0.3%

### 3. Age statement changes

Previously, age statements were prohibited on many types of distilled spirits

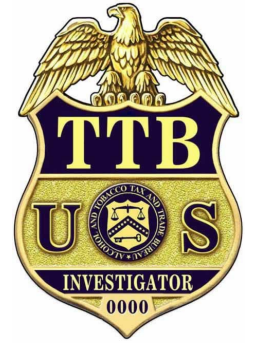
Now, age statements may appear on any distilled spirits except vodka (which may not be aged)

- Age statements may account for the time spent in multiple barrels, which may be optionally separately stated on the label



# Labeling Modernization

## Phase 1 Final Rule (cont.)



### 4. Updates to Standards of Identity

- Vodka no longer must be “**without distinctive character, aroma, taste, or color**”
  - Incorporated rulings allowing for trace amounts of citric acid and sugar
- **Straight** for whisky is an optional designation
- **Agave spirits** was added as a class that includes Tequila and Mezcal, as well as domestic or imported agave spirits



# Labeling Modernization

## Phase 2 Final Rule



On February 9, 2022, we revised the labeling and advertising regulations for:

- Distilled spirits (CFR part 5)
- Malt beverages (CFR part 7)

### Goals of Final Rule:

- Improve the clarity and usability of the regulations
  - Liberalize certain requirements, and
  - Assist industry members in submitting compliant label and formula applications
- See [T.D. TTB-176](#), Modernization of the Labeling and Advertising Regulations for Distilled Spirits and Malt Beverages



# Labeling Modernization

## Phase 2 Final Rule



### Regarding distilled spirits specifically, the final rule:

1. Finalized a number of definitions, such as **container, distilled spirits, distinctive or fanciful name, American proof, and grain**
2. Provides clarity on what constitutes a label and what constitutes advertising material on a bottle
3. Provides specificity on name and address terms: **Blended by, Made by, Prepared by, Manufactured by, and Produced by**



# Labeling Modernization

## Phase 2 Final Rule (cont.)



4. Provides clarity on Standards of Identity
  - Reorganized the Standards of Identity so that each class appears in its own section
  - Clarified that a product may meet more than one standard of identity, but must only list one on the label
  - Created a class **Distilled Spirits Specialty Products**
  - Eliminated the concept of **recognized cocktails**



# American Single Malt Whisky

## TTB Proposal



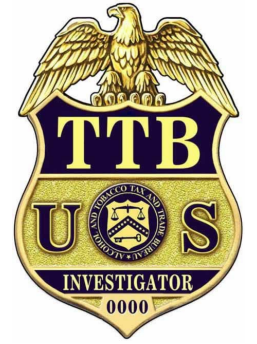
### Standard of Identity: Proposed New Type Within Whisky Class

- We are considering amending the regulations to include a new type of whisky called **American Single Malt Whisky**
  - To comment, see Notice No. 213
- Must be distilled entirely at **one** U.S. distillery, and be mashed, distilled, and aged in the United States (i.e., a distinctive product of U.S.)
- Would permit storage in any oak barrel not exceeding 700 liters
- If finalized, any COLA using term—but not meeting proposed standard of identity—would be revoked





# TTB Trade Investigations Contacts



## Western I District Field Office

21143 Hawthorne Blvd #461  
Torrance, CA 90503-4615  
513-684-2481

**NOTE:** This is a mailing address **ONLY**. This is not a physical address.  
Please direct all inquiries to: 513-684-2481

## Western II District Field Office

5050 NE State Hwy 303 #103, PMB #206  
Bremerton, WA 98311  
513-684-2491

**NOTE:** This is a mailing address **ONLY**. This is not a physical address.  
Please direct all inquiries to: 513-684-2491

## Mountain District Field Office

100 S. 1<sup>st</sup> Street #582331  
Minneapolis, MN 55458  
513-684-3608

**NOTE:** This is a mailing address **ONLY**. This is not a physical address.  
Please direct all inquiries to: 513-684-3608

## Northeast District Field Office

425 Hurffville-Cross Keys Road, #8669  
Blackwood, NJ 08012  
202-453-3144

**NOTE:** This is a mailing address **ONLY**. This is not a physical address.  
Please direct all inquiries to: 202-453-3144

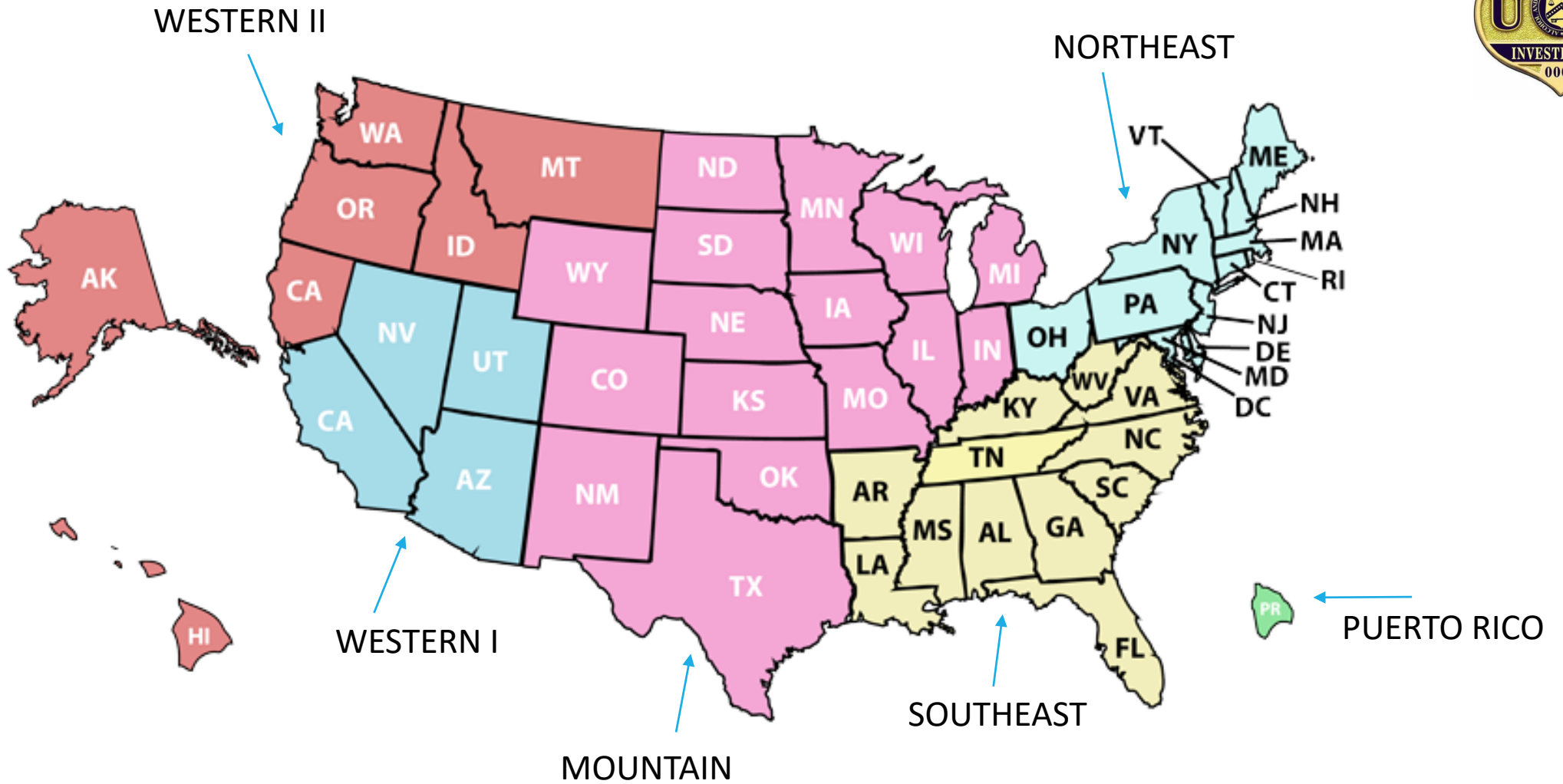
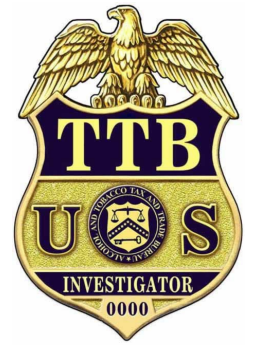
## Southeast District Field Office

4300 West Cypress Street, Suite 340  
Tampa, FL 33607  
202-453-3117

## Puerto Rico District Field Office

Torre Chardon  
350 Ave Carlos Chardon, Suite 310  
San Juan, PR 00918  
202-453-3164

# TTB Trade Investigations District Map





# Internet Resources



## Websites

- [www.ttb.gov](http://www.ttb.gov)
- [www.fda.gov](http://www.fda.gov)
- [www.ecfr.gov](http://www.ecfr.gov)
  - 27 CFR parts 1, 5, 16, 19
- [Distilled Spirits Beverage Alcohol Manual](#)

## Key Search Words

- Formula
- BAM
- Beverage Alcohol Manual
- Distilled Spirits Rulings
- eCFR
- COLA



# Resources on TTB.gov



## Alcohol Beverage Formula Approval Home Page

<https://www.ttb.gov/formulation/index.shtml>

## Subscribe to automatically receive the weekly TTB Newsletter

<https://public.govdelivery.com/accounts/USTTB/subscriber/new>

## Permits Online Help Center

<https://www.ttb.gov/ponl/permits-online-help.shtml>



# Resources on TTB.gov



**Distilled Spirits Laws, Regulations, and Public Guidance:**

<https://www.ttb.gov/distilled-spirits/laws-regulations-and-public-guidance>

**CBMTRA page:** <https://www.ttb.gov/alcohol/craft-beverage-modernization-and-tax-reform-cbmtra>

**TTB Federal Register Publications:**

<https://www.ttb.gov/what-we-do/regs-guidance/federal-register-publications>

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<https://www.ttb.gov/survey>



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