TTB: Navigating The Permit, Formula And COLA Process



DISCUS Inaugural Conference

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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.

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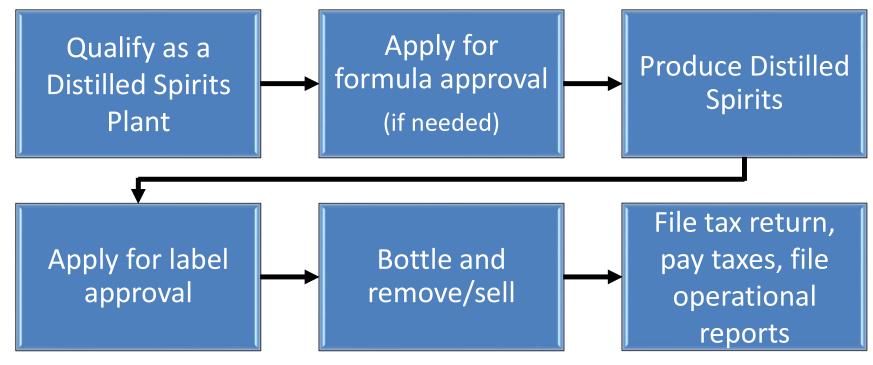
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Follow the TTB Path

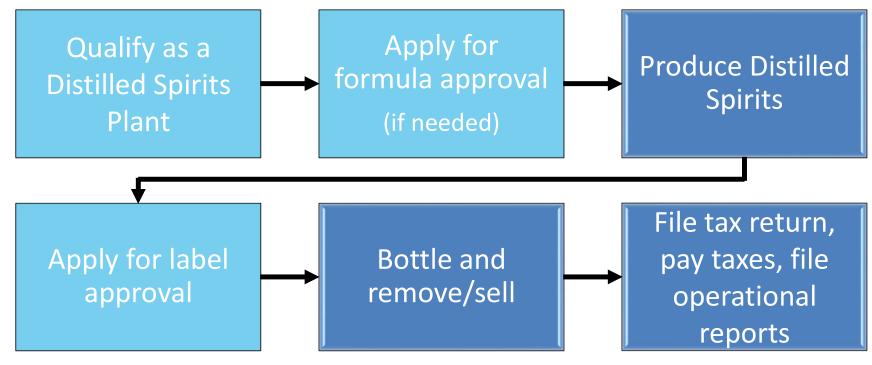


Ongoing once your DSP is approved:

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



Follow the TTB Path



Ongoing once your DSP is approved:

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

Beverage DSP Registrations & Permits

TROY MOON

APPLICATIONS SPECIALIST

NATIONAL REVENUE CENTER



The PATH Act amended the IRC regarding bonds:

- Taxpayers who reasonably expect to be liable for not more than \$50,000 in taxes for the calendar year, and
- were liable for not more than \$50,000 in such taxes in the preceding calendar year
- are exempt from the requirements to file bonds covering operations or withdrawals

Industry Circular 2016-2



Transfers in Bond

- If you will receive bulk spirits in bond from another domestic distilled spirits plant, you should complete this section of the application even if you are not required to obtain a bond
- Once approved, a transfer in bond form will be attached to your application and you should supply a copy to the supplier(s) transferring the spirits to you

27 CFR 19.402 & 19.403



Bonded premises. The premises of a distilled spirits plant, or part thereof, as described in the application for registration, on which the conduct of distilled spirits operations defined in 26 U.S.C. 5002 is authorized. This term includes premises described in the preceding sentence even if the proprietor, as authorized under the exemption set forth in §19.151(d), has not provided a bond for the premises.

27 CFR 19.1



General premises. Any business office, service facility, or other part of the premises described in the notice of registration other than bonded premises. For example; storage of taxpaid spirits, offices, lunch room, restrooms and non-alcohol storage.

27 CFR 19.1



DSP Operations:

- Distiller
 - produces spirits
- Warehouseman
 - stores bulk spirits
- Processor
 - Rectifies (e.g., making changes by cutting, blending, mixing)
 - Bottles

27 CFR 19.1



Restrictions on Location of Plants

A person who intends to establish a distilled spirits plant may not locate it in any of the following places:

- (a) In any residence, shed, yard, or enclosure connected to a residence;
- (b) On any vessel or boat;
- (c) Where beer or wine is produced;
- (d) Where liquors are sold at retail; or
- (e) Where any other business is conducted except as provided in §19.54.

19 CFR 19.52

26 U.S.C. 5178



DSP applicants are asked a series of questions in Permits Online to help distinguish what can and cannot be done at a distillery

Will you have a tasting room?: *	● Yes ○ No
If you charge for samples, parking, or tours then you are prohibited from establishing a tasting room on the premises. The tasting room must be separate from the distillery with floor to ceiling walls and must have its own entrance. It cannot be part of the distilled spirits plant and must be shown on the diagram. Do you understand this requirement?: *	● Yes ○ No
If you do not plan to charge for samples, parking, or tours then the tasting room can be located on the general premises, but must be separate from the bonded premises with floor to ceiling walls, have its own entrance and be shown on the diagram. Do you understand this requirement?: *	Yes ○ No



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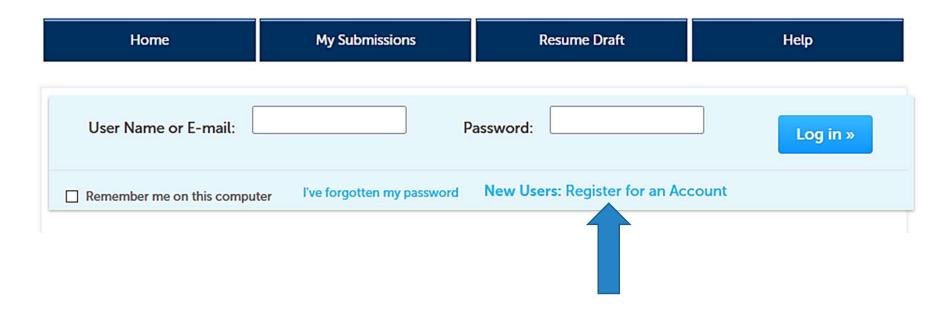
Will you have a retail store?: *	● Yes ○ No
If you are only selling merchandise (e.g., shirts, souvenirs) then the retail store can be located on the general premises and should also be shown on the diagram. Do you understand this requirement?: *	● Yes ○ No
Do you plan to sell any alcohol in the retail store? *	?: ● Yes ○ No
If any alcohol is sold in the retail store then you are prohibited from establishing it on the premises. The retail store must be separated from the premises by floor to ceiling wall separation and have its own entrance from the outside. Do you understand this requirement?: *	● Yes ○ No



- Before you submit your application generally construction should be complete with necessary equipment in place or on order
- You cannot begin producing spirits until you receive your approved DSP Registration and Permit



Register for an Account in Permits Online



https://www.ttbonline.gov/permitsonline/Default.aspx



What to Gather Before You Apply

There are number of supporting documents that you'll be required to submit with your application

Plan ahead and review the list before you begin the application

Use our What to Gather Before You Apply tool to see the full list



What to Gather Before You Apply

- Organizational Documents
- Lease Agreement or Proof of Ownership
- Signing Authority Authorization
 - Signing Authority Form 5100.1
 - Power of Attorney Form 5000.8
- Diagram of the DSP
- Source of Funds
 - documentation/bank statements from investing owners



You Must Report to TTB:

Changes in:

- the legal business name
- controlling ownership
- any partner or general partner
- any stockholder or members holding ownership of 10 percent or more
- corporate officer, directors, or any titled positions

Adding, revoking, or changing:

- signing authority
- power of attorney



You Must Report to TTB:

Changes in:

- premises location
- bond
- construction or use of building
- operations
- DBA/Operating name
- mailing address

Adding or removing:

- trade names
- noncontiguous premises
- alternation of premises
- alternation of proprietor
- variance or alternate method

Termination of operations



Permits Online Guidance

Permits Online will guide you through the entire application process, but if you want to see guidance before you start:

- Permits Online Help Center
- Permits Online tutorial

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Distilled Spirits Formulas

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ALCOHOL LABELING AND FORMULATION DIVISION



Common Formula Questions

- What is a formula?
- Why is a formula required?
- What types of distilled spirits require formula review?
- How is a formula submitted?



What is a Formula - A Basic Definition

- A formula is a recipe
- It must indicate a total yield, or batch size
- It must have a quantitative list of ingredients
- It must include a description of how the product is produced



Why is a Formula Required?

Generally, an approved formula is required to:

- Blend
- Mix
- Purify
- Refine
- Compound
- Or treat spirits in a manner which results in a change of:
 - Character
 - Composition
 - Class or type of the spirits

27 CFR 5.26



Why are Formulas required?

- 27 CFR 5.22 contains the twelve Standards of Identity
 - Some classes are straightforward, for example, Rum, while other products have more working parts that require label disclosure
 - A product may have a particular requirement to satisfy in order to belong to a given class
- Formula review finds a "home" for a product and describes its working parts
- A class, type, or statement of composition represents the outcome of this process
 - Additional information may be added for labeling reasons
- Not all products will require a formula



When is a Formula Required?

- The use (except as authorized for production or storage operations as provided by 27 CFR part 19) of any physical or chemical process or any apparatus which accelerates the maturing of the spirits
- The steeping or soaking of fruits, berries, aromatic herbs, roots, seeds, etc., in spirits and wines
- The artificial carbonation of spirits
- The blending in Puerto Rico of spirits with any liquors manufactured outside of Puerto Rico

Which Alcohol Beverages Require Formula Approval Tool

27 CFR 5.27



How to Submit a Formula

- Formulas Online is part of the TTB electronic storefront on www.ttbonline.gov
 - You must register for an account before you can use Formulas Online:
 - User Registration Form



Common Formula Errors

- Submitter unaware of Class-Type and Standard of Identity requirements
- Incomplete application
- Role of compounded flavors in products
- Impact of limited ingredients on product classification
- GRAS or General Recognized as Safe Requirements



- Supply a quantitative list of ingredients
- Provide a complete method of manufacture
- Indicate proof at distillation
- Flavor Ingredient Data Sheets (FIDS) should include a TTB number, a Flavor Product Number, and the TTB Approval status (Nonbeverage Lab Approval)
- Provide the common name and scientific name (genus and species) for any unusual herbal ingredients
- Ensure that ingredients are GRAS (generally recognized as safe)



What TTB Looks For

- Correct designation (Class and Type) Is the base produced according to the stated standard?
- Colors
- Flavors and Flavor Ingredient Data (FID) sheets
- GRAS (generally recognized as safe) ingredients
- Restricted and prohibited ingredients



Compounded Flavors

- May be classified as:
 - All natural
 - Natural and artificial containing not more than 0.1% artificial content topnote
 - Natural and artificial containing greater than 0.1% artificial content topnote
 - All artificial
 - Non-flavor: product is not a flavor (e.g., cloud emulsion)
- Must be submitted to TTB Nonbeverage Lab for review
- May contain colors



GRAS and Restricted Ingredients

- Regulated by the U.S. Food and Drug Administration
- GRAS Generally Recognized as Safe
 - Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive
- Restricted ingredients



- Formula Approval guidance pages on TTB.gov
- <u>Distilled Spirits Beverage Alcohol Manual (BAM)</u>
 - <u>BAM Chapter 1</u>: Commodity Statements
 - <u>BAM Chapter 4</u>: Quick product reference guide stating basic technical requirements
 - <u>BAM Chapter 7</u>: Provides chart listing limitations placed on harmless coloring blending and flavoring materials (HCBFM)



Are Formulas Required for all Products?

No, not all products require formula review

Time saving resources:

- Which Alcohol Beverages Require Formula Approval Tool
- TTB G 2016-3 Pre-COLA Product Evaluations for Distilled Spirits Products
- TTB G 2017-5 Alcohol Beverage Formula Approval with Lab Sample Analysis
- TTB Ruling 2016-3 TTB Approves General-Use Formulas for Certain Distilled Spirits Produced Using Harmless Coloring, Flavoring, or Blending Materials

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Distilled Spirits Labeling Overview

TRACY MCNEILL

SENIOR LABELING SPECIALIST

ALCOHOL LABELING AND FORMULATION DIVISION



Basics of the Labeling Process

- What is a COLA?
- Why is label approval required?
- How is a COLA submitted?
- Where can I get more information?



A Certificate of Label Approval is:

- A certificate issued on TTB Form 5100.31
- that authorizes
 - the bottling or packing of wine, distilled spirits, or malt beverages, or
 - the removal of bottled wine, distilled spirits, or malt beverages from customs custody

for introduction into commerce,

- as long as the product bears
 - labels identical to the labels affixed to the face of the certificate, or
 - labels with changes authorized by the certificate

27 CFR 13.11



Why is Label Approval Required?

- Imported distilled spirits may not be removed from Customs custody without a COLA
- Domestic distilled spirits may not be bottled or removed from a plant without a COLA
- Exemptions

27 CFR 5.51, 5.55



COLAs Online is accessible from TTB.gov

- You must register for an account before you may use COLAs
 Online
- User Registration Form

27 CFR 13.21



Common DS Labeling Errors

- Class/Type entered in the brand name field
- Formula is required before applying for label approval
- Label images are distorted
- The brand name listed on the application does not match the brand name on label
- Name and address on the label does not match that shown on the application
- Translation of foreign text on label must be supplied
- Alcohol content on label conflicts with the approved formula
- Brand label requirements have not been met



Where Can I Find More Information?

- <u>TTB regulations</u>: 27 CFR parts 5, 16, 19, and 27
- www.TTB.gov
- Distilled Spirits Beverage Alcohol Manual (BAM)
- List of Allowable Revisions
- Distilled Spirits FAQs
- Organic Labeling
- ALFD Technical Information Center (TIC)
 - 866.927.2533 Option 4
 - ALFD@TTB.gov

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Industry Expert TTB Pro-Tips







Meet the Experts



Deborah Ringo Director, Regulatory & Technical Affairs Diageo



Linda Lewis
Regulatory Manager
Brown-Forman Corporation





General TTB Practice Tips

- TTB's focus is to protect tax revenue and consumers
 - Remember this and let it guide your interactions
 - Licensing is a privilege, not a right
- Informed compliance is critical
 - Take ownership over your licensing
 - The more research and self-education, the smoother your application process will be
 - Show up prepared and do your homework
- TTB's website use it as the first stop when you have a question
 - The laws and regulations, Beverage Alcohol Manual, Industry Circulars/Rulings, and search function
- Question the why
 - For each application or question, think of the purpose and let that guide your responses
- Get to know the TTB organization chart and learn the role each office plays
- Think through your timeline and plan accordingly TTB posts average approval times, which are very helpful
- Signing authority it can be power of attorney or by position
- Don't be afraid to pick up the phone and call TTB!







Permit Tips

- Triage and prioritize
 - You can only submit one permit at a time
- You can't start any operations until you have a permit
- TTB has a great permit pre-submittal checklist but here are a few extra tips:
 - Contiguous premise think through local laws and regulations
 - Will need all of your capacity and financial information
 - o Tank serial numbers, capacities and descriptions
 - o Distillation equipment registration numbers, capacities and descriptions
 - Max barrel warehouse capacities
 - Max processing tank storage capacities
 - Max finished case goods storage capacities
- Areas can be designated as alternating premises (bonded and general)
- Any change you make to your operations (e.g., add a tank) you need to let TTB know







Formula Tips

- Start by looking at TTB checklist "Do I need a formula?"
- Formula approvals for imported products expire in 10 years
- Before you submit your formula ingredients are FDA approved and flavors are TTB approved
- Some products require laboratory analysis as a part of formula approval
 - TTB can request lab analysis for any product (for example, imported Class 9 products require testing)
- FONL Online portal that can be used to submit formulas for approval
 - Must have POA or signing authority in place with TTB and must have an approved DSP
- Formula applications should provide the following:
 - Suggested 'Statement of Composition' to point TTB in the direction you want to go
 - DSP that formula will be produced at and include all DSPs that you produce at
 - Qualitative list of ingredients, including
 - o Max use rates for limited ingredients
 - TTB flavor approval Information
 - o Formulas do not have to be exact and do not have to add up to 100% one formula can be used for multiple products
 - o Can use ranges for ingredient amounts
 - Method of manufacture/production process
 - o Does not have to be overly detailed (i.e., all ingredients are mixed together and then bottled)
 - Limited Component Worksheet
 - $\circ \quad \text{This worksheet calculates out all of the limited components based on added flavors and ingredients} \\$







Labeling Tips

- Check the list of allowable changes it is always being updated
 - You can remove non-mandatory information, but you can't change it (i.e., you can remove a recipe from a label, but you can't change it)
- Multiple sizes can use the same COLA approval
 - CAN rearrange information between labels so long as it meets TTB requirements
 - CAN reduce number of labels but CANNOT increase the number of labels
- COLA should not be submitted until the formula is approved (if one is needed)
 - If superseding a formula, COLA revisions can be submitted before formula approval is received
- Be familiar with where on the label information is to be placed based on classification
 - Compliance Matters 94-1 & 94-2
- Full ingredient list and allergens are NOT mandatory labeling requirements for spirits
- Nutritional labeling is also NOT a mandatory labeling requirement for distilled spirits
 - Unless statements/claims about nutrition are made on the package (e.g., Skinny, Light)







Thank You! Questions?