

Using Hemp and Hemp Derivatives in Alcohol Beverages

JANELLE CHRISTIAN

Industry Outreach Program Manager



Note: Policy may have changed since publication of this presentation. Please consult [TTB.gov](https://www.ttb.gov) for the latest information



2000 Hemp Policy

- When drafted, “hemp” referred to the parts of the cannabis plant excluded from the definition of marijuana in the Controlled Substances Act (CSA), 21 U.S.C. Section 802(16) (such as sterilized seeds and seed oil)
- All components in the beverage must comply with FDA and DEA regulations
- Finished product cannot contain a controlled substance
- TTB formula approval is required, even for products sold only intrastate
- You must submit a report of laboratory analysis of the hemp component



Recent Amendment to Law

- The 2018 Farm Bill amended the definition of marijuana under the CSA to exempt “hemp,” as follows:
 - The term ‘hemp’ means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis
- The law explicitly preserved FDA’s authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug and Cosmetic Act (FD&C Act)
- TTB defers to FDA on whether the use of hemp ingredients would violate the FD&C Act



CBD and other Hemp Ingredients in Food

- Any substance intentionally added to food (including alcohol beverages) is a food additive, and therefore subject to premarket review and approval by FDA, unless the substance is generally recognized as safe (GRAS)
- Aside from three hemp seed ingredients, no other cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA
- After enactment of the 2018 Farm Bill, FDA stated that it is unlawful under the FD&C Act to introduce into interstate commerce any food to which CBD has been added (FD&C Act Section 301(l))
 - [See also: FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers](#)



Terpenes and Botanical Extracts

- “Terpene” refers to a class of organic chemical compounds that may be sourced from plants or synthesized in a laboratory
- FDA has issued regulations that authorize individual synthetic terpenes for use in food (see, *e.g.*, 21 CFR 182.60)
- Many forms of botanical extracts are authorized for use in food in specific FDA regulations; **botanical extracts from cannabis (hemp) are not included in these regulations**
- FDA has advised that alcohol beverage industry members interested in using botanical extracts containing mixtures of terpenes sourced from hemp, or any other plant, should consider submitting a GRAS notice



Alcohol Beverage Formulas for Products Containing Hemp Ingredients

- Based on FDA's public statements and TTB's ongoing consultations with FDA, at this time TTB will return for correction any applications for formulas containing hemp ingredients (other than ingredients derived from hemp seeds or hemp seed oil)
- The correction notices will advise formula applicants that they have the option of resubmitting the formula upon receipt of an individual determination from FDA on the regulatory status of their ingredients
- In light of the changes in the 2018 Farm Bill, TTB will update guidance on the use of hemp and hemp derivatives



Summary & Questions

Brewer's Notices

SUSAN EVANS

Director, Office of Industry and State Outreach





Definitions

- ***Brewery:*** The land and buildings described in the Brewer's Notice...where beer is produced and packaged
- ***Brewer:*** Any person who brews beer (except [for home brewers] under 26 U.S.C. 5053(e)) and any person who produces beer for sale
- ***Brewer's Notice:*** the TTB document issued to qualified applicants that authorizes a brewer to produce beer for sale and, optionally, to operate a tavern on the brewery premises

27 CFR 25.11



What is a “Brewpub”?

- “**Brewpub**” is synonymous with “**tavern on premises**,” which is defined as a portion of the brewery premises where beer is sold to consumers
- Food, and/or taxpaid wine, and/or taxpaid distilled spirits may be sold
- Taxpaid beer produced by other brewers may be sold

27 CFR 25.25



Brewpub vs. Tasting/Tap Room

Brewpub on Premises

- Area where beer is sold to consumers (the tavern) that is part of the brewery premises
- You may run lines from the cellar to the serving tanks in the tavern
- Beer transferred to the tavern must be tax-determined, and tax is paid on the entire tank in the next return period
- Beer may be served by the glass or in containers

Tasting Room Off Premises

- Area where beer is sold that is NOT part of the brewery premises, but may be adjacent to it
- You may NOT run lines from the brewery to tasting room (or any areas not qualified as part of the brewery)
- Beer transferred to tasting room must be taxpaid when removed from the brewery
- All beer transferred to tasting room must be in consumer containers, and labeled as per TTB regulations



Tasting Rooms

Brewery applicants are asked a series of questions in Permits Online to help distinguish what can and cannot be done by a brewery

Will you have a tasting room?: * ☒ Yes ☐ No

Do you plan to charge for samples, tours, and/or parking?: * ☒ Yes ☐ No

Do you understand that the tasting room must be physically separated from the brewing area(s)? ☒ Yes ☐ No
This usually consists of walls with a locked door or a fence with a locking gate: *

Do you understand that if a brewery charges for samples, parking, or tours, the tasting room cannot be part of the brewery premises and you must tax pay the beer before removing it to the tasting room?: * ☒ Yes ☐ No

Do you understand you cannot run lines from the brewery to the tasting room (beer should be tax paid and removed to the tasting room in kegs or some other type of TTB approved container)?: * ☒ Yes ☐ No

Describe how the tasting room will be physically separated from the brewing area(s). : *



Alternation of Premises

When the premises is used by the same owner/same EIN to conduct another TTB - regulated business, such as a winery or distilled spirits plant

- If you are an already established brewery and wish to add a winery or distilled spirits plant, you must submit:
 - A new application for the commodity operations that you are adding
 - Updated diagram showing which areas will be alternating
 - Variance request to use brewery for another purpose
 - Variance from the requirement to submit notification of each alternation
 - Change in Bond (Consent of Surety) TTB Form 5000.18 – if applicable



Alternation of Proprietorship

When two or more proprietors with different EINs are operating at the same premises and sharing space and/or equipment. Generally, the proprietor of an existing brewery, the “host brewer,” agrees to rent space and equipment to a new “tenant brewer.”

- The **host** brewer is required to submit:
 - An alternating proprietorship agreement (a contract between the host and tenant)
 - Updated diagram showing which areas will be alternating and which will be the permanent non-alternating space of both the host and tenant
 - Variance Requests:
 - Application to **Use Brewery for Other Purposes**
 - **Change in Premises** to allow the use of brewery records in lieu of filing an amended brewer’s notice with each alternation of the premises



Alternation of Proprietorship

- The **tenant brewer** is required to submit:
 - An alternating proprietorship agreement (a contract between the host and tenant)
 - Variance Requests:
 - **Retention and Preservation of Records** - Place of Maintenance - if the host, under POA for the tenant, plans to prepare or store records on the premises of the host brewery
 - **Notice of Alternation** - to allow the establishment of an alternating proprietorship with the host brewer
 - **Change in Premises** to allow the use of brewery records in lieu of filing an amended brewer's notice with each alternation of the premises
 - A business plan showing the development plans for the business.
- See [TTB Industry Circular 2005–2](#) for more information



Did You Know...?

- Before you submit your application generally construction should be complete with necessary equipment in place or on order
- You cannot begin producing beer until you receive your approved Brewer's Notice
- A brewery cannot be located in a residence
- If you have an adjacent tasting room you must describe it in the description of the premises and it should also be shown on your diagram



The Benefits of Using Permits Online

- You can self-register
- Contains step-by-step guidance
- Some fields are auto-filled
- You may “Save and resume” applications to complete later
- You have 24/7 access
- You’ll receive email notifications of status changes
- You’ll see cost and time savings on mailing, copying, paper storage



Register for an Account in Permits Online

Home	My Submissions	Resume Draft	Help
------	----------------	--------------	------

User Name or E-mail:	<input type="text"/>	Password:	<input type="password"/>	Log in »
<input type="checkbox"/> Remember me on this computer	I've forgotten my password	New Users: Register for an Account		



<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

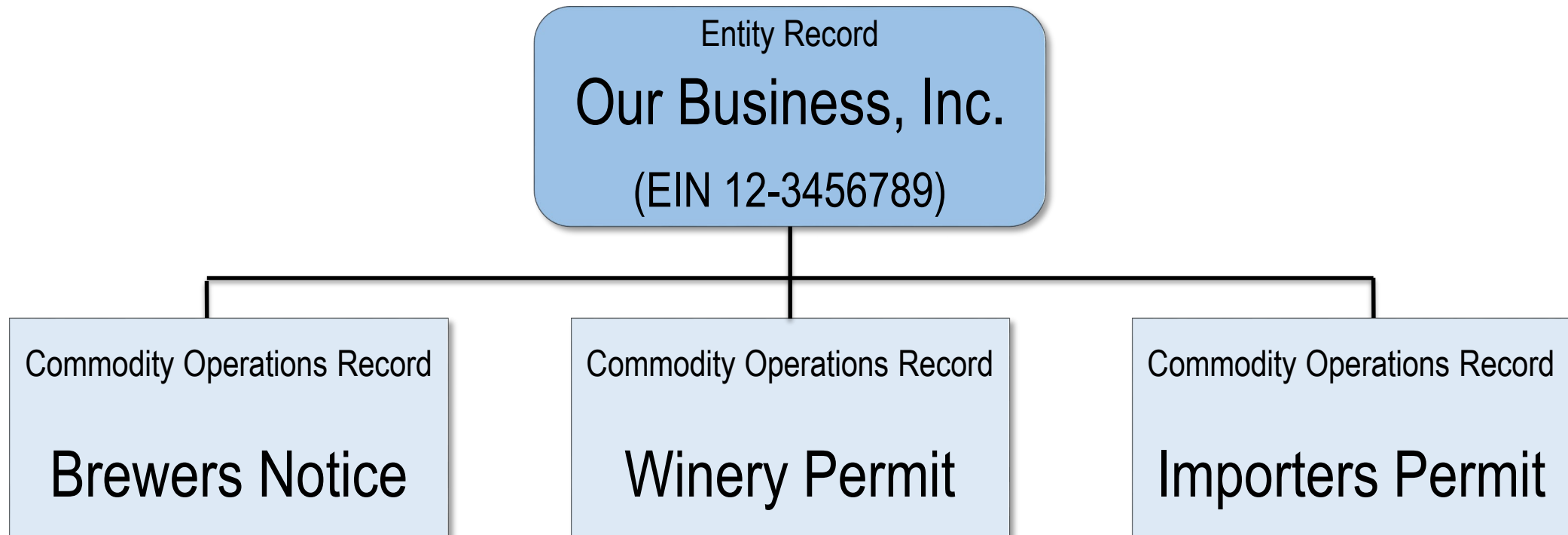


Business Entity and Commodity Operations

- Your information in Permits Online is organized in two different kinds of records
 - The **entity** record equates to a single company or business entity, represented by a unique Employer Identification Number (EIN)
 - A **commodity operations** record is created for each TTB-regulated operation or permit, registration, or notice the entity is approved for
- A typical entity record will have at least one, but may have multiple commodity operations records associated with it



Business Entity and Commodity Operations





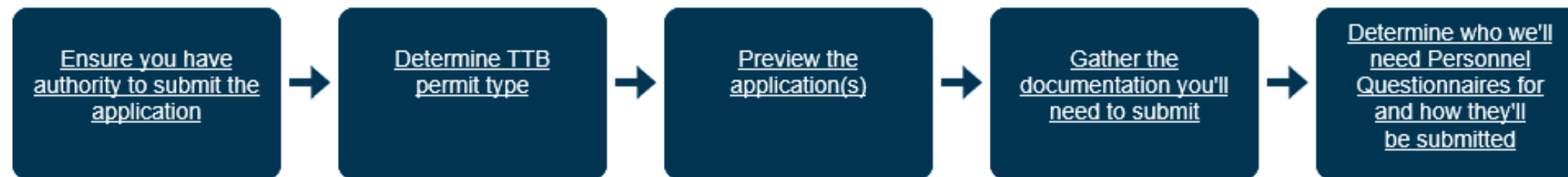
Business Entity and Commodity Operations

- When applying to start a new TTB-regulated business, you'll complete both a new entity application and a new commodity operations application for each permit, registration, or notice you need
- If you need to file an amendment related to the business entity, you file one application and the changes are associated with each TTB permit, registration, or notice held by that company

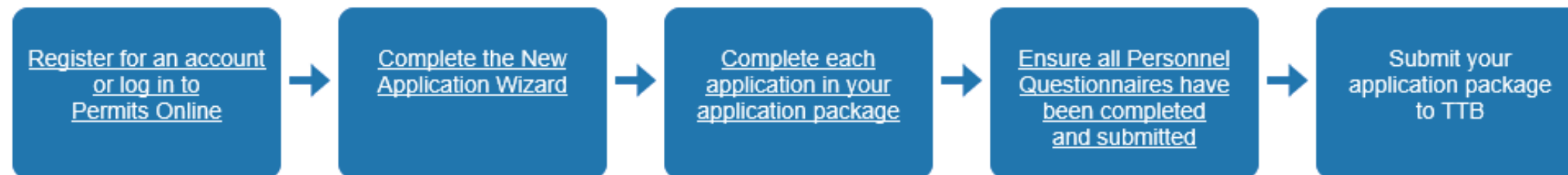


Overview of the Application Process

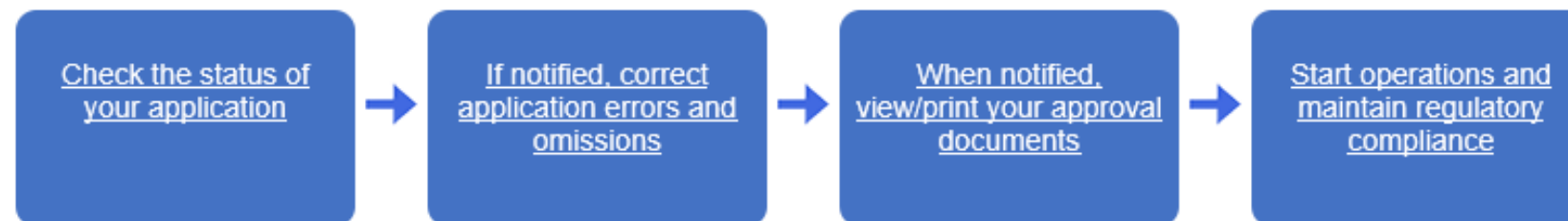
1. Getting Ready



2. Apply and Submit Using Permits Online



3. After Filing



<https://www.ttb.gov/ponl-help/application-process-overview.shtml>



Changes You Must Report to TTB

- Change 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



Changes You Must Report to TTB

- Change 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



Termination of Business

- If you are discontinuing business:
 - File a final Operations Report (TTB Form 5130.9 or TTB Form 5130.26) showing all beer on hand as paid or transferred to new owner before termination
 - The Report must be marked "FINAL REPORT" and have 0.0 "on hand" amount end-of-period
 - File final TTB Form 5000.24, Excise Tax Return, covering the last period of liability marked "FINAL RETURN"
 - The period should cover up to the last day of business as a brewery and should include all removals



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](#)



Summary & Questions