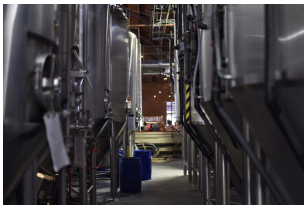

# Opening a Distillery: Formula and Label Approval

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**Categories:**

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In the first article of our *Distillery Start-Up and Compliance* series, we focused on giving distillery start-ups the basics in acquiring Tobacco Tax and Trade Bureau (TTB) approval. After approval from the TTB, the next step is to get formula approval and label approval from the TTB, and register with the Food and Drug Administration (FDA). This article highlights the necessary steps to check formula and label approval and FDA compliance off your list to help your business get one step closer to production.

## Federal Formula Approval

Once generally approved by the TTB, the next step in opening a distillery is to determine whether the product requires formula approval from the TTB. Domestic producers or importers of distilled spirits *may* be required to submit formula applications or product samples for laboratory analysis before applying for a certificate of label approval/exemption (COLA).[1] This is essential to the TTB to ensure that the product does not contain any prohibited ingredients or that limited ingredients are used within prescribed limitations in addition to classifying the product for tax and labeling purposes.[2]

#### Determining Whether Your Spirit Needs Formula Approval

To determine whether your distilled spirit needs formula approval, the TTB has offered an easy, online evaluation. If a business intends to start producing marc brandy, for example, then formula approval would be required. Formula approval is required when there may be harmless coloring, flavoring, or blending materials are added. In the alternative, if a business intends to produce straight malt whisky, then formula approval would not be required. If formula approval is required, then production cannot begin and distillers may not bottle, sell, or market a product until such approval is granted (subject to limited exceptions).[3]


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To apply for formula approval, the TTB offers an online system called "Formulas Online," which allows businesses to track formula and sample submissions. Paper formula applications, TTB Form 5100.51, are also available for businesses that would rather follow the traditional route. In either case, a 750 mL sample of the product (or equivalent volume) must be sent to the TTB's laboratory. More details regarding shipping the sample for analysis can be found here .

**What Information Do I Need for Formula Approval?**

To submit a formula application, a business needs to know whether (1) they are entering a new submission or seeking to update/replace an existing approval, (2) the company formula number, which consists of the applicable permit/brewer's notice number automatically provided by the system followed by a unique number you provide, (3) the appropriate class/type for the product (definitions provided by Formulas Online), (4) units of measurements to measure the quantities listed on the formula, generally either by the percentage of the whole or by volume/weight, (5) total yield: if volume/weight is used as the units of measurement, then the business needs to state the quantity of product made per batch; if the percentage is used, the total percentages of all ingredients should equal 100%, (6) a detailed list of ingredients that includes the kind and quantity of each and every material or ingredient to be used in the formula; each ingredient must be identified as one of the five types: finished alcohol, fermentable ingredients, flavor, color, or other, (7) method of manufacture with a step-by-step description, (8) proof at distillation, which is the alcoholic strength of the spirit after distillation and prior to any addition of water, and (9) final alcohol content, which is the percentage of alcohol by volume of the finished product.[4] Examples of distilled spirit formula applications can be found here.

For imported and domestic products, depending on the ingredients used to manufacture the alcohol beverage, the business may be required to upload certain supporting documents in the "Docs/Links" tab in Formulas Online.[5] For example, if the business


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uses flavors that contain alcohol, natural or artificial flavors, or compounded flavors (purchased from a flavor manufacturer) they must usually submit a Flavor Ingredient Data (FID) Sheet for each flavor and a Limited Ingredient Calculation Worksheet.[6]

An approved formula will include the TTB classification of the product and labeling advice.[7] Once approved, a formula for domestic products remains in effect indefinitely unless the formula is surrendered, superseded, or canceled/revoked by the TTB or by operation of law or regulation.[8]

## Label Approval

Application for the label approval follows formula approval. Prior to submission, a business will need to create a label design. Labeling and advertising of distilled spirits are guided by Federal Regulations that contain requirements and prohibitions. The Regulations include mandatory,[9] restricted, and prohibited labeling information.[10] Some pertinent Regulations include firmly affixed labels,[11] legibility, mandatory size, and separation of mandatory information,[12] and language requirements.[13]

Compared to the previous applications, obtaining a COLA for a product is relatively simple. The information required, in addition to the label design, is provided through the TTB permit and formula approval. The TTB offers COLAs Online for label approval, in addition to Form TTB F 5100.31 if mail is preferred. If the business used its Formulas Online account discussed above, registration is not required for COLAs Online if they request access. Lastly, the TTB offers additional guidance through a step-by-step visual for creating a label application.

Using COLAs Online is preferable as users are given the opportunity to make corrections within 30 days before TTB takes final action on the application.[14] Corrected eApplications receive priority consideration, in addition to the reduction in time and costs associated with filing paper label applications.[15] Further guidance on COLA registration can be found on the TTB's frequently asked questions page.


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## Registration with the FDA

Once TTB forms and applications have been filled out, the business needs to register their facility with the U.S. Food & Drug Administration (FDA). The FDA offers an online system, the FDA Industry Systems (FIS), to facilitate making submissions. Additionally, a step-by-step instruction for registration is provided.

According to the FDA, the registration process requires the following information prior to registration: (1) Previous owner's registration number (if the facility had been registered before by a previous owner), facility name and address, parent company name and address, facility emergency contact information, and alternate trade names (if applicable), (2) General product categories and the types of activities conducted at the facility, (3) Owner, Operator, or Agent in charge information, and an (4) Acknowledgment that the FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetics Act. [16] Upon completion, the business will receive their registration number and PIN to record for future reference.

## Conclusion

Now, some good news: the initial federal regulatory part of the multistep process is generally complete. After you obtain your TTB basic permit, formula approval, and COLA, and register with the FDA, your next big hurdle is attaining all necessary state and local licenses. While the licensing requirements will vary depending on the state you wish to operate in, our next article in the Distillery Start-Up and Compliance series will focus specifically on Kentucky licensing as an example of what you can expect next in the process.

For more information regarding distillery formation, or other tax and regulatory issues in the distilling industry, you can reach out directly to any of the authors or anyone in Frost Brown Todd Consumable Goods service Team.

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Click below to read the other articles in our "*Distillery Start-Up and Compliance*" series.
Part 1: Opening a Distillery: The Federal Application Process

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[1] TTBGov – Approval Basics
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] 27 C.F.R. § 5.61 – 5.74
[10] 27 C.F.R. § 5.81 – 5.103. 27
[11] 27 C.F.R. § 5.51
[12] 27 C.F.R. § 5.52-5.53
[13] 27 C.F.R. § 5.55
[14] TTBGov – COLAs and Formulas Online FAQs
[15] *Id.*
[16] Food Facility Registration User Guide: Step-by-Step Instructions for Registration | FDA

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