



## **TTB Approves General-Use Formulas for Certain Distilled Spirits Produced Using Harmless Coloring, Flavoring, or Blending Materials**

*The Alcohol and Tobacco Tax and Trade Bureau is approving general-use formulas for certain distilled spirits products subject to the formula requirements in 27 CFR 5.26, 5.27, and 19.348. Proprietors of distilled spirits plants producing vodka, whisky, brandy or rum with the harmless coloring, flavoring, or blending materials specified in this ruling, in accordance with these general-use formulas, do not need to submit a formula to TTB for approval.*

### **TTB RULING 2016–3**

#### **Background**

In recent years, TTB has experienced a marked increase in the annual number of formula submissions received for review and approval. As part of its ongoing efforts to reduce for industry members the regulatory burdens associated with formula approval and to increase administrative efficiencies for the Bureau, TTB has reviewed the formula requirements for distilled spirits products to determine where its formula review process could be streamlined and modernized.

Sections 5.26 and 5.27 of the TTB regulations (27 CFR 5.26 and 5.27) require the submission of formulas for certain distilled spirits products, including those that contain harmless coloring, flavoring, or blending materials. Pursuant to § 5.23 of the TTB regulations (27 CFR 5.23), harmless coloring, flavoring, or blending materials that are not an essential component part of the particular distilled spirits to which added, but which are “customarily employed therein in accordance with established trade usage” may be used in certain distilled spirits products, without changing the class or type of such spirits, if the materials do not total more than 2½ percent by volume of the finished product. The determination of whether a non-essential coloring, flavoring, or blending material is customarily employed in the production of a particular distilled spirits product, in accordance with established trade usage, is made on a case-by-case basis through TTB’s review of formulas for such products.

In lieu of issuing a formula approval for each distilled spirits product that contains harmless but non-essential coloring, flavoring, or blending materials, TTB is, through this ruling, approving general formulas for vodka and rum, and certain types of whisky and brandy, made with certain specified harmless coloring, flavoring, or blending materials, in accordance with this ruling. We refer to these formulas as “general-use formulas” and industry members who produce distilled spirits in conformance with a

general-use formula do not need to submit a formula to TTB for approval. By issuing general-use formulas for these products, TTB allows industry members to get their products to the market without having to wait for formula approval.

## **Authority**

### *Statutory Authority*

Sections 105(e) and (f) of the Federal Alcohol Administration Act (FAA Act) ([27 U.S.C. 205\(e\) and \(f\)](#)) vest broad authority in the Secretary of the Treasury to prescribe regulations with respect to the labeling and advertising of wine, distilled spirits, and malt beverages that are introduced into interstate or foreign commerce or imported into the United States. Section 105(e) also provides that, subject to limited exceptions, no person may bottle, or remove from customs custody in bottles, distilled spirits, wine, or malt beverages unless the person has obtained a certificate of label approval (COLA) issued in accordance with regulations prescribed by the Secretary. Regulations that implement the provisions of sections 105(e) and (f), as they relate to distilled spirits, are set forth in 27 CFR part 5, Labeling and Advertising of Distilled Spirits.

Chapter 51 of the Internal Revenue Code of 1986, as amended (IRC), provides the Secretary of the Treasury with authority to promulgate regulations pertaining to the operation of distilled spirits plants and the production of distilled spirits.

TTB administers the FAA Act and chapter 51 of the IRC pursuant to section 1111(d) of the Homeland Security Act of 2002, as codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01, dated December 10, 2013 (superseding Treasury Department Order 120–01, dated January 24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of these provisions.

### *Regulatory Authority*

#### *Standards of Identity under part 5 of the TTB regulations*

Under the statutory authority of 27 U.S.C. 205(e), the TTB regulations at 27 CFR part 5, Subpart C, set forth the standards of identity for the classes and types of distilled spirits for beverage or other nonindustrial purposes. The regulations define 12 classes of distilled spirits, most of which are further divided into specific types. Each class and type has specific production standards for products labeled under such class or type. For example:

Class 1 is “neutral spirits” or “alcohol,” which are distilled spirits produced from any material at or above 190 degrees proof, and bottled at not less than 80 degrees proof. See § 5.22(a). “Vodka” is a type of neutral spirits so distilled, or so treated after distillation with charcoal or other materials, as to be without

distinctive character, aroma, taste, or color. “Grain spirits” are neutral spirits distilled from a fermented mash of grain and stored in oak containers.

Class 2 is “whisky,” which is an alcoholic distillate from a fermented mash of grain produced at less than 190 degrees proof and bottled at not less than 80 degrees proof and stored in oak containers (except that corn whisky need not be so stored), and it includes several specific types of whisky. “Bourbon whisky” is whisky produced at not exceeding 160 degrees proof from a fermented mash of not less than 51 percent corn, and stored at not more than 125 degrees proof in charred new oak containers, and also includes mixtures of bourbon whisky of the same type. See § 5.22(b)(1)(i). Pursuant to § 5.22(l), the word “bourbon” may not be used to describe any whisky or whisky-based distilled spirits not produced in the United States. See § 5.22(b) for several additional types of whisky. The designation “whisky” includes mixtures of such distillates for which no specific standards of identity are prescribed.

Class 4 is “brandy,” which is an alcoholic distillate from the fermented juice, mash, or wine of fruit, or from the residue thereof, produced at less than 190 degrees proof and bottled at not less than 80 degrees proof, and it includes several specific types of brandy. The term “brandy” when appearing alone on a label means “grape brandy.” A brandy that does not conform to any of the types set forth in § 5.22(d) is designated as “brandy,” followed by a truthful and adequate statement of composition.

Class 6 is “rum,” which is an alcoholic distillate from the fermented juice of sugar cane, sugar cane syrup, sugar cane molasses, or other sugar cane by-products, or mixtures thereof, produced at less than 190 degrees proof and bottled at not less than 80 degrees proof. This class includes “Cachaça,” which is a distinctive product of Brazil. See § 5.22(f).

The standards of identity for whisky, brandy, and rum also provide that the product must possess the taste, aroma, and characteristics generally attributed to whisky, brandy, and rum, respectively. See 27 CFR 5.22(b), 5.22(d), and 5.22(f).

#### *Addition of Harmless Coloring, Flavoring, or Blending Materials*

Section 5.23(a)(1) of the TTB regulations (27 CFR 5.23(a)(1)) provides that the addition of any coloring, flavoring, or blending materials to any class or type of distilled spirits, except as otherwise provided in that section, alters the class or type thereof, and the product must be appropriately redesignated. Thus, the general rule is that the addition of such materials to distilled spirits changes the class or type of the product, unless § 5.23 specifically authorizes the addition.

Paragraph (a)(2) allows the addition of coloring, flavoring, or blending materials without altering the class or type of the product under two different circumstances:

- *Essential components:* When harmless coloring, flavoring, or blending materials are an essential component part of the particular class or type of distilled spirits as described in the standards of identity, their use does not change the class or type of the product. An example is the use of flavors in a class 9 flavored brandy, flavored gin, flavored rum, flavored vodka, or flavored whisky.
- *Non-essential components:* Some harmless coloring, flavoring, or blending materials are *not* an essential component part of the particular distilled spirits (that is, their use is not mandated or specifically authorized in the standards of identity), but they are customarily employed in the manufacture of such distilled spirits in accordance with established trade usage. An example is caramel color and blending sherry added to blended whisky to ensure consistency in color and smoothness. These harmless coloring, flavoring, or blending materials may be used in certain products, as long as they do not total more than 2½ percent by volume of the finished product.

Paragraph (a)(3) outlines additional specific rules about what are and are not considered to be harmless coloring, flavoring, and blending materials, including the following:

- Coloring, flavoring, or blending materials that render the product to which added an imitation may not be added without changing the class or type;
- In the case of Cognac brandy, caramel, infusion of oak chips, and sugar, are the only harmless coloring, flavoring, and blending materials authorized; and
- Any coloring, flavoring, or blending materials added to neutral spirits result in an alteration of the class, except that vodka may be treated with sugar in an amount not to exceed 2 grams per liter and a “trace amount” of citric acid.

Section 5.23 also provides that any whisky designated as “straight” may not contain any added coloring, flavoring, or blending materials. This includes “straight bourbon whisky,” “straight corn whisky,” “straight malt whisky,” “straight rye malt whisky,” “straight rye whisky,” “straight wheat whisky,” and “straight whisky.” However, “a blend of straight whiskies” or “blended straight whiskies” may contain added harmless coloring, flavoring, or blending materials.

Furthermore, Chapter 7 of the Distilled Spirits Beverage Alcohol Manual (BAM) (TTB P 5110.7 (04/2007)) provides that bourbon whisky may not contain any amount of added coloring, flavoring or blending materials. This reflects the determination by our predecessor agency, the Bureau of Alcohol, Tobacco and Firearms (ATF), that added coloring, flavoring, or blending materials are not customarily employed in the production of bourbon whisky in accordance with established trade usage.

With regard to neutral spirits, the regulations do not authorize the use of any harmless coloring, flavoring, or blending materials, except that vodka may be treated with sugar in an amount not to exceed 2 grams per liter and a trace amount of citric acid. As

reflected in Chapter 7 of the Distilled Spirits BAM, and ATF Ruling 97-1, a “trace amount” of citric acid means not more than 1,000 parts per million (1 gram per liter).

*Formula Requirements for Domestic Distilled Spirits and Distilled Spirits Shipped from Puerto Rico and the Virgin Islands to the United States*

Under the statutory authority of [26 U.S.C. 5201 and 5555](#), § 19.348 of the TTB regulations (27 CFR 19.348) requires proprietors of distilled spirits plants to obtain approval of a formula on TTB Form 5100.51, as provided in §§ 5.26 and 5.27, before conducting certain operations.

The TTB regulations at 27 CFR part 5, Subpart Ca, require formulas under specified circumstances. These regulations apply to proprietors of distilled spirits plants qualified as processors under 27 CFR part 19, as well as persons in Puerto Rico who manufacture distilled spirits products for shipment to the United States, and persons who ship Virgin Islands distilled spirits products into the United States. See 27 CFR 5.25.

Under § 5.26(a) of the TTB regulations, 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.” Section 5.27 provides that formulas “are required for distilled spirits operations which change the character, composition, class or type of spirits as follows” and then provides a list of such operations. Section 5.27(a) includes the “compounding of spirits through the mixing of any coloring, flavoring, wine, or other material with distilled spirits.” Furthermore, § 5.33(g) of the TTB regulations (27 CFR 5.33(g)) provides that a “complete and accurate statement of the contents of the bottles to which labels are to be or have been affixed” must be submitted, on request, to the appropriate TTB officer.

*Formula Requirements for Imported Distilled Spirits*

Section 5.51(d) of the TTB regulations (27 CFR 5.51(d)) requires a formula or “statement of process” for imported gin bearing the term “distilled” as part of the designation. In addition, as noted for domestic products above, the regulations at § 5.33(g) also apply to imported products. Accordingly, upon request of the appropriate TTB officer, importers must provide a “complete and accurate statement of the contents of the bottles to which labels are to be or have been affixed.”

Pursuant to § 5.33(g), the distilled spirits chart attached to [Industry Circular 2007-4](#) provides that a pre-import letter (formula) and/or a laboratory analysis are required for certain classes and types of imported distilled spirits. The pre-import letter requirements for imported distilled spirits generally, but not always, follow the requirements for domestic products.

## Discussion

### *General-Use Formulas*

Section 5.27 requires the submission of a formula for certain operations that change the character, composition, class or type of spirits in certain ways, including the mixing of any coloring, flavoring, wine, or other material with distilled spirits.

TTB has reviewed its formula requirements, and has concluded that the regulations in § 5.23, together with the provisions of ATF Ruling 97-1, provide very specific guidelines for the types of harmless coloring, flavoring, or blending materials that may be added to vodka without changing the class or type of the product. Accordingly, TTB is approving general-use formulas for vodka produced in accordance with the standards of identity set forth in § 5.22(a)(1) and treated with sugar in an amount not to exceed 2 grams per liter, citric acid in an amount not to exceed 1 gram per liter, or both.

Under current regulations and policy, formulas are required for domestically bottled rum, and several types of domestically bottled whisky and brandy, only when such products contain harmless coloring, flavoring or blending materials. The regulations do not specify exactly what non-essential coloring, flavoring or blending materials may be added to such products without changing the class or type, but they require that such materials be “customarily employed” in such products “in accordance with established trade usage.” Furthermore, such materials may not total more than 2½ percent by volume of the finished product. See 27 CFR 5.23(a)(2).

The formula review process allows TTB to review the production process for these distilled spirits products to ensure the proper classification of the products for labeling purposes. However, TTB has determined that there are some ingredients that are customarily employed in the production of rum, as well as several types of whisky and brandy, and that their use, within the 2½ percent limitation prescribed by the regulations, does not raise classification issues. Accordingly, we are issuing this ruling, which provides immediate relief from the formula submission requirements for these specific products.

This ruling does not apply to certain types of whisky where a formula must always be submitted regardless of whether harmless coloring, flavoring, or blending materials are added. Similarly, the ruling does not affect current formula requirements for substandard brandy, where a formula must always be submitted regardless of whether harmless coloring, flavoring, or blending materials are added. Furthermore, the addition of a material that renders the product an imitation will also continue to require a formula. For example, adding sugar to the distilling material for brandy will render the product an “imitation brandy” if the amount of sugar added exceeds the amount allowed to be added in the production of standard wine. See 27 CFR 5.22(j)(6).

TTB is making similar changes to the formula requirements for imported products through the issuance of [TTB Industry Circular 2016-1](#) and [TTB Guidance No. 2016-3](#), which remove laboratory analysis and/or formula requirements for certain imported

distilled spirits products. As noted earlier, the formula requirements for imported and domestically bottled distilled spirits products will not always be consistent. For example, TTB believes it is important to maintain laboratory analysis requirements for certain imported brandies.

### **Effect on Previously Approved Formulas and Labels**

Previously approved formulas for the distilled spirits products affected by this ruling will continue to be valid. However, TTB will not accept for review new formulas submitted for products approved under this ruling. This ruling serves as the approval that is required by §§ 5.26, 5.27, and 19.348.

Certificates of label approval with associated formulas will continue to be valid, even if the associated formula is changed, as long as the revised product formulation is one that is covered by this ruling.

To avoid delays in processing COLA applications, industry members are encouraged to note on their application that they are requesting approval of a label for a distilled spirits product covered by a general-use formula under this ruling by inserting “Formula Approved Under TTB Ruling 2016-3” in step 3 via COLAs Online or as a comment in item 19 on TTB F 5100.31, Application for and Certification/Exemption of Label/Bottle Approval.

### **Ingredient Safety Issues**

It has always been, and it will remain, the responsibility of the industry member to use good commercial practices to ensure that the ingredients and production processes result in the production of alcohol beverage products suitable for human food consumption and that the ingredients and finished products comply with all applicable regulations of the U.S. Food and Drug Administration (FDA) regarding ingredient safety. This is true regardless of whether the product is subject to the formula requirements of the TTB regulations.

### **TTB Determination**

*Held*, TTB approves a general-use formula under §§ 5.26 and 19.348 for vodka produced in accordance with the standards of identity set forth in § 5.22(a)(1) and containing no harmless coloring, flavoring or blending materials other than sugar in an amount not to exceed 2 grams per liter, citric acid in an amount not to exceed 1 gram per liter, or both.

*Held further*, TTB approves a general-use formula under §§ 5.26 and 19.348 for rum, produced in accordance with the standards of identity set forth in § 5.22(f), which contains no harmless coloring, flavoring or blending materials other than sugar, brown sugar, molasses, or caramel, singly or in combination, in a quantity that does not exceed a total of 2½ percent by volume of the finished rum.

*Held further*, TTB approves a general-use formula under §§ 5.26 and 19.348 for the following types of whisky, if they contain no harmless coloring, flavoring or blending materials other than sugar, caramel, or wine, singly or in combination, in a quantity that does not exceed a total of 2½ percent by volume of the finished whisky:

- Whisky made in accordance with § 5.22(b) that is designated as “whisky” without any type designation;
- Rye whisky, wheat whisky, malt whisky, or rye malt whisky made in accordance with § 5.22(b)(1)(i);
- Corn whisky made in accordance with § 5.22(b)(1)(ii);
- Whisky distilled from bourbon mash, rye mash, wheat mash, malt mash, or rye malt mash in accordance with § 5.22(b)(2); and
- Light whisky made in accordance with § 5.22(b)(3).

*Held further*, no coloring, flavoring, or blending materials may be used in the production of spirits designated as “bourbon whisky” in accordance with § 5.22(b)(1)(i) or “straight” whisky in accordance with § 5.22(b)(1)(iii).

*Held further*, TTB approves a general-use formula under § 5.26 and 19.348 for the following types of brandy, if they contain no harmless coloring, flavoring or blending materials other than sugar, caramel, fruit juice from the same fruit from which the brandy is distilled; or wine fermented from juice of the same fruit from which the brandy is distilled, singly or in combination, in a quantity that does not exceed a total of 2½ percent by volume of the finished brandy:

- Fruit brandy (including grape brandy, immature grape brandy, slivovitz (plum brandy), applejack (apple brandy) or any other type of fruit brandy (e.g., pear brandy)), made in accordance with § 5.22(d)(1);
- Dried fruit brandy made in accordance with § 5.22(d)(3);
- Lees brandy made in accordance with § 5.22(d)(4)
- Pomace brandy, marc brandy, grappa and grappa brandy made in accordance with § 5.22(d)(5);
- Residue brandy made in accordance with § 5.22(d)(6); and
- Neutral brandy made in accordance with § 5.22(d)(7).

*Held further*, Pursuant to § 5.33(g), TTB may require, on a case-by-case basis, information about the formulation and ingredients of any distilled spirits product at any time during the label review process or whenever necessary to enforce TTB regulations.

*Held further*, This ruling does not exempt from the formula requirements the addition of any other coloring, flavoring, or blending materials, not specified in this ruling, whether or not they are within the 2½ percent limitation set forth in § 5.23.

*Held further*, Industry members remain responsible for using good commercial practices to ensure the safety of all ingredients and processes and for ensuring compliance with applicable regulations of the FDA with regard to ingredient safety,

regardless of whether the ingredient or process is subject to formula requirements under TTB regulations.

Date signed: September 28, 2016

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