DEPARTMENT OF THE TREASURY
Alcohol and Tobacco Tax and Trade Bureau

TTB Ruling
Number: 2014–2 February11, 2014

Revised Interim Policy on Gluten Content Statements in the Labeling and Advertising of Wine, Distilled Spirits, and Malt Beverages

Truthful, accurate, and non-misleading gluten content statements, in accordance with this ruling, are permitted on labels and in advertisements for alcohol beverage products regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB). TTB may modify the interim guidance provided in this ruling when the Food and Drug Administration (FDA) issues further guidance or final regulations on use of the term "gluten-free" on labels of fermented foods. TTB Ruling 2012–2 is superseded.

I. Authority:

The Federal Alcohol Administration Act (FAA Act) provides for regulation of the labeling and advertising of wine, distilled spirits, and malt beverages in 27 U.S.C. 205(e) and 205(f). These sections give the Secretary of the Treasury the authority to issue regulations intended to prevent deception of the consumer, to provide the consumer with adequate information as to the identity and quality of the product, and to prohibit false or misleading statements. Additionally, the law provides the Secretary with the authority to prohibit, irrespective of falsity, statements relating to age, manufacturing processes, analyses, guarantees, and scientific or irrelevant matters that are likely to mislead the consumer. TTB administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01 (Revised), dated December 10, 2013, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

The FAA Act generally requires bottlers and importers to obtain a certificate of label approval covering wine, distilled spirits, or malt beverages before bottling them or removing them in bottles from customs custody for introduction in interstate or foreign commerce, in accordance with regulations prescribed by the Secretary. In the case of malt beverages, the labeling and advertising provisions of the FAA Act apply only if the laws of the State into which the malt beverages are to be shipped impose similar requirements.

The implementing regulations, which appear in 27 CFR parts 4, 5, and 7, also contain more specific prohibited practices with respect to the labeling and advertising of alcohol beverages. The regulations prohibit the use of labeling or advertising statements that are false or untrue in any particular. The regulations also prohibit, irrespective of falsity, statements that directly, or by ambiguity, omission, or inference, or by the addition of

irrelevant, scientific, or technical matter, tend to create a misleading impression. See 27 CFR 4.39(a)(1), 4.64(a)(1), 5.42(a)(1), 5.65(a)(1), 7.29(a)(1), and 7.54(a)(1).

Furthermore, the regulations prohibit the use of any health-related statements in the labeling or advertising of wine, distilled spirits, and malt beverages if such statements are untrue in any particular or tend to create a misleading impression. TTB evaluates such statements on a case-by-case basis and may require a disclaimer or some other qualifying statement to dispel any misleading impression created by the health-related statement. See 27 CFR 4.39(h), 4.64(i), 5.42(b)(8), 5.65(d), 7.29(e), and 7.54(e). Statements about gluten content are treated as health-related statements under TTB regulations.

As reflected in the 1987 Memorandum of Understanding between FDA and TTB's predecessor agency, the Bureau of Alcohol, Tobacco and Firearms (ATF), TTB is responsible for the promulgation and enforcement of regulations with respect to the labeling of wine, distilled spirits, and malt beverages pursuant to the FAA Act. TTB consults with FDA about the issuance of regulations regarding the labeling of ingredients and substances contained in alcohol beverages.

Importantly, however, in cases where an alcohol beverage is not covered by the labeling provisions of the FAA Act (i.e., beers that are not saké or malt beverages under the FAA Act and wines with an alcohol content of less than 7 percent alcohol by volume), the product is subject to ingredient and other labeling requirements administered under the Federal Food, Drug, and Cosmetic Act, and the implementing regulations that are administered by FDA. These alcohol beverages are still subject to applicable TTB regulations implementing the requirements of the Internal Revenue Code of 1986 and the health warning statement requirements of the Alcoholic Beverage Labeling Act of 1988.

II. Background:

In 2004, the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), (Public Law 108–282, Title II) was signed into law. Section 206 of FALCPA directed the Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders, to issue a rule to define, and permit use of, the term "gluten-free" on the labeling of foods.

A. FDA Notice of Proposed Rulemaking

On January 23, 2007, the FDA published a notice of proposed rulemaking in the **Federal Register** (72 FR 2795) proposing to define the term "gluten-free" for voluntary use in the labeling of foods. Among other things, the proposed rule provided that foods that contain an ingredient that is a gluten-containing grain (wheat, barley, rye, or crossbred hybrids of those grains) would not be allowed to make a "gluten-free" labeling claim. On August 3, 2011, FDA published a notice in the **Federal Register** (76 FR 46671) to reopen the comment period for the proposed rule. The FDA notice

specifically addressed the issues associated with gluten claims for fermented or hydrolyzed products. The notice stated that:

> FDA recognizes that for some food matrices (e.g., fermented or hydrolyzed foods), there are no currently available validated methods that can be used to accurately determine if these foods contain < 20 ppm gluten. In such cases, FDA is considering whether to require manufacturers of such foods to have a scientifically valid method that will reliably and consistently detect gluten at 20 ppm or less before including a 'gluten-free' claim in the labeling of their foods. FDA is requesting comments on this proposed approach as well as on whether FDA also should require these manufacturers to maintain records on test methods, protocols, and results and to make these records available to FDA upon inspection. See 76 FR 46673, citations omitted.

B. TTB Ruling 2012–2

While FDA was engaged in rulemaking on the definition of the term "gluten-free," TTB received requests from industry members to use "gluten-free" claims in the labeling and advertising of alcohol beverages. Pending the issuance of a final rule by FDA, TTB provided interim guidance in TTB Ruling 2012–2 on the use of the term "gluten-free" on alcohol beverage labels and in advertisements subject to TTB's authority under the FAA Act. In the absence of a regulatory definition of the term "gluten-free," TTB concluded that the term would be interpreted by consumers of alcohol beverages to mean that the product contains no gluten.

Many alcohol beverages subject to the FAA Act are produced without any ingredients that contain gluten. For example, a wine fermented from grapes, or a vodka distilled from potatoes, may not contain any gluten if the producer used good manufacturing practices, such as taking adequate precautions to prevent cross-contact, and did not use additives, yeast, or storage materials that contain gluten. Under the interim policy, TTB allowed the use of a "gluten-free" claim in the labeling and advertising of such products. TTB reminded industry members that it would be the responsibility of the importer or bottler of the product to ensure that the claim is truthful and accurate.

TTB also received inquiries from brewers and importers who wanted to make label claims about the gluten content of malt beverages fermented from malted barley and other gluten-containing grains. In these cases, industry members claimed that they have used various processes to remove most of the gluten from their products, and that the remaining gluten is at low levels (usually below 10 ppm). It also had been suggested that the distillation of mashes fermented from grains containing gluten in the production of distilled spirits removes most of the gluten from such products. Finally, other products may be crafted in a manner that significantly reduces the gluten content of the finished product.

TTB determined that it would be inherently misleading for alcohol beverages produced from grains containing gluten or their derivatives to make a "gluten-free" claim or a claim

of specific gluten content levels absent a means to verify the accuracy of that statement through scientifically validated methods or other reliable means as might be revealed through FDA rulemaking. However, for products that were produced using wheat, barley, rye, or a crossbred hybrid of these grains, and were then processed, treated, or crafted to remove the gluten, TTB announced that it would allow use of the statement "[Processed *or* Treated *or* Crafted] to remove gluten," together with a qualifying statement to inform consumers that: (1) the product was fermented or distilled from a grain that contains gluten; (2) the gluten content of the product cannot be verified; and (3) the product may contain gluten. TTB believed that the qualifying statement was necessary to avoid misleading consumers and because of the serious health consequences associated with the consumption of gluten by individuals with celiac disease. The ruling stated that industry members are responsible for verifying the accuracy of any such labeling or advertising statement.

TTB Ruling 2012–2 also held that TTB would not approve a label containing the statement described above unless a detailed description of the method of manufacture substantiating the claim that gluten has been removed from the product was submitted to TTB's Advertising, Labeling and Formulation Division with the application for label approval. To evaluate whether the method of manufacture successfully removed gluten from the finished product, TTB also required the submission of results of the R5 Mendez Competitive ELISA assay for the finished product showing a response of less than 20 ppm gluten. Because this testing method has not been shown to be scientifically valid for the purpose of accurately quantifying the gluten content of fermented products, TTB used these results for the limited purpose of determining whether there is any change in the amount of gluten detected in the product and the direction and magnitude of that change. TTB also noted that it might request samples to be submitted to the Beverage Alcohol Laboratory to verify the test results.

C. FDA Final Rule

On August 5, 2013, FDA issued a final rule on the use of "gluten-free" claims in food labeling. See 78 FR 47154. In general, the rule provides that foods may be labeled with the term "gluten-free" if they do not contain any one of the following:

(1) An ingredient that is a gluten-containing grain (e.g., spelt wheat);

(2) An ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten (e.g., wheat flour); or

(3) An ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food). See 21 CFR 101.91(a)(3), 78 FR 47178.

If the food meets the above requirements, or if it inherently does not contain gluten, it may bear a "gluten-free" claim as long as any unavoidable presence of gluten in the food bearing the claim in its labeling is below 20 ppm gluten (i.e., below 20 mg gluten

per kg of food). See 21 CFR 101.91(a)(3), 78 FR 47178. A food that bears the claim "gluten-free" in its labeling and fails to meet the requirements of 21 CFR 101.91(a)(3) will be deemed misbranded by FDA. See 21 CFR 101.91(b)(1), 78 FR 47178. Similarly, a food that bears the claim "no gluten," "free of gluten," or "without gluten" in its labeling and fails to meet the requirements of 21 CFR 101.91(a)(3) will also be deemed misbranded by FDA. See 21 CFR 101.91(b)(2), 78 FR 47178. Further, FDA will deem a food bearing a "gluten-free" claim to be misbranded if it lists wheat in the ingredient list or in an allergen statement unless the label also bears additional language clarifying that the wheat has been processed to allow the food to meet FDA requirements for "gluten-free" foods. See 21 CFR 101.91(b)(3), 78 FR 47178.

In the preamble to the final rule, FDA noted that some comments "asserted that there are some competitive enzyme-linked immunosorbent assay (ELISA)-based methods that can accurately detect and measure gluten concentration levels in fermented and hydrolyzed foods as low as 0.24 mg/100 g or 2.4 ppm." However, FDA responded that "currently available sandwich ELISA-based methods are not effective in detecting and quantifying intact gluten proteins in fermented and hydrolyzed foods," and that it did not consider competitive ELISA-based methods to be "scientifically valid for the purposes of analyzing fermented or hydrolyzed foods to determine compliance with this rule under § 101.91(c)." See 78 FR 47165. Accordingly, FDA intends "to issue a proposed rule to address how FDA will evaluate compliance with § 101.91(b) when an evaluation of compliance based on an analysis of the food using a scientifically valid method under § 101.91(c) is not available because the food is fermented or hydrolyzed or contains fermented or hydrolyzed ingredients." See 78 FR 47165. In the interim, if a fermented or hydrolyzed food meets all of the regulatory requirements of 21 CFR 101.91 , FDA stated that it would permit the use of a "gluten-free" claim "even though the gluten content of the food cannot be reliably measured pursuant to § 101.91(c)." Manufacturers are responsible for ensuring that foods bearing a "gluten-free" claim comply with the regulations. See 78 FR 47165.

In the preamble, FDA also discussed other issues specifically relating to beers that are subject to FDA labeling regulations. FDA stated that some comments asked FDA to allow beers to be labeled "gluten-free" if the beers contained less than 20 ppm gluten. In contrast, according to FDA, other comments favored prohibiting the use of a "gluten-free" claim on the label of beers that were made from gluten-containing ingredients but were later "reduced" in gluten due to processing methods. See 78 FR 47165. In response to these comments, FDA stated that "some comments have claimed that beers made from gluten-containing grains can be processed in a way that removes gluten. We are aware of a limited number of such products in the market. As with other fermented foods, we are not aware of any scientifically valid way to evaluate these claims, and there is inadequate evidence in the record concerning the effectiveness of the commenters' gluten removal process." See 78 FR 47166. Accordingly, FDA announced that it intends "to address the 'gluten-free' labeling of beers subject to FDA's labeling requirements" in its planned proposed rule on fermented and hydrolyzed foods.

Nonetheless, "to avoid any changes to labels that may cause further confusion with regard to 'gluten-free' beer until [FDA] issue[s] the separate rule on gluten-free labeling

of hydrolyzed and fermented foods" (including beer), FDA stated that it "intend[s] to exercise enforcement discretion with respect to the requirements for 'gluten-free' labeling for beers subject to FDA labeling requirements" pending the completion of FDA's rulemaking process with respect to fermented or hydrolyzed products. See 78 FR 47166. FDA's enforcement discretion will only extend to "FDA-regulated beers that currently [as of August 5, 2013] make a 'gluten-free' claim and that are: (1) Made from a non-gluten-containing grain or (2) made from a gluten-containing grain, where the beer has been subject to processing that the manufacturer has determined will remove gluten below a 20 ppm threshold." See 78 FR 47155. FDA further noted that, to the extent that a beer manufacturer wants to make a new gluten-free claim on a label for a beer subject to FDA's labeling requirements, "they should contact FDA regarding the possible expansion of FDA's consideration for the exercise of enforcement discretion related to such labeling." See 78 FR 47166.

III. Revisions to TTB Policy

TTB has reviewed the FDA final rule and is updating its policy with regard to gluten content statements in the labeling and advertising of wine, distilled spirits, and malt beverages. Although TTB labeling regulations for alcohol beverages are not always identical to FDA labeling regulations for foods, given the important consumer health considerations relating to "gluten-free" claims, TTB believes that it is important to adopt an approach on this issue that is as consistent as possible with the regulations issued by FDA, while taking into consideration the differences in the statutes administered by TTB and FDA, respectively. Accordingly, we are superseding TTB Ruling 2012–2 with this revised policy. We are designating this policy as "interim" because we may revise it after FDA issues a final rule or other guidance with respect to fermented and hydrolyzed products.

A. Products that meet FDA regulatory standards for "gluten-free" claims.

Under TTB's revised interim policy, the term "gluten-free" may be used on labels and in advertisements if the product would be entitled to make a gluten-free label claim under the standards set forth in the new FDA regulations at 21 CFR 101.91. Thus, alcohol beverages that are made without any ingredients containing gluten (such as wines fermented from grapes or other fruit and distilled spirits distilled from materials other than gluten-containing grains, where such products do not include any ingredients containing gluten) may continue to make "gluten-free" claims in the same way allowed in the new FDA regulations for inherently gluten-free products. This revision only clarifies the standards for these products and should not require any changes to TTB-approved labels for wines and distilled spirits that are made from ingredients that do not contain gluten and currently are labeled or advertised as "gluten-free." TTB expects manufacturers using a "gluten-free" claim to take appropriate measures to prevent cross-contact with gluten-containing grains during production, processing, storage, or other handling practices.

TTB notes that the FDA regulations at 21 CFR 101.91 prohibit use of a "gluten-free" claim where, among other things, a food contains an "ingredient that is derived from a

gluten-containing grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food.)" Thus, foods that are made using an ingredient derived from a gluten-containing grain may be entitled to a "gluten-free" claim if the ingredient itself (not the food) has been processed to remove gluten, and the use of the ingredient does not result in the presence of 20 ppm or more gluten in the food. TTB does not believe that this provision will generally be relevant to malt beverages fermented from malted barley and other gluten-containing grains, or distilled spirits distilled from gluten-containing grains, as these products are usually made from the grains themselves, not from ingredients such as wheat starch or barley starch.

The preamble to the FDA final rule explains that "the final rule limits the use of gluten-containing ingredients to ensure the food, as consumed, contains as little gluten as possible. Allowing the 'gluten-free' label claim on food whose ingredients have been processed to remove gluten, but not on food that has been processed to remove gluten helps ensure that the finished product has the lowest amount of gluten that is reasonably possible, and consistent with the use of specific manufacturing practices that can prevent gluten cross-contact situations." 78 FR 47165. FDA further explains in its "Questions and Answers: Gluten-Free Food Labeling Final Rule" that a "food labeled gluten-free cannot be intentionally made with any amount of a gluten-containing grain (wheat, rye, barley, or their crossbred hybrids like triticale) or an ingredient derived from such grain that was not processed to remove gluten." Any producers with questions on this issue should contact TTB for further guidance.

B. Products that do not meet FDA regulatory standards for "gluten-free" claims.

The new FDA regulations disqualify foods from bearing a "gluten-free" claim if they contain an ingredient that is a gluten-containing grain, such as wheat, rye, barley, or a cross-bred hybrid of those grains. This prohibition applies regardless of the gluten content of the finished product. Thus, consistent with FDA's regulations, TTB will continue to consider "gluten-free" label claims for TTB-regulated alcohol beverages made from gluten-containing grains to be misleading. Moreover, based on FDA's determination that there is still no scientifically valid way to evaluate the claims that beers made from gluten-containing grains can be processed in a way that removes gluten and that there is inadequate evidence about whether such methods are effective, it continues to be TTB's position that use of the term "gluten-free" for such products would mislead consumers who are seeking to avoid the consumption of gluten for health reasons.

Accordingly, consistent with FDA's decision to maintain the status quo for the labeling of beers subject to its regulations pending further rulemaking, TTB has decided that, pending completion of rulemaking by FDA on this issue, TTB will also maintain its current policy, as set forth in TTB Ruling 2012–2, with regard to alcohol beverages made from gluten-containing grains. Because TTB is maintaining the status quo for approved labels for alcohol beverage products made from gluten-containing grains,

there is no need for TTB to implement a temporary enforcement discretion policy akin to that set forth in the preamble to FDA's final rule for FDA-regulated beers.

Further, because industry members are generally required to submit applications for certificates of label approval prior to marketing their products, TTB recognizes that it could not simply exercise enforcement discretion without providing specific guidance to industry members as to what labels will be approved by TTB. In addition, given that TTB has been enforcing for over a year a policy with respect to all alcohol beverages subject to the FAA Act, TTB believes it would be more equitable to the industry, and less confusing to consumers, to establish a level playing field by enforcing the same policy with regard to all TTB-regulated alcohol beverages made from gluten-containing grains rather than granting enforcement discretion for only certain malt beverages.

Although products made from gluten-containing grains may not bear a gluten-free label claim, as set forth in the below holdings, TTB will continue to allow labels for such products to bear a claim that the product was "Processed" or "Treated" or "Crafted" to remove gluten, together with the same qualifying statement set out in TTB Ruling 2012–2, and upon submission of certain supporting documentation. We note that the preamble to the FDA final rule explicitly states that any producers of beer that is subject to FDA labeling regulations and made from a gluten-containing grain "are not precluded from using other statements on the label, such as a gluten statement consistent with the TTB guidance, about processing of beers to reduce gluten." See 78 FR 47166. Thus, TTB will continue to allow such statements on labels and in advertisements pending completion of rulemaking by FDA. It remains TTB's policy that other claims about gluten content are prohibited if such statements are untrue in any particular or tend to create a misleading impression. TTB will evaluate such statements on a case-by-case basis, and may require a disclaimer or some other qualifying statement to dispel any misleading impression created by any health-related statements. See 27 CFR 4.39(h), 4.64(i), 5.42(b)(8), 5.65(d), 7.29(e), and 7.54(e).

Despite the contention of several industry members that some currently available tests can measure the gluten content of fermented foods, such as malt beverages, TTB agrees with FDA's conclusion in its final rule that these methods are inappropriate due to the lack of recognized standards and methodologies that provide a meaningful quantitative analysis of the sample that can be related to 20 ppm intact gluten. Accordingly, it remains TTB's policy that labels or advertisements that state or imply, without an appropriate basis or the necessary qualifications, that the gluten testing methodologies used for fermented and distilled products are scientifically valid and can accurately measure the specific level of gluten in the finished product (such as "contains x ppm") will be considered misleading pending the establishment of a scientifically valid method of determining intact gluten levels in such products. TTB encourages industry members to facilitate the development of the necessary methods and standards to meet the needs associated with relating the quantified amounts of fermented material to 20 ppm intact gluten. TTB will provide guidance to industry members interested in pursuing validation of such methods, where appropriate.

Industry members are reminded that statements, symbols, vignettes, or other forms of labeling or advertising claims that expressly, or by implication, characterize the relationship of the product, or any substance within the product, to a disease or health-related condition (such as celiac disease) are prohibited unless such statements comply with the requirements for specific health claims as set forth in the TTB regulations. See 27 CFR 4.39(h)(2)(ii), 4.64(i)(2)(ii), 5.42(b)(8)(ii)(B), 5.65(d)(2)(ii), 7.29(e)(2)(ii), and 7.54(e)(2)(ii).

When FDA issues a final rule or other guidance with respect to fermented or hydrolyzed products, TTB will evaluate whether the interim policy set forth in this guidance should be revised. Industry members are reminded that it will be their responsibility to make appropriate revisions to their labels and advertisements in that event.

Further, TTB will not approve a label containing the statement described above unless the label application contains a detailed description of the method used to remove gluten from the product, and the submission of results of an appropriate gluten assay for the finished product (as well as the name and manufacturer of the assay). However, because there are not yet scientifically valid assays that can accurately quantify the gluten content of fermented products, TTB will use these results for the limited purpose of determining whether there is any change in the amount of gluten detected in the product and the direction and magnitude of that change, but not for the purpose of quantifying the amount of gluten in the finished product This also does not imply that any results obtained from an assay used for this limited purpose could be used to support a gluten-free claim. TTB may request samples to be submitted to the Beverage Alcohol Laboratory.

IV. TTB Finding:

Held, the term “gluten-free” may be used in the labeling and advertising of any wine, distilled spirits, or malt beverages where the product would be entitled to make a gluten-free labeling claim under the standards set forth in the FDA regulations at 21 CFR 101.91.

Held further, any industry member making a “gluten-free” claim on a label or in an advertisement to describe a product that is not made with gluten-containing grains, or any ingredient derived from these grains, is expected to verify that the producer has taken appropriate measures to ensure that its raw materials, ingredients, production facilities, storage materials, and finished products are not subject to cross-contact with gluten. Industry members are responsible for ensuring that any gluten-free claim is truthful and accurate and should be prepared to substantiate such claims upon request.

Held further, TTB will consider the use of the term “gluten-free” or any other explicit or implicit claim that the product contains no gluten (such as “no gluten,” “free of gluten,” or “without gluten”) to be misleading when used in the labeling or advertising of alcohol beverages to describe an alcohol beverage that would not be entitled to make a gluten-free labeling claim under the standards set forth in the FDA regulations at 21 CFR 101.91.

Held further, labels or advertisements that state or imply, without an appropriate basis or the necessary qualification, that gluten testing methodologies are scientifically valid or validated for use in fermented products or that gluten testing methodologies can accurately measure the specific level of gluten in a fermented or distilled finished product (such as "contains x ppm") will be considered misleading pending the establishment of a scientifically valid method of measuring gluten levels in such products that appropriately measures the amount of gluten and relates the quantified amounts of fermented material to 20 ppm intact gluten.

Held further, labels and advertisements may include truthful and accurate statements that the product was "[Processed *or* Treated *or* Crafted] to remove gluten" for products that were produced using an ingredient that is a gluten-containing grain, or an ingredient that is derived from a gluten-containing grain, where the product is then processed or treated or crafted to remove some or all of the gluten, under the following conditions:

(1) One of the following qualifying statements must also appear legibly and conspicuously on the label or in the advertisement as part of the above statement:

> "Product fermented from grains containing gluten and [processed *or* treated *or* crafted] to remove gluten. The gluten content of this product cannot be verified, and this product may contain gluten."
>
> OR,
>
> "This product was distilled from grains containing gluten, which removed some or all of the gluten. The gluten content of this product cannot be verified, and this product may contain gluten."

2) TTB will not approve labels containing the above claims unless the label application includes a detailed description of the method used to remove gluten from the product and appropriate gluten assay results for the finished product (and the name and manufacturer of the assay). Industry members should also be prepared to substantiate advertising claims with the same information, upon request.

Held further, TTB will approve labels with the statements described above only if TTB concludes, based on the totality of the information submitted, that the statement is truthful, accurate, and not likely to mislead consumers.

Held further, statements, symbols, vignettes, or other forms of labeling or advertising claims that expressly, or by implication, characterize the relationship of the product, or any substance within the product, to a disease or health-related condition (such as celiac disease) are prohibited unless such statements comply with the

requirements for specific health claims as set forth in the TTB regulations. See 27 CFR 4.39(h)(2)(ii),4.64(i)(2)(ii), 5.42(b)(8)(ii)(B), 5.65(d)(2)(ii), 7.29(e)(2)(ii), and 7.54(e)(2)(ii).

Held further, the use of any other explicit or implicit claims about the gluten content of the product is prohibited if such statements are untrue in any particular or tend to create a misleading impression. TTB will evaluate such statements on a case-by-case basis, and may require a disclaimer or some other qualifying statement to dispel any misleading impression created by any health-related statements. See 27 CFR 4.39(h), 4.64(i), 5.42(b)(8), 5.65(d), 7.29(e), and 7.54(e).

Industry members are responsible for verifying the accuracy of any gluten claim on labels and in advertisements. TTB may request the submission of samples to the Beverage Alcohol Laboratory.

When FDA issues further guidance or a final rule with regard to gluten-free statements on labels of foods that are fermented or contain fermented ingredients, TTB will evaluate whether the interim policy set forth in this ruling should be revised.

Questions:

If you have questions about labeling or advertising requirements for wine, distilled spirits, or malt beverages, please contact the TTB Advertising, Labeling and Formulation Division at **202–453–2250**, toll free at **866–927–ALFD (2533)**, by fax at **202–453–2984**, or by email at alfd@ttb.gov.

Date Approved: February 11, 2014

/s/
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