DEPARTMENT OF THE TREASURY
Alcohol and Tobacco Tax and Trade Bureau

TTB Ruling
Number: 2012–2 May 24, 2012

Interim Policy on Gluten Content Statements in the Labeling and Advertising of Wines, 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 final regulations on use of the term "gluten-free" on food labels.

Authority:

The Federal Alcohol Administration Act (FAA Act) provides for regulation of the labeling and advertising of distilled spirits, wine, 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 January 21, 2003, 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 wines, distilled spirits, or 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. Statements about gluten content are considered to be health-related claims and are accordingly treated as health-related statements under TTB regulations. *See* 27 CFR 4.39(h), 4.64(i), 5.42(b)(8), 5.65(d), 7.29(e), and 7.54(e).

TTB and its predecessor agencies have utilized rulings and industry circulars for expressing interpretations of these regulations.

Background:

Pursuant to a 1987 Memorandum of Understanding with the FDA, TTB consults with FDA about the promulgation of regulations regarding the labeling of ingredients and substances contained in alcohol beverages. Currently, there is no FDA regulation that defines the term "gluten-free." In the preamble to a final rule on the declaration of ingredients on food packaging published in the **Federal Register** of January 6, 1993 (58 FR 2850 at 2864), FDA advised that the term "gluten-free" could be used in the labeling of foods, provided that when such claim is used, it is truthful and not misleading. Generally, and absent regulations to the contrary, FDA stated that it would regard a claim that a food is "free" of a substance as false or misleading if the food contains that substance.

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 required the Secretary of Health and Human Services to issue a rule to define and permit the term "gluten-free" on the labeling of foods. Accordingly, 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. Under the proposed FDA rule, a product may be labeled as gluten-free if it does not contain any of the following:

> (1) An ingredient that is a prohibited grain (wheat, barley, rye, or crossbred hybrids of those grains);
>
> (2) An ingredient that is derived from a prohibited grain and that has not been processed to remove gluten;
>
> (3) An ingredient that is derived from a prohibited grain and that has been processed to remove gluten if use of that ingredient results in the presence of 20 ppm or more gluten in the food; or
>
> (4) 20 ppm or more gluten.

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 August 3, 2011 notice specifically addressed certain issues associated with gluten claims for fermented or hydrolyzed products. The notice states 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." [Citations omitted; emphasis added.] The FDA notice also states that:

> A **scientifically valid method** for purposes of substantiating a 'gluten-free' claim for foods matrices where formally validated methods (e.g., that underwent a multi-laboratory performance evaluation) do not exist **is one that is accurate, precise, and specific for its intended purpose and where the results of the method evaluation are published in the peer-reviewed scientific literature.** In other words, a scientifically valid test is one that consistently and reliably does what it is intended to do. [Emphasis added.]

FDA has not yet issued a final rule on the use of the term "gluten-free" on food labels.

TTB is aware of consumer demand for products that contain very little or no gluten, and TTB wishes to allow information about such products to be conveyed to consumers. Under the FAA Act, however, TTB is required to ensure that a product's label adequately informs consumers about the nature of the product and that the label information is truthful, accurate, and not misleading. This requirement is particularly important for gluten content statements because of the potential health consequences associated with the consumption of gluten by individuals with celiac disease. Based on TTB's agreement with FDA that there are no scientifically valid methods for accurately measuring the gluten content of fermented products, and given the potential health consequences associated with gluten consumption for some consumers, TTB is issuing the below guidance regarding gluten content statements in labels and advertisements pending a final rule from FDA on this issue.

A. Products Made from Gluten-Free Materials

TTB has received requests from various alcohol beverage industry members it regulates who wish to use gluten-free statements on their labels and in advertisements. Pending the issuance of a final rule by FDA, TTB is providing interim guidance 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 believes that the term will be interpreted by consumers of alcohol beverages to mean that the product contains no gluten.

Many alcohol beverage products 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 be "gluten-free" if the producer used good manufacturing practices, took adequate precautions to prevent cross-contamination, and did not use additives, yeast, or storage materials that contained gluten. Under this interim policy, TTB will allow the use of a "gluten-free" claim in the labeling and advertising of such products. As always, it will be the responsibility of the importer or bottler of the product to ensure that the claim is truthful and accurate.

TTB has further determined that it would be inherently misleading for products 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. Although some industry members claim that their products have been processed to remove gluten, such claims cannot be properly verified without a scientifically valid method to measure the gluten content of the products. As previously noted, FDA and TTB agree that there are currently no scientifically valid testing methods available to determine the gluten content of fermented products.

B. Products Made from Gluten-Containing Materials

TTB has also received inquiries from brewers and importers who wish 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 claim 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 has been suggested that the distillation of mashes fermented from grains containing gluten in the production of distilled spirits products 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 products.

Despite the contention of several industry members that some currently available tests can measure the gluten content of malt beverage products, pending the issuance of a final rule by FDA, TTB takes the position that these methods cannot be used to substantiate a specific claim about the gluten content of products fermented or distilled from gluten-containing grains, such as "gluten-free" or "x ppm gluten," because the methods have not yet been scientifically validated to accurately measure the gluten content of fermented products. TTB encourages industry members to seek validation of testing methods for alcohol beverage products fermented and distilled from gluten-containing grains through recognized organizations, such as *AOAC International.* TTB will provide guidance to industry members interested in pursuing validation of such methods where appropriate.

Pending the issuance of a final rule by FDA, and pending the validation of a method for accurately measuring the gluten content of fermented and distilled alcohol beverage products, TTB is issuing this interim guidance on the use of labeling and advertising statements regarding the removal of gluten from distilled spirits and malt beverages 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 will 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 made from a grain that contains gluten; (2) there is currently no valid test to verify the gluten content of fermented products; and (3) the finished product may contain gluten. Because the current tests used to measure the gluten content of fermented products have not been scientifically validated, such statements may not include any reference to the level of gluten in the product. TTB believes that the qualifying statement is necessary to avoid misleading consumers about the gluten content of these products because of the serious health consequences associated with the consumption of gluten by individuals with celiac disease.

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. To evaluate whether the method used to remove gluten from the finished product was successful, TTB will also require the submission of results of the R5 Mendez Competitive ELISA assay for the finished product (as well as the name and manufacturer of the assay). Because this testing method has not yet been scientifically validated to accurately quantify the gluten content of fermented products, TTB will use these results for the limited purpose of screening the validity and effectiveness of the method used to remove gluten from the product. The statements authorized for products made from gluten-containing materials may only be placed on a label if the gluten content of the finished product is less than 20 ppm as measured by the submitted test; the 20 ppm gluten level is based on the proposed FDA rule for "gluten-free" label claims. TTB may request samples to be submitted to the Beverage Alcohol Laboratory to verify the test results.

TTB Finding:

Held, the term "gluten-free" is considered misleading when used in the labeling and advertising of alcohol beverages to describe an alcohol beverage product that is made with any amount of wheat, barley, rye, or a crossbred hybrid of these grains, or any ingredient derived from these grains.

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 wheat, barley, rye, or a crossbred hybrid of these grains, or any ingredient derived from these grains, is responsible for verifying that the producer has used good manufacturing practices to ensure that its raw materials, ingredients, production facilities, storage materials, and finished products are not cross-contaminated 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. TTB may request samples to be submitted to TTB's Beverage Alcohol Laboratory to analyze the finished product.

Held further, that labels and advertisements may include truthful and accurate statements that a product was "[Processed *or* Treated *or* Crafted] to remove gluten" for

products that were produced from wheat, barley, rye, or a crossbred hybrid of these grains, or any ingredient derived from these grains, and 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 contains a detailed description of the method used to remove gluten from the product and R5 Mendez Competitive ELISA assay results for the finished product showing a response of less than 20 ppm gluten (and the name and manufacturer of the assay). Industry members should also be prepared to substantiate advertising claims with the same information, upon request.

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

Held further, statements characterizing 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, 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.

Upon issuance of a final rule by FDA, TTB will evaluate whether the interim policy set forth in this ruling should be revised.

Questions:

If you have any questions about labeling or advertising requirements for malt beverages, wines, or distilled spirits, 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 E-mail: alfd@ttb.gov.

Date Approved: May 24, 2012

Signed by John Manfreda

John J. Manfreda
Administrator
Alcohol and Tobacco Tax and Trade Bureau

OPR: RRD