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E-ALERT | Food & Drug

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FDA RELEASES FINAL RULE ON "GLUTEN-FREE" LABELING OF FOODS

On August 2, 2013, FDA released a long-awaited final rule explaining when a company may *voluntarily* label a food "gluten-free."[1] FDA promulgated the final rule pursuant to the Food Allergen Labeling and Consumer Protection Act of 2004's (FALCPA's) directive that FDA define and permit the use of the term "gluten-free" on food labels. The agency issued a proposed rule in January 2007 and subsequently reopened the comment period in August 2011. The final rule contains many of the same provisions as the proposed rule, but with a few notable distinctions, detailed below.

The final rule is intended to benefit the approximately 3 million Americans with celiac disease, an autoimmune disorder of the small intestine for which the only treatment is adherence to a gluten-free diet. It establishes a national, uniform standard for the use of "gluten-free" claims in food labeling. If manufacturers choose to make "gluten-free" labeling claims, they must comply with the requirements of the final rule beginning *August 5, 2014*, although FDA anticipates that manufacturers may choose to follow the requirements as soon as possible.

REQUIREMENTS FOR "GLUTEN-FREE" CLAIMS

The final rule defines the term "gluten" to mean "the proteins that naturally occur in a gluten-containing grain and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins)."[2] The term "gluten-containing grain" is defined as wheat (meaning any species belonging to the genus *Triticum*), rye (meaning any species belonging to the genus *Secale*), barley (meaning any species belonging to the genus *Hordeum*), and any crossbred hybrid of these grains.[3]

Under the final rule, a "gluten-free" food labeling claim can be made only *if both of the following requirements are met*:

1. The food is either (a) inherently free of gluten; or (b) does not contain any of the following ingredients:
   - An ingredient that is a gluten-containing grain. (Examples include wheat, barley, rye, spelt wheat, and triticale.)
   - An ingredient that is derived from a gluten-containing grain and has not been processed to remove gluten. (Examples include wheat flour, semolina, and farina.)

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[1] The final rule was published in the Federal Register on August 5, 2013 (78 Fed. Reg. 47,154) and is available here. FDA also released a related guidance document entitled "Questions and Answers: Gluten-Free Food Labeling Final Rule" (Questions and Answers), which is available here.

[2] 21 C.F.R. § 101.91(a)(2); 78 Fed. Reg. at 47,178.

[3] 21 C.F.R. § 101.91(a)(1); 78 Fed. Reg. at 47,178. The final rule uses the term "gluten-containing grain" instead of the proposed rule's term "prohibited grain." FDA explains that "the word 'prohibited' could create the misimpression that all consumers (rather than solely those individuals with celiac disease) should avoid these grains." 78 Fed. Reg. at 47,162 (Response 8).

- An ingredient that is derived from a gluten-containing grain and has been processed to remove gluten, if the use of that ingredient results in 20 parts per million (ppm) or more gluten in the food. (Examples include wheat starch and modified food starch.)

2. Any unavoidable presence of gluten in the food is below 20 ppm.

KEY ASPECTS OF THE FINAL RULE

- **There are three synonyms for "gluten-free":** FDA considers the labeling claims "no gluten," "free of gluten," and "without gluten" to be equivalent to a "gluten-free" claim. A food that bears any of these claims must also meet the final rule's requirements.
- **The rule retains the proposed < 20 ppm gluten standard:** The proposed rule set forth a < 20 ppm gluten standard for "gluten-free" labeling claims because, as FDA explained, available gluten detection methods could only reliably and consistently detect gluten at 20 ppm or above. FDA subsequently conducted a gluten safety assessment and concluded that the estimated level of concern for individuals with celiac disease ranges from 0.01 to 0.06 ppm gluten, but that these numbers represent "a conservative, highly uncertain estimation of risk."[4] Currently available analytical methods, the ease of enforcement, and the fact that "lowering the gluten level below 20 ppm [would] make it far more difficult for manufacturers to make food products that could be labeled as 'gluten-free'" influenced FDA's decision to adopt a < 20 ppm gluten standard in the final rule.[5]
- **Oats are not considered to be a "gluten-containing grain":** As in the proposed rule, the final rule does not include oats in the definition of a "gluten-containing grain." Thus, oats can be used as an ingredient in a food labeled as "gluten-free," so long as the oats contain < 20 ppm gluten. In the preamble, FDA explains that the commingling of oats with gluten-containing grains is preventable and that "for most individuals with celiac disease, oats can add whole grain options, nutrient enrichment, and dietary variety."[6] Even so, to help individuals with celiac disease who cannot tolerate oats, FDA encourages "manufacturers of foods labeled 'gluten-free' that use an oat-derived ingredient where the word 'oat' does not appear in the ingredient list . . . to indicate in their labeling that an oat-derived ingredient is present."[7]
- **Claims are <u>not</u> allowed for food that has < 20 ppm gluten but contains a "gluten-containing grain":** Consistent with the proposed rule, the final rule does not allow a "gluten-free" claim on food made with small amounts of a gluten-containing grain or ingredients derived from such grains that were not processed to remove gluten, even if the food product itself contains less than 20 ppm gluten. This requirement "helps ensure that the finished product has the lowest amount of gluten that is reasonably possible."[8]
- **There are no format requirements:** The final rule does not impose requirements related to format, the use of symbols, or the use of third-party certification logos for "gluten-free" claims. Manufacturers may choose where to place a "gluten-free" claim on a food label, provided that all applicable legal requirements are met. Manufacturers also may use a third-party certification logo to indicate that a product is free of gluten, provided that its use is truthful and not misleading.
- **The rule applies only to FDA-regulated foods:** The final rule applies to all FDA-regulated foods, including dietary supplements and imported foods. It does not apply to drugs or cosmetics, or to

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[4] 78 Fed. Reg. at 47,158.
[5] 78 Fed. Reg. at 47,161 (Response 6).
[6] 78 Fed. Reg. at 47,163 (Response 9).
[7] *Id.*
[8] 78 Fed. Reg. at 47,165 (Response 13).

foods regulated by the U.S. Department of Agriculture (USDA) (meat, poultry, and egg products) or by the Alcohol and Tobacco Tax and Trade Bureau (TTB) (alcoholic beverages).

SIGNIFICANT CHANGES FROM THE PROPOSED RULE

- **Additional language is required on foods containing wheat:** In the preamble, FDA agreed with several comments that noted that consumers would receive a confusing message if foods bear a "gluten-free" claim and also contain wheat as an ingredient. The final rule addresses this concern by requiring foods that bear a "gluten-free" claim and also include wheat as an ingredient to add after the term "wheat" an asterisk linked to this nearby statement: "The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods."
- **No qualifying language is required for claims on inherently gluten-free foods:** The proposed rule provided that foods that do not inherently contain gluten that bear a "gluten-free" claim must state that all foods of the same type are inherently gluten-free (e.g., "all milk is gluten-free"). Many comments noted that the proposed qualifying language would cause consumer confusion, as not all versions of a product may be gluten-free. FDA agreed and concluded that a "gluten-free" claim on a food that is inherently gluten-free, without qualifying language, is not misleading.
- **Analytical testing is not necessarily required:** In the preamble, FDA clarifies that the final rule does not *require* manufacturers to conduct analytical testing to determine that their products bearing "gluten-free" claims contain < 20 ppm. Manufacturers may develop their own methods that best suit their particular needs to determine the gluten content of their products. For instance, manufacturers may use quality control tools, such as requesting certificates of gluten analysis from ingredient suppliers.
- **The rule preempts state law:** A state may not establish a requirement that is different from the rule's requirements for the use of a "gluten-free" claim. The rule is not intended to preempt other state requirements with respect to statements about gluten, such as information about how the food was processed.

FUTURE ACTION

The agency may reevaluate the 20 ppm standard as new information becomes available. FDA plans to issue a proposed rule to address how it will assess compliance with this final rule with respect to fermented or hydrolyzed foods or ingredients, for which there are no scientifically valid methods for detecting intact gluten proteins. Also, FDA intends to work with USDA and TTB on the issue of gluten-free food labeling to harmonize requirements for food products regulated by these agencies, where possible.

LEGAL RISK MANAGEMENT ISSUES

Failure of a product labeled "gluten-free" to comply with the new gluten-free standard would cause the product to be deemed misbranded. FDA intends to enforce the gluten-free standard through firm inspections, examination of imports, label reviews, and analytical testing of food samples. This labeling standard likely will be cited as the standard by which "gluten-free" claims by restaurants should be evaluated. In addition, this rule could have regulatory compliance and product liability implications for promotional claims made not only in labeling, but for advertising and promotions more generally under both the Federal Trade Commission Act and state consumer protection statutes.

Covington & Burling LLP is experienced in legal matters concerning the development and defense of food marketing programs and promotional claims under federal and state laws and is available to provide individualized legal risk management counseling concerning food formulation and marketing issues.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

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