Contains Nonbinding Recommendations

Guidance for Industry
Gluten-Free Labeling of Foods

Small Entity Compliance Guide

Additional copies are available from:
Office of Nutrition, Labeling, and Dietary Supplements
Food Labeling and Standards Staff (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-2371
http://www.fda.gov/FoodGuidances

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

June 2014

Table of Contents

Guidance for Industry[1]
Gluten-Free Labeling of Foods
Small Entity Compliance Guide

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

On August 5, 2013, FDA (or we) published in the *Federal Register* a final rule that established a regulatory definition of the term "gluten-free" for voluntary use in the labeling of foods (see 78 FR 47154). The rule implements part of the Food Allergen Labeling and Consumer Protection Act of 2004, Title II of Public Law 108-282, enacted on August 2, 2004, which directed the Secretary of Health and Human Services to issue a regulation to define and permit use of the food labeling term "gluten-free." Firms are not required to label their foods "gluten-free," but if firms whose foods are regulated by FDA voluntarily choose to make this labeling claim, those products must conform to our definition for a "gluten-free" food. This final rule is intended to provide a uniform definition of the term "gluten-free" so that consumers, particularly those who have celiac disease, will know what it means when they see it on the labeling of food.

The final rule became effective on September 4, 2013, but August 5, 2014 is the date when FDA-regulated foods labeled "gluten-free" must comply with all requirements established by the final rule. However, we encourage manufacturers that wish to make a "gluten-free" claim for their foods to comply voluntarily before this date.

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This guidance document restates in plain language the requirements set forth in the regulation at 21 CFR 101.91 concerning use of the term "gluten-free" in the labeling of foods. The "gluten-free" regulation is binding and has the full force and effect of law.

[1] This guidance has been prepared by the Food Labeling and Standards Staff, Office of Nutrition, Labeling, and Dietary Supplements in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in our guidances means that something is suggested or recommended, but not required.

In the remainder of this guidance, "you" refers to entities that choose to make a "gluten-free" claim on their food labels. We have organized this guidance in a question/answer format and also identify the relevant regulation in parentheses after each answer.

II. Background

Celiac disease is a hereditary, chronic inflammatory disorder of the small intestines triggered by the ingestion of certain storage proteins, referred to as gluten, occurring in wheat, rye, barley, and crossbreeds of these grains. In such individuals, the consumption of gluten stimulates the production of antibodies and inflammatory cells, resulting in an abnormal immune response which damages the tiny, fingerlike protrusions called "villi," that line the small intestine and function to absorb nutrients from food. Over time, continued dietary exposure to gluten can destroy the intestinal villi of individuals with celiac disease, leading to a lack of absorption of nutrients and a wide variety of other health problems.

The symptoms and clinical manifestations of celiac disease are highly variable among affected individuals and differ in severity. Symptoms of celiac disease may be: (1) "Classical," affecting the digestive tract (e.g., abdominal bloating; cramping and pain; chronic diarrhea; vomiting; constipation) and resulting in gastrointestinal malabsorption; or (2) "atypical," affecting mainly other parts of the body (e.g., fatigue; irritability; behavior changes; bone or joint pain; tingling numbness in the legs; ulcers in the mouth; tooth discoloration or loss of enamel; itchy skin rash with blisters called dermatitis herpetiformis). A large portion of the subpopulation that has celiac disease may not experience any symptoms at all, and these individuals are classified as having either the "silent" or "latent" form of celiac disease. Persons who have the silent form of celiac disease have most of the diagnostic features commonly seen in individuals with classical or atypical celiac disease, such as specific serum antibodies and evidence of damaged intestinal villi. Those who have the latent form of celiac disease have specific serum antibodies, but no evidence of damaged intestinal villi. In addition to the aforementioned clinical symptoms and ailments, celiac disease is associated with a number of significant health problems and disorders, including iron-deficiency anemia, vitamin deficiencies, protein-calorie malnutrition, weight loss, short stature, growth retardation in children, delayed puberty, infertility, miscarriage, and osteoporosis. Individuals with unmanaged celiac disease are at an increased risk of developing other serious medical conditions, such as Type I diabetes mellitus, intestinal cancers, and both intestinal and extraintestinal non-Hodgkin's lymphomas.

Celiac disease has no cure, but individuals who have this disease are advised to avoid all sources of gluten in their diet. Over time, strictly avoiding consumption of gluten can resolve the symptoms, mitigate and possibly reverse the damage, and reduce the associated health risks of celiac disease.

III. Questions and Answers

1. Who is subject to the rule?

The rule does not require anyone to use the term "gluten-free" on a food label. However, if you choose to label your food as "gluten-free," the rule defines what we mean by "gluten-free" and also establishes requirements regarding the use of the claim.

2. What does the term "gluten-containing grain" mean?

The term "gluten-containing grain" means wheat, rye, barley, and other grains produced by breeding wheat, rye, or barley with each other or breeding them with different grains. For example, triticale is produced by breeding wheat with rye, and so triticale also is considered to be a gluten-containing grain under the rule.

Specifically, the rule defines "gluten-containing grain" as:

> any one of the following grains or their crossbred hybrids (e.g., triticale, which is a cross between wheat and rye):
> - Wheat, including any species belonging to the genus *Triticum*;
> - Rye, including any species belonging to the genus *Secale*; or
> - Barley, including any species belonging to the genus *Hordeum*.

(21 CFR 101.91(a)(1))

3. What does the term "gluten" mean?

The term "gluten" means the proteins that naturally occur in a gluten-containing grain and that may cause adverse health effects in persons with celiac disease. Examples of such proteins are called "prolamins" and "glutelins."

(21 CFR 101.91(a)(2))

4. What does the food labeling claim "gluten-free" mean?

The labeling claim that a food is "gluten-free" means that the food bearing the claim in its labeling does not contain *any* of the following ingredients:

- An ingredient that is a gluten-containing grain; or

- An ingredient that is made from a gluten-containing grain and that <u>has not been</u> processed to remove gluten. For example, "wheat flour" is an ingredient made from wheat that has not been processed to remove the naturally occurring gluten in wheat. Therefore, wheat flour cannot be used as an ingredient to make a food labeled "gluten-free;" or

- An ingredient that is made from a gluten-containing grain and that has been processed to remove gluten, if the use of that ingredient contains 20 parts per million (ppm) or more gluten. For example, wheat starch is an ingredient made from wheat that has been processed to remove gluten. However, the use of this ingredient must result in under 20 parts per million gluten in the finished food for the food to be labeled "gluten-free."

A "gluten-free" claim also can appear on the labels of foods that inherently do not contain gluten (e.g. raw carrots and grapefruit juice).

Additionally, any unavoidable presence of gluten in a food bearing a "gluten-free" claim, whether manufactured to be gluten-free or inherently free of gluten, must be below 20 ppm gluten. This means that foods may not use the claim if they contain 20 ppm or more gluten as a result of cross-contact with gluten-containing grains or other gluten-containing ingredients.

Twenty ppm gluten is a concentration level rather than an absolute quantity of gluten in a food. It is equivalent to 20 milligrams of gluten per 1 kilogram (or 1000 grams (g)) of food.

(21 CFR 101.91(a)(3))

5. Does the rule require a "gluten-free" claim to appear in a particular size or color?

No. The rule does not require the claim to be in any particular size or color.

6. Does the gluten-free label claim have to appear in a particular place on the food label?

No. The rule does not limit where you place the "gluten-free" claim on the product.

7. How can I determine the gluten content of my food?

The rule does not require you to use any specific method to determine a food's gluten content. However, there are scientifically valid methods[2] that can reliably detect the presence of 20 ppm gluten in a variety of foods, including both raw and cooked or baked products. For example, certain enzyme-linked immunosorbent assay (ELISA) based methods can be used reliably and consistently to detect gluten at 20 ppm levels. These test methods are used by testing laboratories.

We will use scientifically valid test methods to determine compliance with the gluten-free labeling requirements.

8. Am I required to test my food for gluten to make a gluten-free claim on my food labels?

[2] For purposes of this guidance, 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.

The rule does not require you to test for the presence of gluten in your starting ingredients or finished foods labeled "gluten-free." However, you are responsible for ensuring that foods bearing a gluten-free claim meet our requirements, including that any unavoidable gluten present in a food labeled gluten-free is less than 20 ppm. We encourage you to use effective measures to ensure that any foods labeled as "gluten-free" comply with our requirements; such measures may include:

- testing the ingredients to determine their gluten content;
- requesting certificates of gluten analysis from ingredient suppliers; or
- participating in a third-party gluten-free certification program.

If you choose to have someone, such as a laboratory, test ingredients for their gluten content, we suggest that you consider whether the laboratory is capable of testing food ingredients for gluten and ask what type of test it uses. For example, we are aware that the R5-Mendez Method (sometimes referred to as the ELISA R5 Mendez Method) and another test method known as the "Morinaga method" can be used to detect gluten in a variety of food matrices.

9. When will FDA consider a food labeled "gluten-free" to be misbranded?

We will consider a food labeled "gluten-free" to be misbranded if its labeling:

- States "gluten-free," but the food does not meet all of our requirements for a "gluten-free" claim;

- States "no gluten," "free of gluten," or "without gluten," but the food does not meet all of our requirements for a "gluten-free" claim; **or**

- States both "gluten-free" and either the term "wheat" appears in the ingredient list (e.g., wheat starch) or in a separate "Contains wheat" statement to meet our food allergen labeling requirements, but additional wording is absent that would clarify that the food still meets our requirements for a "gluten-free" claim. In such cases when both the terms "wheat" and "gluten-free" are declared on the same food label, the word "wheat" must be followed immediately by an asterisk or other symbol that refers to this same asterisk or other symbol with the words, "The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods."

(21 CFR 101.91(b))

10. **Can I make a different claim, such as "low gluten" or "very low gluten?"**

The rule does not define terms such as "low gluten" or "very low gluten." If you use such claims, we will evaluate them, on a case-by-case basis, to determine if the claim is truthful and not misleading. We discourage the use of claims other than "gluten-free" and will evaluate any such statements under sections 403(a)(1) and 201(n) of the Federal Food, Drug, and Cosmetic Act (which require labels to be truthful and not misleading).

11. What type of method will FDA use if it decides to analyze a food labeled "gluten-free" to determine if it complies with the agency's definition of gluten-free"?

We will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food substances, including both raw and cooked or baked products. We will also issue a separate proposed rule regarding the way that we intend to determine compliance for hydrolyzed and fermented foods wishing to make a "gluten-free" claim.

(21 CFR 101.91(c))

12. **What happens if I label my food as "gluten-free" and the food is not in compliance with the "gluten-free" regulation, such as it has a gluten level above 20 ppm?**

If you label your food as "gluten-free," but it is not in compliance with the "gluten-free" regulation, such as its gluten content level is above 20 ppm, then it would be "misbranded" under the Federal Food, Drug, and Cosmetic Act, and FDA could take regulatory action.