



CFSAN Constituent Update 08/02/2013
FDA Defines "Gluten-Free" Claim for Food Labels

The U.S. Food and Drug Administration (FDA) today published a new regulation defining the term "gluten-free" for voluntary use in food labeling. The regulation provides a uniform standard for manufacturers who label food products as "gluten-free," and will help the up to 3 million Americans who have celiac disease, which can be effectively managed only by eating a gluten-free diet.

In addition to other requirements, the regulation sets a threshold for gluten of less than 20 parts per million in foods that are labeled "gluten-free," "no gluten," "free of gluten," and "without gluten."

The term "gluten" refers to proteins that occur naturally in wheat, rye, barley and cross-bred hybrids of these grains. In people with celiac disease, foods that contain gluten trigger the production of antibodies that attack and damage the lining of the small intestine. Such damage limits the ability of celiac disease patients to absorb nutrients and puts them at risk of other very serious health problems, including nutritional deficiencies, osteoporosis, growth retardation, infertility, miscarriages, short stature, and intestinal cancers.

The FDA was directed to issue the regulation by the Food Allergen Labeling and Consumer Protection Act (FALCPA). FALCPA requires food manufacturers to explicitly list on food labels the presence of major food allergens included as ingredients in the labeled products. While gluten is not one of the major food allergens identified in FALCPA, Congress specifically directed FDA to set guidelines for the use of the term "gluten-free" to help people with celiac disease maintain a gluten-free diet.

Food manufacturers will have a year after the rule is published to bring their labels into compliance with the new requirements.

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