

## **SUMMARY:**

The Food and Drug Administration (FDA) is proposing to define the term “gluten-free” for voluntary use in the labeling of foods, to mean that the food does not contain any of the following: An ingredient that is any species of the grains wheat, rye, barley, or a crossbred hybrid of these grains (all noted grains are collectively referred to as “prohibited grains”); an ingredient that is derived from a prohibited grain and that has not been processed to remove gluten (e.g., wheat flour); an ingredient that is derived from a prohibited 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; or 20 ppm or more gluten. A food that bears the claim “gluten-free” or similar claim in its labeling and fails to meet the conditions specified in the proposed definition of “gluten-free” would be deemed misbranded. FDA also is proposing to deem misbranded a food bearing a gluten-free claim in its labeling if the food is inherently free of gluten and if the claim does not refer to all foods of that same type (e.g., “milk, a glutenfree food” or “all milk is gluten-free”). In addition, a food made from oats that bears a gluten-free claim in its labeling would be deemed misbranded if the claim suggests that all such foods are gluten-free or if 20 ppm or more gluten is present in the food. Establishing a definition of the term “glutenfree” and uniform conditions for its use in the labeling of foods is needed to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled. This proposed action is in response to the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).