PATIENT SAFETY BLOG

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FDA Reopens Discussion of Gluten-Free Labeling

August 11, 2011 by Patrick A. Malone

In 2007, the FDA proposed guidelines for gluten-free labeling. The gluten component of foods is important to people with celiac disease, a disorder in which essential nutrients can't be metabolized when gluten is consumed. Gluten is a constituent of many grains, such as wheat, barley and rye.

Now, the FDA-approved definition of "gluten-free" is up for review, and the agency is reopening the comment period. Rules for what can be deemed gluten-free were never adopted.

As reported in Food Safety News, last week Michael Taylor of the FDA said, "We want to get the most up-to-date information and data from affected consumers, from the food industry, researchers and others to ensure that we're making the right public health call in defining gluten-free."

Approximately 3 million Americans suffer from celiac disease. "We want to make sure that those suffering from celiac disease avoid adverse health consequences from being exposed to food that may trigger the symptoms and cause long-term health effects," said Taylor.

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The proposed language requires any food with the gluten-free label to contain fewer than 20 parts per million of gluten -- the equivalent of, roughly, about 2 grains of salt in a piece of bread. That recommendation includes a peer-reviewed assessment of the existing literature on gluten safety.

Some people believe that any amount of gluten is unacceptable in a product labeled “gluten-free.”

The rules are expected to be finalized next year.

To view the FDA documents related to the discussion, link here and here. The proposed regulations for gluten-free labeling are in the Federal Register, docket no. FDA-2005-N-0404 at www.regulations.gov.

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