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Department of Health and Human Services
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The Honorable Martin A. Makary, M.D.
Commissioner
Food and Drug Administration
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Re: Issuing New Rulemaking to Require Labeling of Gluten Grains (Barley, Rye and Oats) as
“Major Food Allergens” Docket FDA-2023-P-3942-1120

Consumer Reports applauds the Food and Drug Administration for seeking information on policy reforms that could make a meaningful difference in the lives of 3.3 million Americans with Celiac Disease, including approximately 729,000 children.

However, while receiving comments and seeking additional information on certain questions is an important step, it should not delay meaningful action that would reduce chronic diet-related disease. Ultimately, the FDA should undertake an expedited process requiring the labeling of gluten-containing grains on all packaged foods in the United States, just like gluten must be declared on all food labels in 87 other countries.

The FDA can address this critical consumer protection food safety issue with the urgency it requires and issue rulemaking requiring the labeling of gluten as a “Major Food Allergen” based on the Secretary of HHS’s existing statutory authority under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

Gluten is a protein found in wheat, barley, rye and most oats. Since 2006, only wheat has been required to be labeled in the United States, but barley, rye and oats have not been required to be declared.

FALCPA “does not preclude FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA’s labeling scheme.” Section 203(b) states that the labeling requirements established under new section 403(w) “do not prevent the Secretary from requiring labels or labeling changes for other food allergens that are not [yet] major food allergens.”

In 1985, the FDA Final Rule stated, “The agency finds that labeling packaged foods as ‘gluten free’ would not be as desirable as actually identifying on the food label the source of the gluten that is used in the food. Under 21 CFR 101.4(a), wheat gluten and other gluten sources must be identified by name when they are used in food.” That was 40 years ago, but to date, the FDA has never enforced this, and the labeling of barley, rye and oats has remained voluntary in the United States.

Gluten free food is the only medicine available for Celiacs, but unfortunately, 44% of people with Celiac Disease who follow a strict Gluten Free diet still get glutened once a month. That is why we need mandatory labeling of all gluten grains in the United States as Major Food Allergens.

High Risk of Digestive Cancers in Patients With Celiac Disease

In December 2024, the journal “Clinical Gastroenterology and Hepatology” [published](#) in-depth research that confirmed high risks of lymphoma and small bowel cancer in Celiac patients, as well as indicated increased risks of pancreatic, esophageal, gastric, and colonic cancers. Additionally, the research demonstrated significantly increased risk for Celiacs to develop Type 1 diabetes, thyroiditis, rheumatoid arthritis and osteoporosis.

The research also found that patients with Celiac had a higher risk for pernicious anemia, Crohn’s disease, ulcerative colitis and noninfectious enterocolitis, which included microscopic colitis as well as nonalcoholic chronic pancreatitis. The study examined data from 27,114 hospitalized Celiac patients over a nine-year period. When compared to non-Celiac controls, individuals with Celiac Disease had significantly higher risks for small bowel cancer, non-Hodgkin lymphoma, pancreatic cancer, esophageal cancer, colon cancer and gastric cancer.

Previous [published](#) research found that a gluten free diet (GFD) did decrease risk of cancer. As the study noted, "The results indicate that for coeliac patients who have taken a GFD for five years or more the risk of developing cancer over all sites is not increased when compared with the general population. The risk is increased, however, in those taking a reduced gluten, or a normal diet, with an excess of cancers of the mouth, pharynx and oesophagus, and also of lymphoma. A significant decreasing trend in the excess morbidity rate over increasing use of GFD was found. The results are suggestive of a protective role for a GFD against malignancy in coeliac disease and give further support for advising all patients to adhere to a strict GFD for life."

It’s evident that there is an urgent need to address this issue in a meaningful way. While gathering additional information is helpful, it merely bolsters the significant data that already exists. Consumer Reports urges the FDA to expedite the review process and proceed with rulemaking that would require the labeling of gluten-containing grains on all packaged foods in the U.S. This is already being done in 87 other countries and it’s time for the U.S. to join this list.

Thank you for your attention to this issue.

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