

Phoenix Celiac Support Group

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The Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Attention: L. Robert Lake - FAX 202-205-0165
Center for Food Safety and Applied Nutrition

Dear Mr. Lake:

As President of the Phoenix Celiac Support Group of Arizona, I, on behalf of this organization, would like to submit comments regarding revisions to the current food labeling rules before your August 13, 2001 meeting. (See 66 Fed. Reg., No. 143, pp. 38591 - 94 (July 25, 2001)) Our organization membership includes those suffering from celiac disease and their immediate families. We have over 100 members at the end of our first year and membership is rapidly growing.

First, I would like to explain this disease. Celiac disease (CD), which affects approximately 1:150 people in the United States, is "a genetic disorder affecting children and adults. People with celiac disease are unable to eat foods that contain gluten, which is found in wheat and other grains. In people with celiac disease, gluten sets off an autoimmune reaction that causes the destruction of the villi in the small intestine. Celiac sufferers produce antibodies that attack the intestine, causing damage and illness." (University of Maryland Center for Disease Research 8/2001 web site www.celiaccenter.org/)

There is no cure, medication to provide relief, or corrective surgery to remediate the effects of this disease. The only successful treatment is lifelong adherence to a gluten-free diet which, given current food labeling standards, is very difficult. For those of us suffering from this disease, continued ingestion of gluten-containing products, even in small quantities, leads to malabsorption in the small intestine and damage to the villi, which can be very painful and damaging. The malnourishment can lead to serious life threatening complications such as lymphoma and possibly death.

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For these reasons, celiacs across the country are extremely concerned about the ambiguity of the current food labeling rules. Every person who is diagnosed with CD must always purchase gluten-free (GF) products or suffer serious consequences. Therefore, we strongly recommend the following:

Comment 1: We ask that manufacturers identify more clearly all ingredients that may or do contain gluten or derived from gluten in wheat, rye, oats and barley, including, but not limited to vinegars, starches, malt, natural ingredients, colorings, and spices.

Every man, woman and child with celiac disease buys or does not buy each food (and detergent, make-up...as well) product based on food labeling. If the food label is ambiguous, and most labels are, most members of this group will now call the company if we can ferret out their phone number. Most large companies like Frito-Lay now understand what GF means, are quite helpful and now provide gluten-free food lists. This has been enormously helpful.

We buy only those foods that we know are verified gluten-free (GF). If we err once, we can be quite ill for a between several hours and several days due to the body's reaction (similar to that of poison). The more errors, the higher our chances of serious long-term health consequences as mentioned above. Finding out if a product is GF is a time-consuming, often frustrating task now, but it shouldn't have to be.

It is clearly financially advantageous to companies to comply with this labeling change. A few companies have refused to say that their product is or is not GF, likely due to lack of knowledge or possibly due to fear of legal action.

Changes in food labeling requirements should help. If a company is uncertain about a food source because, for example, they may have possible cross-contamination during the manufacturing process, (i.e. conveyor belt not thoroughly washed before a line change), then their food label should say that the food "may contain gluten", as is done for peanuts at times. It would be even better if they thoroughly clean the belt and avoid the problem, but this is not always possible, we realize, for other reasons.

Comment 2: We ask that you consider using the term "intolerance" along with "allergen", and educate all involved about celiac disease. This is not an allergy.

Comment 3: Cross-contamination during food production is just as much of a health issue. Labels should therefore indicate the possibility of cross-contamination during production with the words "may contain gluten." We do hope that in the near future this issue will be eliminated with improvements to quality-control.

Comment 4: Testing is a proven way to eliminate questions. We would support the testing of products for gluten in federally-funded laboratories. If testing were required by each company, the cost for the small companies could be prohibitive. Also, this is a national problem, and certainly a growing one.

Comment 5: We support the idea of adding an 800 company contact phone number on each food product and are grateful to every company already providing one.

Thank you for your consideration of our comments. Thanks also to all of those who have worked on this issue. Your efforts thus far are truly appreciated by all of us with celiac disease. Should you have any questions, please contact our regulatory representative, Ms. Sarah Day at (480) 315-8193.

We are planning to submit further, more comprehensive comments before the October 29 deadline, but hope to have this at the table on Monday, August 13.

Sincerely,



Nina Spitzer
President

Cc: Representative Nita Lowey
Senator Edward Kennedy

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