

August 31, 2005

Food and Drug Administration  
(U.S. Department of Health and Human Services)  
Division of Dockets Management  
5630 Fishers Lane, RM 1061  
Rockville, MD 20852

RE: Docket No. 2005N-0279

I hereby offer comments, as requested by the Food and Drug Administration in the notice “Food Labeling: Gluten-Free Labeling of Foods”, issued in the Tuesday July 19, 2005 edition of the Federal Register. My comments will pertain to two (2) of the sections mentioned in the notice.

I am a 47 year old, female consumer with celiac disease and was diagnosed with the disease in September 2002. I would like to offer comments on the sections stated as: D) Foods Marketed as “Gluten-Free”; and E) Consumer Purchasing Practices.

**Question 8 in Section D of the notice asks: Are there available research data or findings on what consumers with celiac disease or their caregivers believe the term “gluten-free” means?**

My answer is “not much, if at all.” In fact, I am not aware of any studies pertaining to this question. From my experience in searching for material on this matter on the internet, talking with support groups and reading scientific studies, I have come to the conclusion there has not been adequate study of consumers with celiac disease. The focus of research data has been on the discovery of the disease, but very little education of the celiac consumer by the food industry or the medical community.

**Question 9 in Section E of the notice asks: Are there available research data or findings on how consumers with celiac disease or their caregivers identify package goods that do not contain gluten? Do the data establish how much time these consumers devote to identifying such foods?**

My response to this question is again “not much, if at all.” I am not aware of any studies that pertain to these questions. From my own experience, I have learned to read labels very carefully. The amount of time to shop for gluten free products at stores depends upon the market where the celiac consumer lives. In my case, it takes me over an hour, two times a week, to complete my shopping for my son and I for gluten free products. Additionally, I would have to visit two or more specialty stores that actually market gluten-free products. In contrast, before I was diagnosed, it would take me 45-60 minutes at one store (once a week), to complete my food shopping. My daughter who is not celiac does her own shopping and we store our groceries in a separate cabinet.

**Question 10 in Section E of the notice asks: Are there available research data or findings on whether the packaged food that consumers with celiac disease or their caregivers currently purchase or consume, are primarily or exclusively those foods labeled “gluten-free”? Do the research data or findings identify the types of “gluten-free” packaged foods purchased or consumed by persons with celiac disease or their caregivers? Do the research data or findings show whether a “gluten-free” label influences the purchasing decision of persons with celiac disease, or their caregivers when presented with products having identical ingredient lists?**

My answer is that I am not aware of any research data or findings in how celiac consumers shop. I have found that a gluten free label certainly will influence my decision on whether to purchase a product, especially if the store is a standard grocery store, or even a Wal-Mart. Except for meat, fruit and vegetables, and dairy products, all packaged foods I purchase are exclusively foods labeled “gluten-free”.

Recommendations and Conclusion:

I recommend the Food and Drug Administration obtain an emergency clearance from the Office of Management and Budget, for the purpose of sponsoring “information collection data” on these questions you have addressed in this notice. In obtaining data directly from Celiac disease consumers and their caregivers, the FDA will be able to obtain an objective and empirical sample, which would be difficult to refute. The results from the information collection sample would assist the Food and Drug Administration in its quest to comply with the law.

In addition to the information collection sample, I further recommend that the FDA contact various celiac support groups for advocacy and assistance. This would allow the FDA to obtain the highest possible sample of consumers with celiac disease. I am the founder of the Near West Suburban Celiac Group and would like to offer my assistance.

Thank you for considering my comments and recommendations today. If you need to contact me about them, please call me at 708 819-0866 during the day, or at [ljoy824@hotmail.com](mailto:ljoy824@hotmail.com)

Sincerely,

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