

Federal Drug Administration
FDA Docket # 2005N-0279
Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

4432 5 SEP -7 A10 :08

Details in Federal Register Vol. 70 No. 137

Wednesday August 31, 2005

To Whom It May Concern:

I am writing in regards to the FDA to DEFINE GLUTEN-FREE for food labels. I would like to respond to the questions regarding why gluten-free should be labeled on food descriptions. When the label Gluten-free is placed on a product it should mean there are NO ingredients containing gluten/flour/or wheat of any form. This should also consider the equipment, processing methods and cross-contamination of ingredients in the product. This could mean the difference between life and death or severe illness to some people.

It is critical the wheat/flour/gluten is not ingested into those who have Celiac. Depending on the severity of the person varying levels can or can not be tolerated. The best case is to label the product Gluten-Free. That way, those who have the worst case sensitivity will be sure they are not ingesting Gluten. Those who have less severity will only benefit from the extra effort in proper product handling and labeling.

Identification of food products that are Gluten Free is very difficult! I (a person who lives with Celiac) do not assume that any products are "SAFE" (Gluten-Free) until I have researched the product in my Gluten-Free product reference book, checked the label and made sure that the product is truly Gluten-Free. I check products by using online resources, talking to manufacturers, Grocery store managers and books about foods. Another indication I use is there is a label with a green triangle corner on some boxes with a wheat stock on it with a slash thought it meaning no wheat.

I spend a lot of time looking for Gluten-Free food and it is very hard to find. Sometimes I have to drive to three stores (1 hour away) to find the things I am looking for. I spend a lot of time and money invested in my search for Gluten-Free products. I would say at least 3-4 hours a week. When ever I question weather or not it is "SAFE" I will not but it.

I buy food for a family of four. At this time I am the only one who eats Gluten-Free but my two children will probably be soon. It is twice as expensive sometimes more to purchase Gluten-Free so I buy regular food or my family and Gluten-Free for myself.

2005N-0279

C 389

I spend about 40% on marked foods. This doesn't include fresh fruits, vegetables, meats that don't require labeling. The labeled foods include; cereals, crackers, rice cakes, special flours, breakfast bars, pasta, special cookies, bread mix, dough mix, pancake mix, brownie mix, pretzels, soup mix, chili, and chips.

If products have the Gluten-free labels on them I will prefer to buy them 100% over not labeled items. It is more costly but I know I can trust the label not to make me sick or do long term damage. I think Celiac is a very common condition and it is just now being wildly diagnosed (I think 1 in 10 have it). The issue of Gluten-Free labeling is left up to the Federal Government to make and enforce these manufacturer regulations. Most of the products I buy are not from the U.S. but I see a few more here and there. I realize it is often less cost effective for the producers to make products Gluten-free. I have found it is worth every penny to know I can trust a label and I can put my faith in it. In this case paying more is worth it especially when short and long term health is priceless!

Yours truly,

Correna Simpson
Winemaker
Franzia Winery
The Wine Group
2916 S. Reed Ave.
Sanger, CA 93657
(559)638-3511