



American Celiac Disease Alliance

September 19, 2005

Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. 2005N- 0279 Public Comment

The ACDA commends the FDA for seeking the views of the celiac community about what the term 'gluten-free' means, and what influences their choice in gluten-free foods. We are also grateful that the Agency has sought information from food manufacturers regarding the production of gluten-free foods, cross-contamination, and practices to avoid such contamination.

As the FDA moves forward in the development of the rules for the voluntary labeling of gluten-free foods, the ACDA strongly urges the Agency to:

- Limit the definition of "gluten" to those grains which have been scientifically proven to cause damage to the small intestine, specifically wheat, rye and barley;
- Establish a single scientifically defensible, and verifiable threshold below which the vast majority (>99%) of people with celiac disease will not respond whether exposed acutely or chronically. This threshold should also reflect the realities of the food processing industry and test methods for verification. No testing method has been validated at the zero-tolerance level, and therefore such a tolerance level should not be adopted.
- Avoid additional and unnecessary confusion in gluten-free product labeling. Do not permit use of the term 'gluten-free' on foods or products that are inherently, or naturally 'gluten-free,' such as a can of tomatoes. This is consistent with FDA's policy on the use of health claims such as 'fat-free.'

The American Celiac Disease Alliance (ACDA), formerly the American Celiac Task Force, is a coalition of support, research and industry organizations was formed in 2003 to advocate for changes to the nation's food labeling laws. A number of our members including: Alessio Fasano, MD, (Center for Celiac Research, University of Maryland); Joseph Murray, MD, (Celiac Clinic at Mayo Clinic), Cynthia Kupper, RD, (Gluten Intolerance Group); and Anne Lee, RD, (Columbia Celiac Disease Center), participated in the FDA's public meetings on Thresholds for Food Allergens, and Gluten-Free Labeling.

The members of our organization have years of expertise in serving the medical, dietary, and support needs of individuals (and their family members) with celiac disease. We encourage the FDA to use the ACDA as a resource, to respond to questions that may arise, as the Agency begins developing the new rules.

The goal of FALCPA was to ensure that individuals with food allergies and celiac disease could easily identify ingredients that could cause life-threatening consequences. It is our hope, that the FDA will achieve this same goal with the gluten-free labeling regulations.

Again, thank you for the opportunity to share our views.

Sincerely,

Andrea S. Levario, J.D.
American Celiac Disease Alliance