



# Stonewall Enterprises, Inc.

9174 '01

Builder & Developer  
Greentree Communities  
Churchill Oaks  
Wahoo Enterprises, Inc.  
Thoroughbred Consultant

Bartow Ned Jones  
President

October 25, 2001

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

Dear FDA:

We need your help so that our daughter, Shelley, and as many as 1 in 150 Americans can lead a healthy life. Shelley has been diagnosed with Celiac Disease. According to the American Academy of Family Physicians "Celiac disease is a disorder that causes problems in your intestines when you eat gluten, which is in wheat, rye, barley and oats. Gluten is like a poison to people with celiac disease because it damages their intestines." The problem for people with celiac disease is that gluten is in a whole host of food products not associated with wheat. Tomato soup, cottage cheese, and spices are just a few examples of the foods which are hazardous for persons diagnosed with celiac disease. Without adequate labeling, it is impossible for them to scrupulously avoid wheat gluten. Please help. The Food And Drug Administration can supply the protection that is so desperately needed.

Celiac disease may be the most under-diagnosed disease in our country. The National Digestive Diseases Information Clearinghouse (NDDIC), which is a service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), states: "A recent study in which random blood samples from the Red Cross were tested for celiac disease suggests that as many as 1 in every 250 Americans may have it." And another recent study from The University of Maryland Center for Celiac Research in Baltimore, Maryland shows that it could even be more frequent: "**Nearly one out of every 150 Americans suffer from celiac disease. ...The research indicates that celiac is twice as common as Crohn's disease, ulcerative colitis and cystic fibrosis combined.**"

The report from the NDDIC goes on to identify the consequences of having celiac disease: "Damage to the small intestine and the resulting problems with nutrient absorption put a person with celiac disease at risk for several diseases and health problems.

- **Lymphoma and adenocarcinoma** are types of cancer that can develop in the intestine.
- **Osteoporosis** is a condition in which the bones become weak, brittle, and prone to breaking. Poor calcium absorption is a contributing factor to osteoporosis.
- **Miscarriage and congenital malformation** of the baby, such as neural tube defects, are risks for untreated pregnant women with celiac disease because of malabsorption of nutrients.
- **Short stature** results when childhood celiac disease prevents nutrient absorption during the years when nutrition is critical to a child's normal growth and development. Children who are diagnosed and treated before their growth stops may have a catch-up period.
- **Seizures**, or convulsions, result from inadequate absorption of folic acid. Lack of folic acid causes calcium deposits, called calcifications, to form in the brain, which in turn cause seizures."

00P-1322

1615 6th Avenue • Huntington, West Virginia 25703

C 479

Office (304) 529-3902 • Fax (304) 529-3943

What is the treatment for Celiac disease? According to the Celiac Sprue Association of America: "The present known treatment for celiac disease is both simple and complex. All that is required is lifelong, scrupulous avoidance of gluten, specifically, the gliadin fraction of gluten found in selected grains (especially in wheat, barley, rye and oats). The gluten-free diet is essential for persons with diagnosed conditions of celiac disease and dermatitis herpetiformis. ... Without a strict clinical diet, children may have both growth and stature seriously affected in the absence of complete treatment. Adults who do not follow the diet may have ongoing inflammation and damage without being aware of clinical symptoms. Research studies on the relation between diet and malignancy (typically lymphoma) indicate the best protection factor is strict adherence to all details of a strictly defined gluten-free diet can lead to a completely normal digestive system. However, previous ravages and/or side effects may not be corrected"

All the doctors my daughter has consulted and all the medical literature I have read agree that there is no prescriptive drug that will cure celiacs, but patients can live a normal life if they permanently eliminate gluten from their diet. As stated earlier, without accurate labeling, this "lifelong, scrupulous avoidance of gluten" is not possible. Wheat is often used to thicken many food products, to prevent caking, and to coat bags of packaged food. Even some lipsticks and stamps have gluten. It can be almost anywhere.

In addition, certain foods, which are supposed to be "gluten free," may have been contaminated with gluten from products on their assembly line or previously in their mixer/vat. For example, a web site which lists many contaminate foods for persons diagnosed with celiac states for just one of those contaminated products the following warning: "although they sanitize between runs after making products with gluten on the same equipment, reactions due to contamination have been reported from products produced on these lines."

Every person should have the opportunity to overcome celiac disease and have a chance to lead a healthy life. **Please mandate that all foods be properly labeled for gluten.** Several countries in Europe already require accurate labeling for gluten in all food products. We need to do the same. After all, gluten is a "poison" for as many as 1 in 150 Americans.

Please help us.

Sincerely,

  
Ned Jones

Attachment  
BNJ/ms

----- Original Message -----

From: "George G" <primavera@qwest.net>

To: <joel@rochester.rr.com>

Sent: Sunday, October 07, 2001 12:10 PM

Subject: FDA Comment Request

> The Food and Drug Administration is asking for comment on "may contain  
> wheat..." , amongst many allergens like "peanuts." They also request  
> comment on the current (inadequate) labeling of ingredients exempted from declaration (common  
> or usual names of flavorings, spices and colors; incidental  
> additives). The FDA recognized in the public notice that "the  
> undeclared presence of allergens in food is a serious public health  
> issue because ingestion of food allergens is potentially  
> life-threatening to sensitive individuals."

>

> Before the public meeting held in Aug. in D.C., the FDA made it clear  
> that while they are dealing with allergens and not specifically with the  
> intolerance to gluten, they will accept comment on this. Eight of the 30  
> speakers represented at that meeting discussed Celiac Disease. Good  
> news.

>

> Comments from all of us are due on Oct. 29 to the FDA. I urge all of you  
> to send a letter to the FDA expressing your interest in revisions to  
> food labeling, why, and how, based on our comments below. It would be  
> good to send it also to your Congressional Reps. and Senator, if you  
> have time. We need recognition.

>

> Send comments directly to:

>

> The Dockets Management Branch (HFA-305)

> Food and Drug Administration

> 5630 Fishers Lane, Rm. 1061

> Rockville, MD 20852

>

>



Stonewall Enterprises, Inc.

1615 6th Avenue • Huntington, West Virginia 25703



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

20852+0001

