Tuesday, June 14, 2022

To Whom It May Concern:

The National Celiac Association (NCA) is a 501(c)3 nonprofit organization dedicated to educating and advocating for individuals with celiac disease and gluten-related conditions, their families, and communities throughout the nation. NCA provides the resources and programs to help people not only manage a gluten-free diet but to thrive as healthy individuals of all ages.

The proposed FDA Docket Number FDA-2021-N-0553-0005, FDA draft guidance: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders, has us and our constituents most concerned here at the National Celiac Association.

If adopted, this guidance will prevent people with celiac disease and gluten-related conditions from having a voice for future change in labeling under FALCPA standards. Nothing is static, and we are always learning about scientific breakthroughs that could have an impact on our community. By ruling out future changes, we do not take into account these possible breakthroughs. Additionally, the current Gluten-Free Labeling regulation isn't perfect and lacks enforcement as evidenced by the countless mislabeled or misbranded products that contain gluten (barley malt, for example), that have been reported, about which little has been done by the FDA.

Also, this guidance suggests that people who are afflicted with celiac disease do not suffer significant damage from gluten exposure, not differentiating the fact that it is an autoimmune disease with both acute and ongoing medical consequences:

> *Food allergy can be broadly defined as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. A food allergen is the food or component(s) (often a protein) of a food that elicits specific immunologic reactions. While many different types of food allergies have been identified, food allergies that are most studied and understood clinically are those due to*

immunoglobulin E antibodies (IgE) that cause the body to release inflammatory chemicals. The most severe and immediately life-threatening food allergies are those that are mediated by IgE and are capable of triggering anaphylaxis, which can be fatal. The focus of the draft guidance is IgE-mediated food allergy.

From speaking with people suffering every day, the National Celiac Association can attest that celiac disease is a very serious autoimmune disease and should be considered as significant as IgE-mediated responses.

Gluten is a toxin to those diagnosed with celiac disease or gluten sensitivity and when exposed to gluten, some people DO have immediate and serious reactions. Others have to deal with feeling chronically ill from any number of 200+ symptoms and being unable to live a healthy life because they are so sick.

Celiac disease can affect all body systems, and some people have been so ill at the time of diagnosis that they have been hospitalized and on death's door. A single exposure to gluten when this sick can land them back in the hospital.

Science tells us that it can take 1-3 years to recover after initial diagnosis but ONLY if there is adherence to a STRICT gluten-free diet. What is being proposed is very dangerous for people who medically require the gluten-free diet, which is the only treatment option for celiac disease.

FDA should be willing to receive citizen petitions regarding foods that cause **any** immune-mediated adverse reaction under FALCPA standards. Additionally, FDA should not limit its review of citizen petitions to only foods causing IgE-mediated reactions.

We strongly urge you to consider our request to move no further with this guidance document and to pursue scientifically valid ways of protecting people with celiac disease and gluten-related conditions instead of proposing actions such as this.

Thank you for your time.

Sincerely,

Elizabeth Graham

Elizabeth B. Graham, CEO, National Celiac Association