American Celiac Disease Alliance

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FDA Proposed Rule for Gluten-Free Labeling

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To Whom It May Concern:

The American Celiac Disease Alliance (ACDA) includes representatives from a range of entities, all of whom have an interest in the FDA proposed gluten-free (GF) labeling rule and applauds the FDA for its outstanding work in developing the proposed rule. We spearheaded the advocacy effort within the celiac community for passage of the Food Allergen Labeling and Consumer Protection Act (FALCPA) and the provisions requiring the advancement of this rulemaking. As an organization that represents the interests of consumers with celiac disease, food industry, physicians and medical research centers, we support the overall intent of this regulatory proposal and offer the following comments for your consideration.

Proposed Standard for Gluten-Free Labeling

The ACDA concurs with the FDA proposed standard for gluten-free labeling, which states that a product may be labeled "gluten-free" if it does not contain:

- an ingredient that is a species of wheat, rye, barley, or a crossbred hybrid of these grains;
- an ingredient derived from these grains and that has not been processed to remove gluten;
- an ingredient derived from these grains and that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 or more parts per million gluten in the food; or
- 20 ppm or more gluten.

The ACDA firmly believes that the standard adopted by the FDA must be substantiated by evidence-based research with limits established through double-blind, randomized trials. Research conducted in 2007 supports setting the gluten-free standard at the proposed level. There are few studies assessing toxicity and safety of gluten exposure and none published thus far which demonstrate different or safer levels for individuals with celiac disease. [1]

Labeling 'Inherently Gluten-Free' Foods or Grains

The proposed gluten-free labeling rule requests comment on whether it is appropriate to have 'qualifying language' relating to the gluten-free food label. For example, white rice is a naturally gluten-free grain. FDA queries whether adding a qualifying language is appropriate, e.g., 'all rice is gluten-free' or 'rice, a gluten-free food.'

Current FDA regulations state (for “low” and “free” claims only): If a food is “low in” or “free of” a nutrient because it is inherent to the product, a statement must be included to show that not just one particular brand but all products of that type are inherently “low in” or “free of” whatever nutrient is being claimed for that product. For example: “Whole milk — a low-sodium food.”

The case of oats serves as the example in support of our position. Oats do not contain the gliadin protein, and should be safe for celiac consumers. However, grain standards for the United States allow a set percentage of foreign grains to be present in packages of single name grains. By definition oats may contain up to 25 percent of wild oats and other grains for which standards have been established under the United States Grain Standards Act. Research has shown, and FDA acknowledges, that regular oats pose a risk to celiac consumers due to cross-contamination.

Pure oats, free of cross-contamination, have been grown and marketed in the U.S. for several years. The grain is grown under strict requirements and undergoes rigorous testing, beginning with seed selection and continuing through the manufacturing process. These pure oats are certified to be gluten-free, and are enjoyed by many celiac consumers. Thanks to the educational efforts of national patient support organizations, individuals are aware of the differences between off-the-shelf Quaker Oats and those demonstrated to be gluten-free.

Given the manner in which grain crops are rotated in the U.S., it is likely that similar contamination issues will arise with regard to other inherently gluten-free grains. In fact, a recent study found that among 22 samples of inherently gluten-free grains, seeds and flour, seven (22%) exceeded the proposed FDA standard of < 20ppm and would not be permitted to be labeled gluten-free. [2]

This research has heightened concern about the implied safety of such grains for individuals on the medically prescribed gluten-free diet. Due to the limited sample size, the authors note that a broader scale study is warranted to determine whether certain gluten-free grains are at higher risk of contamination. The ACDA finds this study instructive, and urges the FDA and USDA to support further research in this area.

Additionally, FDA itself has found that qualifying language is confusing to consumers. In its *Draft Report on Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims,* the FDA notes that “even when qualified health claims were understood as intended, qualifying statements had unexpected effects on consumers'

judgments about the health benefits and overall healthfulness of the product bearing the claim."

The ACDA strongly urges the FDA to bar the use of qualifying claims for inherently gluten-free foods and require all products labeled 'gluten-free' to be in compliance with the <20ppm standard, and follow the same labeling protocols. Although this position differs from existing policy for the labeling of inherently 'free' foods, it is warranted to help maximize the safety of celiac consumers.

This approach eliminates the need for consumers to differentiate among products that are inherently gluten-free foods and those which are not. It will also eliminate the use of other statements on products such as "made with gluten-free ingredients", which can be misleading. Finally, it will, in our view, simplify the education process for patients, and the public at large.

"Gluten-Free" Is Not Misleading

The FDA's proposed gluten-free labeling rule states that the agency will permit some claims of 'free' even though the product is not 100% free of the particular nutrient. The NPRM reads, "A consequence of using the analytical methods-based approach is that the words ''gluten-free'' could be used on a product that is not, in fact, entirely free of gluten.

The FDA seeks comments regarding whether, in light of FDA's safety assessment and the data underlying it, the possible presence of more than 0.01 ppm but < 20 ppm gluten in a food bearing a ''gluten-free'' labeling claim should be disclosed on the label in order to prevent a ''gluten-free'' claim from being false or misleading under the statutory definitions of misbranding found at 21 U.S.C. 321(n) and 343(a)." We believe such a disclosure is unwarranted and would conflict with existing regulations for nutrient content claims.

Current FDA regulations on defined ''free'' nutrient content labeling claims allow up to a specified measurable amount of the substance that is the subject of each of those claims to be present in the food. For example, per reference amount customarily consumed or per labeled serving, a food labeled:

''fat free'' could contain < 0.5 gram (g) of fat	(§ 101.62(b)(1)(i) (21 CFR 101.62(b)(1)(i)))
''cholesterol free'' could contain < 2 mg cholesterol	(§ 101.62(d)(1)(i)(A))
''sodium free'' could contain < 5 mg sodium	(21 CFR 101.61(b)(1)(i))

Individuals with celiac disease are readily aware that products they purchase are not 100% gluten-free. National patient support organizations, celiac research centers, food manufacturers and others, provide detailed information on the gluten-free diet; none states nor infers that 'gluten-free' products are completely free of gluten.

Based on comments submitted for this rulemaking and revealed in survey results, a large segment of the celiac community believes 'free' to mean containing zero gluten. The position is based, in part, on the mistaken belief that nutrient claims like 'fat free' mean the product contains zero fat. Clearly, the misperception is one that transcends

the issue of gluten-free labeling. The ACDA strongly discourages the FDA from reversing its position on this point. Additionally, any deviation on this point would be at odds with international labeling standards under the Codex Alimentarius.

Gluten-Free and Low-Gluten

The FDA recognized that Australia and New Zealand have adopted a two-tiered gluten-free labeling system, and requested comment on whether there was support for such a labeling convention in the U.S. We do not believe that the dual standard utilized in these countries is an appropriate model for this country.

The current labeling requirements in Australia and New Zealand dictate that to bear a 'gluten-free' label, a product must contain 'no detectable level of gluten.' A product may bear a 'low-gluten' claim if it contains no more than 20 mg gluten (200ppm) per 100 g of the food. [3]. According to Coeliac New Zealand, few products are labeled low-gluten, and it is readily known that these items are not appropriate for individuals with celiac disease. While the standard permits tiers for labeling, the 'low-gluten' standard does not appear to be of benefit for the consumer.

Another issue with regard to labeling in Australia and New Zealand merits attention. The national support organizations in these countries (Coeliac Australia and Coeliac New Zealand) have programs in which they endorse products at < 20ppm, the Codex level. Products endorsed by the organizations may not be labeled gluten free but may display a cross grain symbol, which is recognized internationally to mean gluten-free. [4] The actions of these national organizations appear to indicate that products tested to the Codex standard are safe and the food standard unnecessarily restrictive.

The Codex standard is tiered as well, with gluten-free set at <20ppm and low-gluten at <100ppm. The U.S. did not agree with this option and proposed only one level to define "gluten free" in its draft positions to the Codex Committee on Nutrition and Foods for Special Dietary Uses, in September 2007. It was joined by other countries opposing the dual standard for labeling, (gluten-free < 20ppm, low-gluten < 100 ppm), when considered by the Committee on Nutrition and Foods for Special Dietary Uses of the Codex Alimentarius Commission in November 2007. [5]

European countries have had some standard for gluten-free labeling for three decades. During that time celiac consumers have had access to products that are both gluten-free, by definition, and those containing ingredients such as wheat starch, that have been rendered gluten-free. This point was noted by delegations to the Codex Alimentarius Commission when the standard for gluten-free labeling was in the process of being revised. Countries in which food products are readily available, and marketed as having a reduced gluten content (e.g. between 20 ppm and 100 ppm), advocated for a tiered labeling approach, because consumers had used such gluten free foods for a long time without any negative consequence. Further, that the removal of these products would limit consumers' choice for their diets. [6]

Products containing wheat starch or other ingredients 'rendered' gluten-free are not readily available in the U.S. market. Food manufacturers are not using such ingredients in large part because consumers are unfamiliar with them and question their safety. The arguments that led to the Codex dual standard are not valid for the U.S. population.

Celiac consumers have waited years for a clear, straightforward standard. A tiered approach for gluten-free labeling will compound, rather than minimize, confusion for consumers and the ACDA strongly believes the option should be rejected.

Extremely Sensitive Celiac Consumers

The FDA requested information about the number of individuals for whom the proposed standard would not be sufficiently protective, and data identifying the proportion of the celiac population that may have adverse reactions when exposed to gluten levels between 0.01 ppm and < 20 ppm.

The ACDA is unaware of any studies to assess the specific sensitivity levels of persons with celiac disease. Anecdotal evidence is not a substitute for peer-reviewed scientific research and should not be considered as basis for determinations relating to this rulemaking.

Once research is conducted and published on this topic, we would recommend that it be evaluated for consideration with regard to revising the 20ppm standard.

Standard Lower Than 20 ppm

The ACDA does not believe that reducing the level of parts per million to 1 ppm, as advanced in the Gluten Report, would be advantageous to industry and would in fact negatively impact consumers who rely on trusted manufacturers to provide safe foods. We believe this to be the case for many reasons:

First, research has demonstrated that a 20 ppm standard is safe for the majority of individuals with celiac disease. [7] This research was cited by the U.S. delegation, as a basis for the adoption of that standard by the Codex Alimentarius Commission. [8]

Next, forcing manufacturers to produce gluten-free foods with extremely low levels of gluten will be detrimental to those people who need gluten free products the most, as it will unnecessarily cause (at a minimum) a significant reduction in the array of gluten-free products or the disappearance of gluten free labeled products all together.

It is unclear how many companies currently producing gluten-free products would be able to meet a standard significantly lower than 20ppm, or the rigors required to maintain compliance. The margin of error in testing for gluten, using the best methodologies, can range from 10 - 20%. At an extremely low threshold like 5ppm, the variability would mean ingredients testing at or below that standard, could exceed that threshold in subsequent testing. The most vigilant manufacturers could experience economic harm when a slightly out of compliance ingredient (but still under 20ppm) would result in the company not being able to ship product that its consumers want and need.

Additionally, this would lead to increased food costs as manufacturers would need to be appropriately compensated to take on this additional risk, with less supply sources, in order to maintain this level. Research shows that the costs of gluten-free products range from 5% to 1000% higher than gluten-containing products. Gluten-free bread and pasta

on average are twice as expensive as comparable wheat products. [9,10] Further increases would negatively effect celiac consumers with some being unable to afford products, resulting in the difficulty to adhere to their medical diet.

It could further have an adverse impact on international trade due to creating a standard that is not the norm in many parts of the world including Europe, where the Codex standard is 20ppm. Forcing U.S. manufacturers to abide by this unnecessary level will unfairly harm their ability to compete successfully outside of the U.S. borders. Conversely, foreign companies who are testing their products to a higher parts per million will not be able to sell their products in the U.S. As a result, consumers will be more confused as to what products they can and can't eat thus creating more difficulty for the celiac consumer.

As more scientific research becomes available, we urge the FDA to regularly review the testing methodologies, and standards and revise where appropriate, to ensure the safety of celiac consumers.

Codified Standard

We believe that having a codified statement for testing purposes would prove beneficial in maintaining uniformity throughout the industry. Other related issues that are not specifically related to testing, (e.g., standard, methodologies) would be served by guidance language, as this will allow the FDA and food manufacturers alike the flexibility to address and respond to issues and make changes as warranted in the most timely manner.

The following comments, while not specific to the establishment of the gluten-free standard, are important for consideration with regard to the implementation of the final rule.

Education

As noted in the opening summary to this rulemaking, "establishing a definition of the term `gluten-free' and uniform conditions for its use in the labeling of foods is needed to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled." On this point, we are in complete agreement. After resolving the standard and compliance issues relating to labeling, another major hurdle must be cleared if celiac consumers are to feel confident in their product choices. Educating the consumer must be a top priority once this rulemaking is completed.

The ACDA noted in comments submitted in April 2007, that conducting a series of educational programs will be critical to ensuring that celiac consumers understand the changes set forth by these regulations. We again urge the FDA to enlist the assistance of health care professionals and advocacy organizations in preparing and disseminating educational materials for celiac consumers. With the advances in social media, the

agency has better opportunities to reach individuals and share information about the new labeling requirements at minimal cost.

Additionally, food manufacturers will look to the FDA for detailed guidance to ensure they are in compliance with the new regulations. The ACDA stands ready to assist you in the development of training and educational modules.

Advisory Labeling

The scope of this NPRM does not address another significant problem -- advisory labeling. There are a great many instances where the consumer is confused by reading conflicting statements on product labels. For example, a product labeled as 'gluten-free' yet bearing the statement "manufactured in a facility that also manufactures gluten containing products" or "made in a facility that also produces products made with wheat." The FDA must evaluate the appropriateness of such advisory statements in light of the overall public policy goal sought by this rulemaking. A defined gluten-free standard along with strict labeling requirements will give consumers greater confidence in making safe product selections.

Advisory statements raise questions in the mind of the celiac consumer, undermine product confidence, and unnecessarily lead one to limit his or her food choices. Concern about such statements resonate beyond the celiac community, generating confusion for millions of food allergic Americans as well. If similar labeling is permitted after these rules are promulgated, questions will persist in the minds of celiac consumers potentially undermining the intent of this rulemaking.

Harmonization

This rulemaking, as required by FALCPA, only governs products regulated by the FDA. Those regulated by the USDA are beyond its scope. The need for and issues relating to gluten-free products are universal and not isolated to those within the regulatory purview of a particular agency.

We understand that the USDA has expressed an interest in requiring firms who wish to label meat, poultry, etc., 'gluten-free, to meet FDA's standards once finalized. However, a definitive statement on this point has not been made. The ACDA strongly encourages the FDA to collaborate closely with its colleagues at USDA to ensure there is harmonization between the agencies with regard to gluten-free labeling. In the best interest of the celiac consumer, that effort must entail setting a single effective date for compliance with the FDA labeling standard.

Having a single effective date for products regulated by both agencies will help to minimize confusion about what gluten-free labeling means across the board. Individuals will have confidence that the label on the gluten-free chicken nuggets means exactly the same as it does on a similarly labeled breakfast cereal. This will also make it easier for organizations such as the ACDA, and others serving the celiac community, to educate consumers about the new labeling requirements.

We believe it is critical for the FDA and USDA to take advantage of this opportunity to accomplish a goal that is long overdue, by providing consumers with consistent information they need to maintain their health.

Conclusion

There is no medical intervention for the treatment of celiac disease, no drug, no ongoing therapy. The treatment, while medically prescribed, is self-administered and in many instances without medical oversight. Gluten-free foods, in all forms, are the equivalent of a prescription medication used to manage another lifelong, chronic condition. The laws differ dramatically with regard to the labeling, and manufacturing between drugs and foods, and we do not imply the two should be equal.

We do however, implore the FDA to consider the following: it takes an individual, on average, six years of being ill, of bouncing from doctor to doctor before being properly diagnosed with celiac disease. Gluten-free foods don't undergo years of safety testing before going on the market, like medications. Each and every day, celiac consumers are placed at risk when trying to determine if the foods intended to maintain their health are safe. They have only the clarity and accuracy of the labeling on which to rely. It is a heavy burden, but one that will be eased dramatically with the completion of this rulemaking.

FDA Deputy Commissioner for Food, Mike Taylor, stated in the teleconference to stakeholders announcing the reopening of this NPRM, and in the press, that the agency 'must get this right.' We cannot agree more and believe that reflecting on the experience of other countries, the FDA can determine the approach to gluten-free labeling which best protects and works for the American celiac consumer.

Again, we appreciate the opportunity to comment on these proposed rules and look forward to working with the FDA to ensure their timely and smooth implementation once finalized in the third quarter of next year.

Respectfully,

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