FOOD MARKETING INSTITUTE

Your Neighborhood Supermarkets

April 23, 2007

Docket No. 2005N-0279
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Food Labeling; Gluten-Free Labeling of Foods; Docket No. 2005N-0279

Dear Sir or Madam,

The Food Marketing Institute[1] (FMI) applauds the Food and Drug Administration (FDA) for proposing to define the term "gluten-free" for use in the voluntary labeling of food. 72 Fed. Reg. 2795 (Jan. 23, 2007). As discussed more fully below, our primary concern lies with the Agency's proposal to require a qualifying statement to accompany "gluten-free" claims on foods that do not inherently contain gluten.

In this regard, the proposed rule does not meet the fundamental purpose of the Food Allergen Labeling and Consumer Protection Act (FALCPA): FALCPA was intended to make allergen information simpler and more plentiful for those in need, not more confusing. FDA's proposal to require qualifying language is at once too restrictive – limiting the food industry's ability to provide needed information – and overly broad because few foods will be uniformly gluten-free. Accordingly, as the qualifying language is not legally required or consistent with FDA precedent, FDA's final rule should allow the use of a "gluten-free" claim on all food that meets the scientific standard ultimately established by the Agency, regardless of the manner in which the food became "gluten-free."

A. Background

FALCPA requires FDA to promulgate a final regulation that defines and permits the use of the term "gluten-free" on food labeling. In response, FDA published a proposed regulation that essentially would permit the use of a "gluten-free" claim on any food that contains less than 20 parts per million (ppm) of gluten. Proposed 21 CFR 101.91(a). In addition, FDA's proposal requires that a food that does not inherently contain gluten from a prohibited grain (with the exception of oats) may not bear a "gluten-free" claim unless the food has less than 20 ppm of gluten and the claim is accompanied by a disclaimer that refers to all foods of the same type, e.g. "milk, a gluten-free food". Proposed 21 CFR 101.91(b).

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[1] Food Marketing Institute (FMI) conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all food retail store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

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As discussed more fully below, although we defer to FDA to determine the appropriate scientific standard,[2] we strongly urge the Agency to remove the requirement that foods that do not naturally contain gluten must include a statement regarding all foods of that type. Given the variability in manufacturing processes and, indeed, in foods themselves, and the strict scientific standard that must be met, such information is potentially misleading; lengthier descriptions of all possible situations would only increase confusion.

B. Discussion

1. Consumers Are Concerned About Gluten and the Supermarket Industry Has Responded

Consumers who are impacted by gluten need clear information. Indeed, one retailer reported that the single most frequently asked question on their customer help line was the gluten status of various foods sold in its stores. As the link in the food chain that is most closely connected to consumers, our primary concern here is to ensure that consumers have clear, helpful information.

Many retailers have responded by developing programs that place gluten-free foods in special sections of the store or use icons or symbols to designate foods that are gluten-free. FMI members agree that a single, clear, scientifically justified standard for foods that should be considered "gluten-free" will be helpful to all parties concerned. However, retailers and others should not be discouraged from providing useful information on the absence of gluten.

2. Proposed Qualifying Language May Promote Consumer Confusion

FDA's proposal to require qualifying language to accompany "gluten-free" claims on foods that do not inherently have gluten will cause consumer confusion. Consider the following scenarios.

If Retailer A were to follow what is now proposed by the FDA and label a product such as Swiss cheese: Swiss cheese, a gluten free food. At the same time Retailer B does not label his Swiss cheese as such because it is made by a manufacturer that manufactures other products in his facility that are not gluten free, this could easily cause consumer confusion. The consumer who has seen the "Swiss Cheese, a gluten-free food" label at Retailer A may infer that all Swiss cheese is gluten-free, purchase the cheese at Retailer B and as a result have an adverse reaction.

Another example where consumers could easily be confused is in the case of blended products. If a retailer labels a product: "All beans are gluten-free," it is possible that a customer will think that a package of rice, beans and herbs are gluten-free as well. Or, in all likelihood, singling out one ingredient on a product as gluten-free will raise questions in the consumers mind as to whether the rest of the ingredients are gluten-free as well. If the rice/bean/herb product bore a label saying "gluten-free," there is no question as to whether the product suits a particular diet or not.

[2] We encourage FDA to finalize the safety assessment and include its findings in the final rule to address the issues raised regarding the proposed 20 ppm standard.

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Both above examples would be further exacerbated if the customer in question was a recently diagnosed celiac-sufferer and on his or her initial trip to the grocery store to try to fill his or her grocery cart with gluten-free product. FMI believes that it does not matter to a gluten-sensitive consumer how a product came to be gluten-free — naturally or due to processing. By using the label "gluten-free" there is no confusion for the consumer; it is succinct and clear.

3. Qualifying Language Is Neither Legally Required Nor Consistent with FDA Precedent

The qualifying language FDA proposes to require to accompany "gluten-free" claims on foods that do not naturally contain gluten is neither legally required nor consistent with FDA precedent. Specifically, in support of this provision, FDA cites the approach adopted for nutrient content claims that describe a food as "free" of a particular nutrient. However, these rules are based on Section 403(r)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which allows "free" claims on a food that is naturally free of the relevant nutrient only if the label discloses that the nutrient is not usually present. In regulations implementing this provision, FDA requires "free" claims to be qualified (e.g., "broccoli is a fat free food') unless the relevant food has been specially processed, altered, or formulated to qualify for the claim.

This approach is not required here because gluten is not a nutrient and, therefore, gluten is not subject to the statutory qualification requirement for nutrient content claims. Accordingly, FDA is not obligated to treat "gluten-free" claims in the same manner as "fat free" or "sodium-free" claims.

From a legal perspective, then, the only relevant question is whether gluten-free claims are truthful and not misleading when made on foods that do not naturally contain gluten. A gluten-free claim is truthful and not misleading so long as the food meets the scientifically established threshold for gluten. Indeed, since gluten may be present in such a wide variety of foods, either naturally or as a result of cross-contamination through the manufacturing process, *in many instances it will be misleading to suggest that a particular food or food category is always gluten-free*.

With respect to cross-contact, as a practical matter, almost any food may contain gluten as a result of the production or manufacturing process. Unlike nutrients such as fat and cholesterol, gluten can be transferred to foods that do not naturally contain it. Cross-contact may be avoidable in some situations, such as dedicated facilities, but unavoidable in others. For example, rice flour may be milled and further processed in a facility that produces other flours. A rice flour produced in the same facility as a wheat flour may not be gluten-free. If FDA requires labels to tell consumers that "rice flour is a gluten-free food" consumers will mistakenly believe that all rice flours, even those produced in proximity to wheat flour, is gluten-free. Indeed, FDA's analysis of oats reflects this very challenge. As FDA explained in the proposed rule, because oats are often commingled with prohibited grains, FDA believes that a claim suggesting that all foods made from oats are gluten-free would be misleading. 72 Fed. Reg. at 2802. This same rationale applies to many foods, not just oats.

Additionally, a wide variety of ingredients may contain gluten, adding to the categories of food that are not reasonably viewed as uniformly gluten-free. For example, plain milk does not ordinarily contain gluten, but flavored milk or yogurt might; plain almonds do not ordinarily contain gluten, but seasoned almonds might; uncoated fruits and vegetables do not contain gluten, but as FDA points out, fresh produce coated with a gluten-containing wax or resin could. These are but a few of the many examples demonstrating

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the difficulty of drawing a sharp line between foods that are naturally gluten free and those that may contain gluten. As a result, a rule that oversimplifies the nature of gluten and gluten-containing foods will likely not be truthful and it certainly bears significant potential to mislead them. Moreover, an individual manufacturer cannot and should not be required to make representations about all products in a given category – especially those produced outside of that manufacturer's control.

* * *

As discussed more fully above, we strongly encourage FDA to promulgate a final regulation permitting the use of a "gluten-free" claim on any food that meets the scientific threshold established by the Agency, regardless of the way in which the product became "gluten-free." A qualifying statement is not legally required and it is inconsistent with FDA precedent. The methodology by which the food meets the standard is irrelevant to consumers – they simply need to know which foods have low levels of gluten. Accordingly, FDA should promulgate a final rule that allows "gluten-free" claims to be made for all foods that can be scientifically demonstrated to be free of gluten.

We appreciate the opportunity to comment on this important issue. Please do not hesitate to contact us if we can provide you with any further information in this regard.

Sincerely,

/S/

Deborah R. White
Vice President &
Associate General Counsel

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