



JUN 2 2003

Mrs. Christine Spreitzer  
2 Milano Court  
Croton On Hudson, New York 10520

Dear Mrs. Spreitzer:

This is in response to your e-mail of April 5, 2001 to the Food and Drug Administration (FDA) in which you asked FDA to require "gluten free" labeling on products that do not contain gluten. In addition, you asked that FDA consider the addition of gluten containing grains other than wheat to be added to the allergens list. We regret the delay in our response and trust that the following explains our regulations regarding the labeling of foods.

We are sorry to hear of your daughters' intolerance to the cereal grains that have resulted in celiac disease. FDA appreciates the complexity of grocery shopping faced by persons with food allergies and intolerances.

We would like to point out the Federal Food Drug and Cosmetic Act (the act) and its implementing regulations govern our requirements for labeling of foods. Specifically, Title 21 Code of Federal Regulations (CFR), section 101.4 requires, in most cases, that the labels of food fabricated from two or more ingredients bear a declaration of each ingredient. The ingredients must be declared by their common or usual name, in descending order of predominance by weight. We believe that, to a large extent, the disclosure of ingredients in foods helps consumers suffering from food allergies/intolerances to identify foods containing specific substances. However, there are two very narrow exemptions from these ingredient labeling requirements. First, section 403(i) of the act provides that spices, flavors, and colors may be declared collectively without naming each one. Second, FDA regulations (21 CFR 101.100 (a)(3)) exempt, from ingredient declaration, incidental additives such as processing aids that are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food.

At this time, FDA has a major food allergy initiative underway to make food labels more helpful to persons with food allergies. Currently, we are working to develop a proposed rule for the labeling of the most common allergens using consumer and industry input from a public meeting we held on August 13, 2001, regarding food allergies. We also plan to develop a comprehensive food allergen strategy to address considerations such as cross-contact so that persons with allergies can be assured that all the ingredients are named.

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We want you to be aware that FDA has received a citizen petition (docket number 00P-1322) from nine State Attorneys General that raises concerns on allergen labeling. We will send your letter to our Dockets Management Branch to add to the other letters responding to the petition. We will consider your concerns before we make a decision.

In regard to the use of the term “gluten free,” FDA advises that even though it has not specifically defined “gluten free,” this phrase can be used on foods provided that when it is used it is not false or misleading. The term “gluten free” may be misleading when the food ordinarily contains no gluten (e.g., green beans). Further, the agency has advised that foods labeled “gluten free” that purport to be or are represented for special dietary use should adhere to the provisions for hypoallergenic foods in 21 CFR 105.62 by declaring the common or usual name, and the quantity or proportion, of each ingredient (including spices, flavorings and non-certified color additives) when the food is fabricated from two or more ingredients. Additionally, under section 105.62(b) the name of the food or of its ingredients must be qualified to reveal clearly the specific plant or animal source of the food or ingredient.

We thank you for your interest in this issue and hope the above information addresses your concerns. If we may be of further assistance, please let us know.

Sincerely yours,



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