



JUN 27 2003

Ms. Marie Kawaguchi  
Founder  
Celiac Association of Northern Utah  
4761 West 3450 South  
West Haven, Utah 84315

Dear Ms. Kawaguchi:

This is in response to your letter of July 5, 2001, to the Food and Drug Administration (FDA) regarding your concerns about the labeling of foods that contain gluten. You wanted to know what steps are being taken to clearly label the ingredients in these products. 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 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.

The Federal Food, Drug, and Cosmetic Act (the act) and its implementing regulations in Title 21 of the Code of Federal Regulations (CFR), section 101.4 require, in most cases, that 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 names, in descending order of predominance by weight. Such ingredients may include grains, for example, wheat, corn, rice, oats, etc. 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. Thus, when used as ingredients, these may be labeled as "spices," "flavor" or "color" without declaring their common or usual names. 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.

We recognize that the labeling of food allergens is a concern of allergic/food intolerant consumers and additional measures may be needed to ensure that consumers obtain adequate information about the foods that they eat. Currently, FDA has a major food allergy initiative underway to make food labels more helpful to persons who have food allergies. One of FDA's priorities in fiscal year 2003 is to develop a proposed rule to require manufacturers to clearly identify in the ingredient list on food labels the presence of the most common food allergens, cow's milk, eggs, fish, crustacea, tree nuts, wheat, peanuts, and soybeans. We fully understand the importance of making this type of information available to allergic consumers. Though we recognize that all of the grains that you noted are not captured in our list, we believe the inclusion of wheat will also assist gluten intolerant consumers to a large degree. We will also be

OOP-1322

ANS 11

Page 2 – Ms. Marie Kawaguchi

determining whether we need additional labeling to provide “plain English” terms that reveal the source of foods, including flavors, spices and colors that contain allergens so that persons with allergies can be assured that all the ingredients are named.

In regard to modified food starch, FDA does not require manufacturers to name the source of the starch because the starch isolation process used in preparing modified food starch removes the protein (i.e., gluten) component. Thus, modified food starch is the common or usual name of the product regardless of source. Although we acknowledge the possibility that traces of protein might occasionally trigger an adverse reaction, and we acknowledge your concerns, we have not been able to document reported cases of food intolerance to the modified food starches commonly available for commercial use. Thus, irrespective of the source, modified food starch is not likely to be a problem for most gluten intolerant consumers. Therefore, in the absence of information showing that modified food starch will trigger adverse reactions, there is no basis at this time to require source declaration.

When the term “starch” is used alone it is considered the common or usual name for granules of starch made from corn; alternatively, the name “cornstarch” may be used. Starch from other sources must be named using a non-misleading term for the source of the starch such as “wheat starch” or “potato starch.”

Regarding another ingredient that you listed, we point out that we would not consider “vegetable protein” to be a sufficiently descriptive term of an ingredient. If a protein such as wheat gluten were used as an ingredient in a food, it should be listed by its common or usual name, i.e., “wheat gluten.”

We thank you for your interest in these issues and hope the above information addresses your concerns. Your letter will be sent to our Dockets Management Branch to be added to a citizen petition (docket number 00P-1322) submitted from nine State Attorneys General that raises concerns on allergen labeling. If we may be of further assistance, please let us know.

Sincerely yours,



Catalina Ferré-Hockensmith  
Consumer Safety Officer  
Division of Food Labeling  
and Standards  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition