

To: smtp[mjw@berkeleycollege.edu]
From: Catalina Ferre Hockensmith@OFL@FDA.CFSAN
Certify: N
Priority: Normal
Subject: RE: Product Labeling
Date: Wed Jan 12 08:30:36 2000
Attached: None

Dear Ms. Wereschagin:

This is in response to your e-mail of November 29, 1999, to Joseph Levitt, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, regarding the labeling of all ingredients that are used in the preparation of foods to protect celiac and other consumers. Your e-mail was forwarded to our office for reply.

We understand your concern regarding your and your daughter's celiac disease. FDA, as well, is concerned about informing consumers about allergenic substances in food.

Let me begin by explaining that the Food, Drug, and Cosmetic Act (the act) requires, in virtually all cases, that labels of food fabricated from two or more ingredients bear a declaration of each ingredient, by its common or usual name, in descending order of predominance by weight in the ingredient statement. There are two very narrow exemptions from these ingredient labeling requirements. First, section 403(i) of the act provides that spices, flavorings, and colorings may be declared collectively without naming each one. Secondly, 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. In other words, when an ingredient is used during processing or is added as a secondary ingredient, and is present at insignificant levels and has no technical or functional effect in the finished food, the ingredient may not be required to be declared in ingredient labeling.

As stated above, FDA recognizes that some foods are a concern to food intolerant and allergic consumers and is considering whether it is necessary to clarify or amend its ingredient labeling regulations to ensure that manufacturers fully understand the circumstances in which allergenic food ingredients must be declared. The agency addressed its concerns in a 1996 Notice to Manufacturers about declaration of allergenic substances in food. Because we had received reports of adverse reactions to foods in which allergenic substances were likely used as flavors, and not declared by name, FDA discussed in the notice whether an allergenic ingredient in a spice, flavor, or color should be required to be declared, 403(i) notwithstanding. On a substance-by-substance basis, the agency has required ingredients covered by the exemption in section 403(i) to be declared when necessary to protect individuals who experience adverse reactions to the substance. Please note that wheat is included in the list of common allergens. While the agency recognizes that Celiac disease is a food intolerance and not an "allergy," we believe, however, that the inclusion of wheat in the list will likely increase the potential for the Celiac patient to avoid proscribed products. The agency also discussed, in the notice, its concern with the inadvertent introduction of an allergenic ingredient to a food. For example, a bakery that is manufacturing two food products on one production line, one product with peanuts and one without, may inadvertently introduce traces of peanuts or peanut products into the product that does not normally contain peanuts. Good manufacturing practices notwithstanding, the agency is considering how best to alert sensitive consumers to the inadvertent introduction of allergens into food since its presence would not be declared in the ingredient statement.

The agency is aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (insert the name of allergenic ingredient)." FDA has advised manufacturers that, because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMP. The agency has urged manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of the allergenic food before relying on "may contain" labels to protect the consumer.

We have recently received a citizen petition (docket number 99P-2148/CP) raising concerns similar to those raised in your e-mail and requesting FDA to amend its food labeling regulations to require the specific ingredient listing of spices and natural and artificial flavors on the label. We will forward your e-mail to the Dockets Management Branch to be included with other letters responding to the petition. Please be assured that we will consider all comments before making a final decision on this issue.

If you have any further questions on this issue, do not hesitate to contact us.

Sincerely yours,

Catalina Ferre-Hockensmith
Division of Programs and
Enforcement Policy
Office of Food Labeling
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and Applied Nutrition

99P-2148


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