



February 27, 2001 1413 '01 MAR -9 A9:40

Mr. Pat Potok
5402 Sandy Grove
Kingwood, Texas 77345

Dear Mr. Potok:

Your letter to Commissioner Henney regarding the labeling of all ingredients that are used in the preparation of foods was referred to this office for response. We apologize for the delay in responding to your to your letter.

We understand your concern about your son's allergy to certain foods. The Food and Drug Administration, as well, is concerned about informing consumers about allergenic substances in food. We hope the following information is helpful.

Your letter raised several concerns: (1) It asserts that FDA only recognizes milk, eggs, fish and wheat as allergens (2) It suggests that the spice tumeric is a allergen (3) It requests that the FDA contact a few top allergy experts to find out which foods including spices and preservatives have caused severe allergic reactions and (4) It requests that all food ingredients to be declared on the food label.

The statement that FDA recognizes only milk, eggs, fish, and wheat as allergens is not supported by the facts. In a policy statement published in the Federal Register of May 29, 1992 (57 FR 20984- 22987) FDA recognized the eight commonly known food allergens (milk, eggs, fish, wheat, peanut, tree nuts, legumes (particularly peanuts and soy beans), crustaceans and mollusks). We have talked to our experts and we have not found any creditable evidence that ingested tumeric is an allergen.

As further information, consult FDA's website at www.cfsan.fda.gov about which foods including spices and preservatives have caused severe allergic reactions. Also, the Food Allergy and Anaphylaxis Network (FAAN) provides valuable information to consumers on allergic reactions. They are located at 10400 Eaton Place Suite 107, Fairfax, Virginia 22030-2208, Phone (800) 929-4040, and www.foodallergy.org. We are also enclosing a copy of a publication by Steve Taylor et.al. entitled " The Role of Flavoring Substances in Food Allergy and Intolerance"

In responding to your concern about declaring all food ingredients on the ingredient statement, I thought it would be helpful to describe the labeling requirements of the Act. The Federal Food, Drug, and Cosmetic Act requires, in virtually all cases, that labels of food fabricated from two or more ingredients bear a declaration of each ingredients, 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-

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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 101.00(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 is not required in the ingredient list.

FDA recognizes that some foods are a concern to consumers who suffer with allergies 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 about declaration of allergenic substances in food in a 1996 Notice to Manufacturers (copy enclosed). Because we had received reports of adverse reactions to foods in which allergenic substance were likely used as flavors, and not declared by name, FDA discussed in the notice whether an allergenic ingredients in a spice, flavor, or color should be required to be declared, section 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. The agency also discussed, in the notice, its concern with the inadvertent introduction of an allergenic ingredient in 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 is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMPs. 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" labeling to protect the consumer.

Over the last several years the Center for Food Safety and Applied Nutrition (the Center) has made public its program priorities for the year. On January 9, 2001 FDA announced its 2001 program priorities which is the work plan for the Center for the

current fiscal year. That document talks about allergens as an emerging area of concern for us. As per the work plan (copy of relevant pages enclosed) the Center will develop a strategy for exploring clearer labeling of food allergens on the food label, emphasizing the eight major food that are allergens. The plan calls for the issuance of a field allergen inspection guide and training for FDA field Offices staff. It includes publishing a draft allergen Compliance Policy Guide concerning manufacturing and labeling practices and holding a public meeting on allergens. We ask that to the extent possible, you should participate in that meeting and comment on other Center action concerning allergens.

FDA will consider all options for providing consumers with information about the presence of allergens in foods and is open to suggestions on how best to address these problems. Please be assured that we will take your comments into consideration.

Sincerely yours,



Kenneth J. Falci, Ph.D.
Director, OSAS
Center for Food Safety
And Applied Nutrition

Enclosure

Cc:

HFS-001 (Levitt)
HFS-022 (Bailey/Gordon)
HFS-700 (Falci)
HFS-800 (Lewis)
HFS-820 (Satchell)

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(based on labeling language from J.Gordon/Jforet

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K.J. Falci HFS- 150 1/25/00

Reviewed by C. Bailey HFS- 22 1/29/00

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