



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 3 2000
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The Honorable Michael R. McNulty
Member, U.S. House of Representatives
Leo O'Brien Federal Building, Room 827
Albany, New York 12207

Dear Mr. McNulty:

Thank you for your letter of September 8, 1999, on behalf of your constituent, Sister Rose Bernard of Latham, New York. We regret our delay in responding but trust that the following information is helpful. Sister Rose Bernard has a condition, celiac sprue, which causes intolerance to the protein component of the gluten in wheat, barley, rye, and oats. This means she needs to avoid food products containing these grains. She is concerned that food manufacturers are including wheat and other grain flours in their products without stating so on the label's ingredient statement. She would like legislation to require the disclosure of all ingredients on food labels.

By way of background, the Federal Food, Drug, and Cosmetic (FD&C) Act requires that all foods fabricated from two or more ingredients must declare each ingredient by its common or usual name in the ingredient statement in descending order of predominance by weight. The FD&C Act provides two narrow exemptions from ingredient labeling requirements. The first one provides that spices, flavorings, and certain colorings may be declared collectively without naming each one. The second one provides that incidental additives, such as processing aids that are present at insignificant levels and do not have a functional effect in the finished food, do not have to be declared on the label.

Staff at the Food and Drug Administration's (FDA or the Agency) Center for Food Safety and Applied Nutrition (CFSAN) have been considering whether to revise the regulation regarding natural flavorings to make it more user friendly and to make it more meaningful to consumers. We have forwarded

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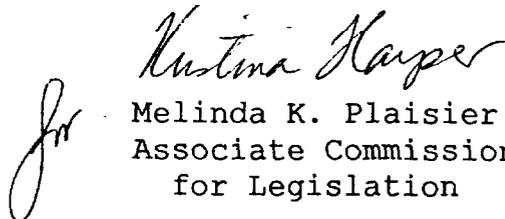
your correspondence to our staff at CFSAN for their consideration.

In addition, we have recently received a citizen petition raising concerns similar to those raised in your letter and requesting FDA to amend its food labeling regulations to require the specific ingredient listing of spices and natural and artificial flavorings on the label. We have forwarded your correspondence to the docket for this matter for inclusion in the record. Please be assured that we will consider all comments before making a final decision on this issue.

FDA understands the difficulties faced by persons with food allergies and food intolerance. Being able to identify and avoid allergens and other specific ingredients is of great importance to such people. We have enclosed a Notice to Manufacturers that FDA distributed to food manufacturers, trade associations, and other food industry groups. It advises the industry on the steps that it needs to take to ensure that allergens are declared on food labels. FDA encourages manufacturers to specifically declare ingredients used as flavors and colors that are known allergens. Please note that wheat is included in the list of common allergens. While the Agency recognizes that celiac sprue is a food intolerance and not an allergy, we believe that the inclusion of wheat in the list will help enable persons with celiac sprue to avoid certain proscribed products.

We have enclosed an article from FDA Consumer magazine, "The New Food Label: Better Information for Special Diets," that may be of interest to Sister Rose Bernard. We trust this information responds to your concerns. If we may be of any further assistance, please contact us again.

Sincerely,


Melinda K. Plaisier
Associate Commissioner
for Legislation

3 Enclosures
Constituent's correspondence

cc: Dockets Management Branch (#99P-2148/CP)

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MICHAEL R. McNULTY
CONGRESS OF THE UNITED STATES
21ST DISTRICT, NEW YORK

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September 8, 1998

Diane Thompson
Associate Commissioner for Legislative Affairs
Food and Drug Administration
U.S. Department of Health and Human Services
Parklawn Building
5600 Fishers Lane, Room 15-55
Rockville MD 20857

Dear Ms. Thompson:

The attached correspondence from Sister Rose Bernard, is sent for your review.

I would appreciate it if you would investigate the enclosed statements and forward me the necessary information for reply.

Please send your reply to my Albany Office, Leo O'Brien Federal Building, Albany, New York 12207.

Thank you for your consideration in this matter.

Sincerely,

A handwritten signature in cursive script that reads "Michael R. McNulty".

MICHAEL R. MC NULTY
Member of Congress

MRM/bjf
Enclosure

St. Joseph's Provincial House
Watervliet-Shaker Road
Latham, NY 12110-4799

Congressman Michael McNulty
Leo O'Brien Federal Building
Albany, New York 12207

Dear Congressman McNulty:

Since I know of your concern for the various problems of your constituency, I am asking whether you are aware of a serious omission involving truth in advertising as it affects food. Failure to list certain ingredients in a product poses a major health hazard, even a danger for those with certain allergies. My particular problem, caused by an allergy to gluten (found in most grains except rice and corn) is celiac disease.

Because this is a disease found chiefly among European countries and among immigrants coming from Europe, with Ireland and Italy having a high percentage of victims, it is strange that, until recent years, doctors did not realize that the allergy came with the settlers. Undoubtedly, celiac disease caused undiagnosed deaths. Until well into this century, doctors, knowing of the disease only as caused by a parasite in the tropics, were told that it was not a concern in the temperate zones.

In 1965, the disease struck me. Dr. Maguire, my physician and an excellent diagnostician, knew the problem was malabsorption but he could not figure the cause. He did ask me whether I had ever been in the tropics by inquiring how far south I had been. Washington, D.C. was not far enough to explain my problem. Dr. Maguire then called in outstanding doctors in the area but they were also baffled by my great loss of weight and serious illness.

The doctor asked a newly qualified physician with a more recent background in gastroenterology, then waiting to be called for military service. Dr. Puleo immediately diagnosed celiac disease caused by an allergy to gluten. He put me on a diet which began working slowly but immediately; there was then no need for extra testing. This diet required avoidance of all of the grains except rice and corn. The list of ingredients in the food had to be the guide to follow.

My good fortune ended in February 1999 necessitating my return to Dr. Puleo. Because I had been faithful to the diet, we did not consider this the problem. This meant that Dr. Puleo had to start intensive testing which required more time but got no specific results. It came back to gluten still as the cause. Apparently some manufacturers of food products, though omitting wheat and other grain flours from the list of ingredients, were using them to extend shelf life or to dilute a more expensive item (chocolate, for example). Only if the list of ingredients mentioned flour, could it be trusted.

Dr. Puleo's office told me to check the internet for "celiac disease". I am enclosing the article with its suggestions as well as an essay which Stewart's kindly sent. These are helpful in

general but, without accuracy in listing ingredients in food, there is still a great difficulty necessitating constant calling of companies to inquire about gluten in their products.

I am now eating only what I am sure of but, since this entails calling the companies for specific information, what I can eat is quite restricted. Our concession is helping also in finding out about their own products; their soup stock, for example, has a flour base. There are various other examples, some quite surprising. Would you expect to find flour in ice cream, in candy, in cereals with malt flavoring when otherwise they are all right? Rice Krispies are spoiled by just the flavoring of malt.

This is a rather long statement of a problem which probably only Congress can fix but I have tried to make clear that, when the patient's sole guide to what it allowed is a list of ingredients, it is crucial to have it accurate. There is no way that every celiac patient, including the mother of a child with the disease, can spend the time calling the makers of given products to ascertain the safety of the products for celiac patients.

Many victims of celiac disease and I shall be very grateful if you can solve this problem by legislation before other lives are lost.

Thank you very much for your time and attention.

Sincerely yours,

A handwritten signature in cursive script that reads "Sister Rose Bernard". The signature is written in dark ink and is positioned below the typed name.

Sister Rose Bernard