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Chapel Hill, North Carolina 27514
June 18,2001

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Docket Management Branch, HFA-305
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 00P—1322

Dear Sirs:

Having come through the "Dark Ages" of indefinite labeling for the last three decades as a multiple food allergic family, it is heartening to witness the dawn of a new era – an era of enlightenment, acknowledgment, and recognition of the plight of the food-restricted consumer, whether they be food allergic, food sensitive, diabetic, lactose intolerant, etc. Definitive and "consumer-friendly" ingredient labeling is a necessity.

As founder and president of the Asthma and Allergy Foundation of America's Central New Jersey Chapter (the first in the state) in 1971, I initially expressed the concerns and needs of the food-sensitive population to then FDA Commissioner Charles Edwards. Subsequent letters of comment followed in 1978 to Congressman Paul Rogers, Chairman of the Subcommittee on Health and the Environment, followed by a meeting with his legislative aide in Palm Beach to discuss such issues; in 1979 to Congressman Bill Smith, in 1986 to the Ad Hoc Advisory Committee on Hypersensitivity to Food Constituents; and in 1989 to FDA Commissioner Frank E. Young. In 1991 I again voiced my comments and concerns regarding Docket Nos. 91N-0219 and 90N-0361. Additionally, I served as an FDA resource person both in Washington and Florida during those years. In this regard, my comments were quoted and recorded in the Federal Register of June 21, 1991. As you can see, I have maintained a complete file over the years awaiting resolution of this very serious issue.

Repeating what I have voiced these many years, maintaining a nutritionally sound diet regimen can be tedious even under the best of circumstances but when faced with a medical problem, it can become a very difficult and apprehensive situation further hampered by insufficient labeling information. The situation has intensified today with the multiplicity of new ingredients found in processed foods. Food-restricted consumers face a challenge with each excursion down the grocery aisle searching for acceptable foods for their condition.

Therefore, I heartily endorse the directives presented in Representative Nita Lowey's Food Allergen Consumer Protection Act, the NFPA's recent Code of Practice for managing food allergens, and the Food Allergy Issues Alliance guidelines that were presented to the FDA and the USDA.

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There can be no question as to the benefits of such new and improved legislation. Adverse reactions which can sometimes be life-threatening will be reduced and improved dietary regimens will be possible. What a powerful tool rests in your decisions.

The FDA has come a long way since 1970 and I commend each new step taken, but there is more than can and must be done. It is imperative that you continue your pursuit of the needs of allergic consumers and all those who are required to adhere to medically-restricted diets. I repeat what I said in 1989 to Commissioner Young: "Most assuredly the health benefits from revised food labeling will more than justify the economic costs of this action and food manufacturers will definitely notice an increase in sales if consumers are assured that their purchases meet their needs." A case in point is the "Cheerios" battle to remove Yellow #5 from this product which I started in the 1970s as a massive write-in to General Mills. This intense consumer action resulted in removal of the color and the product was then declared the #1 cold cereal nationally by nutritionists. General Mills loudly pro-claimed "NO ARTIFICIAL COLOR" in their advertising materials and reaped the financial results of such tenacious activity. It is indifference that will cost companies lost dollars.

Thank you for allowing me to again voice my comments. It has been a long and difficult road but there has been progress and it must be continued.

Sincerely,

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