**Consumer Federation of America**

**Howard M. Metzenbaum**
U S Senator (Ret )
*Chairman*

December 27, 2002

The Honorable Mark McClellan
Commissioner of Food and Drugs
U.S. Food and Drug Administration
14-17 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner McClellan:

I was the lead Senate sponsor of the Nutrition Labeling and Education Act. Few pieces of legislation I was associated with have had as broad or beneficial an impact as this one.

Since my retirement in 1996, I have chaired the Consumer Federation of America.[1] News accounts of your recent decision to allow "qualified" health claims on food products caught my attention. I must say I'm convinced this is bad news for consumers. Hailed as "leveling the playing field" by industry, this change will lower the bar for making food health claims and send the food industry down the path of confusing and misleading claims that has characterized dietary supplements in recent years.

It was a proliferation of misleading or unreliable disease-related claims on foods that led to enactment of the Nutrition Labeling and Education Act in 1990. NLEA set strict rules for health claims on foods and dietary supplements alike. Over the years, additional legislation and industry legal challenges have eroded the requirements for health claims on supplements. Now, the Food and Drug Administration's December 18 announcement threatens to do the same for foods.

Until now, qualified claims have been permitted for supplements only. They can be approved if the scientific evidence supporting the claim merely outweighs the evidence in opposition. Food products, on the other hand, have had to meet the more stringent "significant scientific agreement" standard, which requires more of a consensus among the experts.

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[1] Consumer Federation of America is an association of approximately 300 pro-consumer groups organized in 1968 to advance the consumer interest through advocacy and education CFA's positions are determined by its members, who vote on them in annual meetings, and by its elected board of directors

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FDA promises to accompany its loosening of the rules for food health claims with a vigorous approval process and stepped up enforcement once products enter the marketplace. But there are substantial questions whether your perennially underfunded agency has the staff and resources to accomplish either of these.

Whether it is food or supplements, consumers deserve health claims they can trust, supported by general scientific agreement. It serves no one's interest to fill grocery store shelves with products making health claims that could disappear with the next published study. This will only further confuse consumers and erode confidence in food labels.

I urge you to rethink your decision. If current laws are not adequate to require significant scientific agreement for health claims, I suggest you propose legislation to amend NLEA to provide this protection for consumers. I would be pleased to work with you on a legislative solution if one is necessary.

Sincerely,

Howard M. Metzenbaum
United States Senate (Ret.)

cc: Dockets Management Branch