



GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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March 27, 2000

Jeanne Latham
Center for Food Safety and Applied Nutrition
Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

**Re: Scope of April 4, 2000 Public Meeting Agenda - - Request
to Broaden Agenda to Foods; Announcement of Public
Meeting; Docket No. 00N-0598**

Dear Ms. Latham:

In reference to the Food and Drug Administration's March 16, 2000 Notice, the Grocery Manufacturers of America (GMA) respectfully requests that the agenda for the April 4 public meeting be expanded to formally include consideration of traditional foods. GMA commends the agency for providing a public forum to address how the *Pearson* decision will be implemented and to consider whether to permit health claims about an effect on an existing disease. GMA is the world's largest association of food, beverage, and consumer brand companies. The subject of the public meeting has a direct bearing on GMA member companies and the food industry as a whole.

To ensure a fair, balanced and efficient policy development process, it is incumbent upon FDA to consider directly conventional foods along with dietary supplements. Indeed, the Notice acknowledges that the treatment of health claims with respect to dietary supplements is directly relevant to conventional foods.

The agency's apparent intent to consider these issues solely in the context of dietary supplements is ill-conceived. FDA misses a valuable opportunity to use its resources efficiently by considering a single set of issues once in connection with both dietary supplements and conventional foods. This concurrent approach also facilitates timely development of policies. Ultimately, these policies will be applied to conventional foods. It is, therefore, rational and prudent to directly consider conventional foods when such policies are developed.

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We also object to FDA's determination that it will not consider foods in connection with its implementation of *Pearson* due to purported limits on its statutory authority and because *Pearson* only involved dietary supplements. This viewpoint is incorrect as a matter of law, and represents unsound public policy. FDA's continued preference to read the First Amendment protections narrowly to the facts of the *Pearson* case is short-sighted. FDA should not postpone consideration of these important issues in the context of conventional foods until ordered to do so by a Federal court.

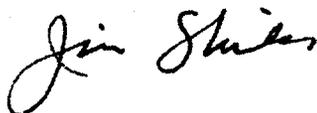
Accordingly, GMA requests that a supplemental Notice be issued whereby the agency clarifies that the questions raised for public input should be considered in the context of both dietary supplements and conventional foods. Moreover, FDA should further request comment on the legal analysis included in its Notice.

Thank you for your consideration of GMA's request. We would be pleased to meet with agency officials to discuss further the concerns set forth in this letter.

Sincerely,



Stacey A. Zawel, Ph.D.
Vice President, Scientific and Regulatory Policy



James H. Skiles
Vice President and General Counsel

cc: Margaret M. Dotzel
Joseph A. Levitt, CFSAN
Janet Woodcock, CDER