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July 6, 1999

To: Dockets Management Branch
Email: FDA_Dockets@bangate.fda.gov

From: Produce Marketing Association
PO Box 6036
Newark, DE 19714-6036

Re: Docket No. 99N-1174
Dietary Supplements: Center for Food Safety and
Applied Nutrition Strategy
Comments from the Produce Marketing Association

The Produce Marketing Association is pleased to submit this information in response to FDA's request for comments on effective regulation of dietary supplements.

PMA is the largest worldwide not-for-profit trade association representing companies that market fresh fruits and vegetables. Our membership of more than 2,500 ranges from supermarket retailers to grower-shippers, and from hotel and restaurant chains to overseas importers.

Within the United States, PMA's members handle more than 90% of fresh produce sold at consumer level. The association's mission is to create a favorable, responsible environment that advances the marketing of produce and floral products and services for North American buyers and sellers and their international partners.

The Produce Marketing Association is deeply concerned about the regulation of dietary supplements. We believe a level playing field for health claims on food and dietary supplements must be maintained.

In these comments, PMA does not intend to address every issue identified in the request for comments. Rather we specifically turn to the issue of claims.

Health Claims

Congress passed the Nutrition Labeling and Education Act (NLEA) to provide consumers with nutrition information and to regulate various claims made on the labels of food and dietary supplements. Under the NLEA, health claims, which assert a relationship between a food or

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nutrient and a chronic disease condition, must be determined by FDA to be supported by "significant scientific agreement."

As the NLEA originally intended, supplements must meet the same strict standards for health claims as those that exist for foods. We urge the FDA to maintain that parity. At a time when all health and government authorities are urging consumers to eat more fruits and vegetables for better health, it would be a real disservice to Americans to put such healthful products at a competitive disadvantage by any action taken vis a vis dietary supplements.

Any action that potentially undermines consumer confidence in labeling and provides dietary supplements with a competitive advantage over fruits and vegetables and other foods would inevitably damage the integrity of health claims and product safety. Further, any actions should impose equal treatment in all respects for health claims on supplements and on foods.

We discourage any action on FDA's part that will give the public the idea that they can take pills, eat a high-fat, fiberless diet, and still maintain their health. There is no substitute for a low-fat, high-fiber diet with plenty of fruits, vegetables, and whole grains. Vitamin supplements do not provide the same health benefits as eating a variety of fruits and vegetables [NIH Publication No. 92-3248]. Nutrient overdoses from foods are far less common than nutrient overdoses from supplements. Will supplements have to carry claims stating that large doses may inhibit the absorption of other nutrients? Or that large doses may have drug-like effects?

Because there are other components in fruits and vegetables besides antioxidant nutrients that may promote good health and reduce the risk of many diseases (dithiolthiones, glucosinolates and indoles, isothiocyanates and thiocyanates, coumarins, phenols, saponins, allium compounds, carotenoids other than b-carotene like lycopene, etc.), we support health claims for foods, as opposed to nutrients.

We recognize the role of dietary supplement products and support consumer access to them in the market, but strongly encourage consistent regulatory standards that enable U.S. consumers to have reason to trust health claims, whether the product is a food or dietary supplement.

Overall Dietary Supplement Strategy

In the Dietary Guidelines for Americans, the federal government puts its emphasis on diets based on whole foods, not supplements. PMA urges FDA to maintain that emphasis in a consistent and positive way in all of its dietary guidance, including guidance about supplements.

The bottom line is that, for healthy consumers, a diet based on fruits, vegetables, and whole grains is the best approach to healthful eating and nutrition. As Americans strive to meet and beat the 5 A Day goal for fruit and vegetable consumption, PMA urges FDA to use every prudent caution against allowing claims or information for dietary supplements that would confuse consumers or lead them to choose supplements over fresh produce.

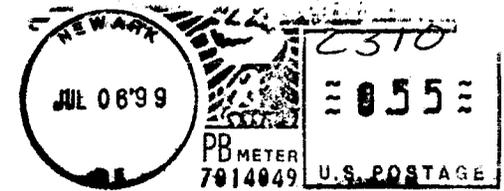
Thank you for this opportunity to submit comments. Please call on PMA at any time we can be of assistance on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Bryan Silberman", with a horizontal line underneath.

Bryan Silberman, CAE
President

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