July 8, 2003

Dockets Management Branch (FDA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements (Docket No. 02D-0515)

We, the undersigned organizations, wish to respond to a request for comments on the Food and Drug Administration's (FDA) *Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements* (67 Fed. Reg. 78002 (Dec. 20, 2002)). As discussed below, we believe that the Initiative is (1) contrary to law; (2) modeled on an inappropriate regulatory approach used by the Federal Trade Commission (FTC); and (3) likely to confuse and mislead consumers.

I. The Policy Embodied in the Guidance is Contrary to the Law

The FDA's Guidance document indicates that the FDA will bypass the notice and comment rulemaking procedures required by the Nutritional Labeling and Education Act (NLEA) for so-called qualified health claims, i.e., those claims not supported by significant scientific agreement. The FDA will instead exercise its enforcement discretion by informing the petitioner by letter that a qualified health claim may be used so long as it is accompanied by disclaimers indicating that the scientific evidence is inconclusive or preliminary. This approach takes qualified health claims outside the Congressionally mandated authorization process and permits such claims to be made before the Agency has received public comment. Such an approach is contrary to the plain requirements of the law.

II. The FDA's Desire to Emulate the Federal Trade Commission is Inappropriate

The FDA has felt compelled in this proceeding to emulate the policies of the FTC by adopting that Agency's standard for determining whether a health claim is misleading. However, apart from one action last year, the FTC has not obtained a single cease and desist order against a food advertiser for making false and misleading health claims since it issued its Enforcement Policy Statement (EPS) on Food Advertising in 1994 – more than eight years ago! We thus question the FTC's commitment to consumer protection in this area and are dismayed that the FDA would want to follow that Agency's policies.

The FDA's deference to, and reliance on, FTC policy is also improper because of the significant difference in each of the Agencies' missions. The FDA has a broader mandate than the FTC. In addition to preventing false and misleading claims, the NLEA requires the FDA to educate consumers to help them maintain healthy dietary practices. The FDA's current document, which allows food companies to make health claims based on preliminary scientific evidence, however, does not help educate the public. Providing consumers with claims based on

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preliminary scientific evidence that may not bear the test of time simply leaves consumers in a quandary. Instead of taking a "buyer beware" approach, the FDA should be using its scientific expertise to educate consumers about truly valid claims that consumers confidently can depend on to improve their health.

III. Disclaimers will Confuse Consumers

The FDA's Guidance document relies on the use of disclaimers to warn consumers that a health claim is based on preliminary scientific evidence. Yet disclaimers may not be helpful in informing consumers about the uncertainty of the science supporting a claim. In an era of information overload, consumers may not even read the disclaimer or may simply skim it without understanding its significance. For example, a survey commissioned by AARP on dietary supplement use and knowledge among older consumers concluded that the disclaimer required by the Dietary Supplement Health and Education Act on dietary supplements may not function as intended. Most of the respondents in the study indicated that they had either never seen the disclaimer or did not know if they had ever seen it (59 percent).[1]

IV. Conclusion

For the forgoing reasons, we urge the FDA to rescind its Guidance document and to approve only those health claims for foods that are supported by significant scientific agreement as established through notice and comment rulemaking.

Sincerely,

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1 AARP Public Policy Institute, *Dietary Supplements and Older Consumers Data* Digest 66 (Dec. 2001).