

American Frozen Food Institute • 2000 Corporate Ridge, Suite 1000 • McLean, Virginia 22102
Telephone (703) 821-0770 • Fax (703) 821-1350 • E-Mail info@affi.com
<http://www.affi.com> • <http://www.HealthyFood.org>

August 5, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

**RE: Request for Comments on First Amendment Issues; Notice; 67FR
34942 (May 16, 2002).**

The American Frozen Food Institute (AFFI or the Institute) is the national trade association representing frozen food processors, suppliers and marketers. AFFI's more than 540 member companies account for over 90 percent of the frozen food production in the United States, valued at approximately \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationwide.

AFFI supports FDA's efforts to ensure that all agency regulations, guidance, policies, and practices comply with applicable First Amendment requirements, including those set forth in the recent Supreme Court decision, *Thompson v. Western States Medical Center*.¹ FDA's decision to seek public input is an important first step in this process.

AFFI concurs that public interest in useful and truthful health-related information has skyrocketed in recent years. In AFFI's experience, consumers desire credible information regarding food attributes and the relationship between food and health. AFFI has long been a proponent of using the food label to convey truthful and nonmisleading information regarding product attributes and health benefits.

FDA specifically requested comment as to whether the agency may distinguish between conventional food and dietary supplements for First Amendment purposes. AFFI submits that the public interest and need for information regarding food and health exist regardless of whether a product is a conventional food or a dietary supplement. Continual advances in nutritional science have demonstrated that substances in everyday foods can and do have a positive impact on health when consumed as part of a balanced diet. Speech regarding the healthful benefits of food should be permitted so long as it is truthful and not misleading.

¹ 535 U.S. ___, No. 01-344 (April 29, 2002)

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A policy that permits appropriate distribution of health and diet information also provides strong incentives for industry to offer an even greater array of healthful products. There is little incentive to commit resources to development and production of new or reformulated products if product benefits cannot be communicated freely.

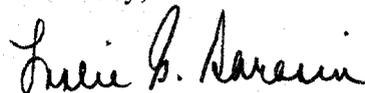
The FTC has been successful in striking a balance between access to information and protecting consumers from deceptive advertising claims. FDA is urged to critically evaluate and borrow from the FTC's substantiation standard as an effective means of meeting its First Amendment obligations.

AFFI recognizes that the Federal Food, Drug, and Cosmetic Act (FFDCA) differs in many respects from the legal authorities under which the FTC operates, and that classification of products under the FFDCA is determined largely by intended use as reflected in promotional and other materials. AFFI believes, however, that the FFDCA is sufficiently flexible to permit the agency to remain true to the legal boundaries between product categories (e.g., "drug" versus "food") while permitting the communication of product benefits to consumers.

In conclusion, AFFI believes the food label is an excellent medium to convey to consumers truthful and nonmisleading information regarding product attributes and health benefits. The Institute supports efforts to ensure that all agency regulations, guidance, policies, and practices comply with applicable First Amendment requirements, and that the public interest and need for information regarding food and health exists regardless of whether a product is a conventional food or a dietary supplement. We urge the agency to consider all non-speech alternatives prior to taking any action that restricts the free flow of commercial information. Finally, FDA is urged to regulate food labeling, including health claims, nutrient content claims, and structure/function claims, among other labeling information, in a manner that promotes public access to and understanding of important developments and trends in nutrition and food science.

AFFI would welcome the opportunity to discuss this issue further with the agency.

Sincerely,



Leslie G. Sarasin, CAE
President and
Chief Executive Officer

The Supreme Court in *Thompson v. Western States Medical Center* reaffirmed that the free flow of commercial information is “indispensable” to intelligent and well-informed consumer decisions. AFFI understands *Western States Medical Center* to require the consideration of all non-speech measures that may advance a government interest prior to the adoption of measures that restrict speech (i.e., the use of speech restrictions as a “last resort”). FDA is urged, as a matter of routine policy in any rulemaking or administrative action involving the potential regulation of speech, to consider all non-speech alternatives prior to taking any action that restricts the free flow of commercial information. With specific regard to the regulation of food labels, FDA is urged to consider the adequacy of information already required to be provided on food labels, including nutrition information, ingredient information, and the like, prior to contemplating new restrictions on speech.

In those circumstances in which FDA determines that speech must be regulated to advance a substantial government interest, AFFI understands the First Amendment to require the agency to do so in the least restrictive manner that will achieve the pertinent government interest. Useful guidance is provided by *Pearson v. Shalala*,² which confirmed that the First Amendment does not allow the prohibition of commercial speech such as health claims if that speech can be presented in a truthful and nonmisleading manner (e.g., through the use of an appropriate disclaimer to clarify the scope of a claim). This important principle has equal application to dietary supplements and conventional foods, and FDA is urged to ensure consistent regulatory treatment of these product categories.

AFFI believes food labeling is an important medium for conveying health-related information to consumers. FDA is urged to regulate food labeling, including health claims, nutrient content claims, and structure/function claims, among other labeling information, in a manner that promotes public access to and understanding of important developments and trends in nutrition and food science. By promoting the free flow of information, FDA avoids paternalism and ensures that consumers are not “kept in the dark for what the government perceives to be their own good.”³

There is impressive evidence to suggest that such an approach may confer substantial public health benefits. In studies conducted by the Federal Trade Commission’s (FTC) Bureau of Economics, researchers examined the impact of certain health-related advertising campaigns on consumer knowledge and dietary behaviors. The FTC found advertising messages complement and, in certain circumstances, surpass other sources of information. The researchers also found the advertising examined to result in measurable positive effects on dietary patterns.⁴ The FTC studies offer remarkable insight into the public policy consequences of government regulation of speech.

² 164 F.3d 650 (D.C. Cir. 1999)

³ 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996).

⁴ FTC, *Health Claims in Advertising and Labeling, A Study of the Cereal Market* (Aug. 1989); FTC, Bureau of Econ. Staff Report, *Information and Advertising Policy, a Study of Fat and Cholesterol Consumption in the United States* (Sept. 1996)