

THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1687 5 NOV 18 PM 35

Assessing Consumer Perceptions)
of Health Claims; Public Meeting;)
Request for Comments)
_____)

Docket No. 2005N-0413

Comments of

AMERICAN COLLEGE OF PREVENTIVE MEDICINE
AMERICAN DIETETIC ASSOCIATION
AARP
CAMPAIGN FOR TOBACCO-FREE KIDS
CENTER FOR SCIENCE IN THE PUBLIC INTEREST
NATIONAL CONSUMERS LEAGUE

November 17, 2005

2005N-0413

C2

November 17, 2005

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland

**Re: Assessing Consumer Perceptions of Health Claims; Public Meeting;
Request for Comments (Docket No. 2005N-0413)**

We, the undersigned organizations, wish to respond to the request for comments related to the Food and Drug Administration's (FDA) public meeting on "Assessing Consumer Perceptions of Health Claims." 70 Fed. Reg. 60749 (October 19, 2005). As discussed below, the results of consumer research conducted by both the FDA and the International Food Information Council (IFIC) indicate that disclaimers do not cure the deception created by claims based on emerging science. Given the inadequacy of the disclaimers, FDA should rescind its prior authorizations of qualified health claims and refrain from further authorizations.

The food industry has argued that FDA must allow health claims with disclaimers, citing the U.S. Court of Appeals decision in *Pearson v. Shalala*. However, the court stated that under the First Amendment, FDA could prohibit claims if it had "empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness." In any event, no court has ever held that *Pearson* applies to health claims on food, and the Supreme Court has not yet decided this important issue.

FDA now has its own evidence, as well as corroborating evidence from IFIC, which is funded by the food industry, that demonstrates that disclaimers do not cure the deception created by preliminary health claims. Thus, the FDA should no longer authorize qualified health claims.

In passing the Nutrition Labeling and Education Act (NLEA), Congress was well aware of First Amendment concerns. Based on extensive hearings on abuses in food labeling, Congress concluded that unless claims met the "significant scientific agreement" standard, consumers would be misled. FDA's own research underscores the appropriateness of Congress' approach to regulating health claims. Therefore, the FDA should: (1) rescind its approval of all qualified health claims and (2) impose a moratorium on the approval of additional qualified health claims that do not meet the standards of the NLEA.

Respectfully submitted,



Bruce Silverglade
Center for Science in the Public Interest

On behalf of:

Larry White
AARP

William V. Corr
Campaign for Tobacco-Free Kids

Paul Bonta
American College of Preventive
Medicine

Irene Ringel Heller
Center for Science in the Public Interest

Stephanie Patrick
American Dietetic Association

Linda Golodner
National Consumers League