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

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
ASSOCIATION OF AMERICAN MEDICAL COLLEGES
CAMPAIGN FOR TOBACCO-FREE KIDS
CENTER FOR SCIENCE IN THE PUBLIC INTEREST
CONSUMER FEDERATION OF AMERICA
NATIONAL CONSUMERS LEAGUE

January 17, 2006

2005N-0413

C7

January 17, 2006

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)

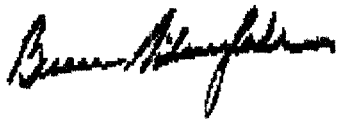
We, the undersigned organizations, wish to respond to the request for comments related to the Food and Drug Administration's (FDA) public meeting on "Assessing Consumer Perceptions of Health Claims." 70 Fed. Reg. 60749 (October 19, 2005). As discussed below, the results of consumer research conducted 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, let alone the Supreme Court, has ever held that *Pearson* applies to health claims on food.

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) stop approving any qualified health claims that do not meet the standards of the NLEA.

Respectfully submitted,



Center for Science in the Public Interest

On behalf of:

David Korn
Association of American Medical Colleges

Linda Golodner
National Consumers League

David Certner
AARP

William V. Corr
Campaign for Tobacco-Free Kids

Paul Bonta
American College of Preventive Medicine

Ilene Ringel Heller
Center for Science in the Public Interest

Stephanie Patrick
American Dietetic Association

Carole Tucker Foreman
Consumer Federation of America

Date: 1/17/06

Please deliver the following pages to:

Name: Dockets Management

Company: FDA

Fax number: 301-827-6870

Phone number: 301-827-6860

Total # of pages *including* this cover sheet: 4

Sender: Ilene Heller

(Should you not receive all pages as indicated, call the sender.)

Subject: Docket No. 2005N-0413

Comments:

Submission of comments for Docket No. 2005N-0413: Assessing Consumer Perceptions of Health Claims