



NATIONAL CONSUMERS LEAGUE

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November 27, 2006

BY ELECTRONIC MAIL

Division of Dockets Management – HFA 305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Conventional Foods Being Marketed as “Functional Foods;” Public Hearing; Requests for Comments Docket No. 2002P-0122

The National Consumers League (NCL) is a private, nonprofit advocacy group representing consumers on marketplace and workplace issues. We are the nation’s oldest consumer organization. NCL provides government, businesses, and other organizations with the consumer’s perspective on concerns including child labor, privacy, food safety, and healthcare, including medication information. Our mission is to protect and promote social and economic justice for consumers and workers in the United States and abroad.

NCL commends the Food and Drug Administration (FDA) for conducting a public hearing on the important regulatory issues raised by the market proliferation of “functional” foods. As an organization committed to improving product labeling and ensuring truth in advertising, we hope you will take the following actions to protect increasingly health/nutrition-motivated consumers.

We support the recommendations made by the General Accounting Office (GAO) in its 2000 report – “Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods” – and agree with the Center for Science in the Public Interest’s conclusions that the FDA can make the recommended improvements without additional Congressional authority. We recommend that the FDA:

- Require manufacturers to provide pre-market notification to the FDA of the use of novel ingredients;
- Require manufacturers to submit structure/function claims for foods with novel ingredients to the FDA prior to marketing;
- Promulgate regulations or issue industry guidance clearly establishing the nature and extent of scientific evidence needed to substantiate structure/function claims;

- Promulgate regulations or issue industry guidance on the safety-related information required on labels of foods with novel ingredients;
- Develop an enhanced system to record and analyze reports of health problems associated with novel ingredients.

In addition, we urge the FDA to dramatically increase its enforcement efforts against products containing unauthorized ingredients and/or making illegal claims. There are many adulterated and misbranded “functional” foods on supermarket shelves today. It is the FDA’s responsibility to let manufacturers know through well publicized enforcement actions that the Agency will not permit such marketing practices to continue.

NCL appreciates this opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda F. Golodner", written in a cursive style.

LINDA F. GOLODNER
President