Consumer Federation of America

Carol Tucker Foreman
Distinguished Fellow and
Director
The Food Policy Institute

April 26, 2004

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner (HF-1)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Nutrient Content Claims and Health Claims for Specific Omega-3 Fatty Acids

Dear Dr. Crawford:

The Consumer Federation of America (CFA) is a non-profit association of 300 consumer groups, with a combined membership of more than 50 million people. CFA was founded in 1968 to advance the consumers' interest through advocacy, research and education. The Food Policy Institute was created within CFA in 1999 to promote a safer, healthier, and more affordable food supply. We write to urge FDA to act promptly to facilitate consumer identification of foods that are significant sources of DHA and EPA and to do so in a legally sound manner.

Over the past few years, a number of expert scientific panels have commented on the health benefits of omega-3 (*n*-3) fatty acids.

- The Institute of Medicine (IOM) recently reported that "growing evidence suggests that dietary *n*-3 polyunsaturated fatty acids (eicosapentaenoic acid [EPA] and docosahexaenoic acid [DHA]) reduce the risk of coronary heart disease (CHD) and stroke."[1]

- The American Heart Association's (AHA) dietary guidelines recommend consuming fish, sources of DHA and EPA, twice weekly to reduce risk of CHD.

- The Office of Management and Budget in May 2003 urged the Department of Health and Human Services and the Department of Agriculture to revise the dietary guidelines for Americans to include new information about the health benefits of omega-3 fatty acids.

[1] IOM, *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*, 11-40 (Sept. 2002 pre-publication copy).

1424 16th Street, N.W., Suite 604 • Washington, D.C. 20036
Telephone (202) 387-6121 • Fax (202) 265-7989 • E-mail tuckfore@aol.com

- The Fatty Acids Subcommittee of the Dietary Guidelines Advisory Committee at its March 30-31, 2004 meeting proposed a statement recommending increased consumption of omega-3 fatty acid-rich fish (*i.e.*, containing EPA and DHA). Specifically, they recommended that individuals include 8-9 ounces (*i.e.*, about 2 servings, consistent with the AHA recommendation) of omega-3 rich fish per week in their diets. The Subcommittee also discussed the importance of establishing a nutrient intake recommendation (*e.g.*, Daily Value (DV)) to help consumers gauge nutrient intake from all sources.

It is important to note that there is increasing scientific evidence DHA and EPA, but not other omega-3 fatty acids, provide cardiovascular benefits. CFA believes it is important to have accurate information and favors prompt action by FDA to authorize nutrient content claims to facilitate consumer identification of foods that are significant sources of DHA and EPA. A nutrient content claim should characterize the levels of specific *n*-3 fatty acids, rather than all omega-3 fatty acids collectively or generically. CFA is aware that salmon purveyors have submitted a notification to FDA pursuant to procedures instituted by the FDA Modernization Act (FDAMA). FDAMA provides an expeditious and legally sound way of providing specific content claims for DHA and EPA that would serve the consumer interest.

CFA is also aware that FDA currently is reviewing petitions for qualified health claims about omega-3 fatty acids (*i.e.*, DHA and EPA) and risk of CHD. Consumer organizations have challenged the legality of FDA's new qualified health claims regulations. Guidance that cannot sustain a legal challenge is of no value to consumers. We urge FDA to act quickly to authorize nutrient content claims to facilitate consumer identification of foods that are significant sources of DHA and EPA. Since relying on flawed interpretations of the law will only delay getting important information to consumers, we urge the Agency to abandon consideration of the qualified health claims petitions. CFA urges FDA to authorize only health claims that are supported by "significant scientific agreement," whether pursuant to FDAMA notification or petitioning procedures.

Consumers need this information. The agency should act to make it available in the most effective fashion, authorizing nutrient content claims about DHA and EPA pursuant to the pending FDAMA notification, which is a procedure authorized by statute.

Respectfully submitted,

Carol Tucker Foreman

CC: Dr. Robert Bracket, Director, Center for Food Science and Applied Nutrition