



April 3, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No: 91N-0103
Food Labeling: Health Claims and Label Statements --
Omega-3 Fatty Acids (EPA and DHA) and Heart Disease

Dear Sir or Madame:

These comments are submitted on behalf of a joint task group of the Consumer Healthcare Products Association (CHPA)¹, Council for Responsible Nutrition (CRN)² and the National Fisheries Institute (NFI)³ on health claims for omega-3 fatty acids (EPA and DHA)⁴ in response to the Food and Drug Administration's request for scientific information and data in order to evaluate the evidence for the relationship between omega-3 fatty acids (EPA and DHA) and heart disease.⁵ The eight volumes submitted here replace those submitted on November 22, 1999 by these organizations during the FDA's first call for information on this topic. All information in the November 22, 1999 submission has been included in this submission along with additional data.

¹ CHPA is a 119 - year-old trade association of manufacturers of over-the-counter drugs and dietary supplements.

² CRN is a trade association representing approximately 100 companies in the dietary supplement industry.

³ The National Fisheries Institute is a non-profit trade association of over 800 companies involved in all aspects of the U.S. fish and seafood industry.

⁴ Here in referred to as THE JOINT TASK GROUP

⁵ September 8, 1999. *Federal Register* 64 (173): 48841-48842 and January 26, 2000 *Federal Register*. 65(17): 4252-4253.

C124

Actions Requested

THE JOINT TASK GROUP request that Food and Drug Administration (FDA) issue a proposed rule to authorize a health claim for the relationship between omega-3 fatty acids (EPA and DHA) and heart disease focusing on health benefits demonstrated in clinical trials.

1. THE JOINT TASK GROUP requests that FDA publish a notice of proposed rulemaking, both, (1) to authorize the use of a “health claim” in labeling of foods including conventional foods and dietary supplements, and, (2) to delete from the agency’s regulations the current text of 21 C.F.R. § 101.71(e), which now provides that “health claims” about “omega-3 fatty acids (EPA and DHA) and heart disease” are “not authorized.”
2. THE JOINT TASK GROUP asks FDA to consider whether the “health claim” for omega-3 fatty acids (EPA and DHA) under review should be authorized for all types of foods, including both conventional foods and dietary supplement products. If a qualified health claim is approved, the same First Amendment rights of speech apply to both foods in conventional form and dietary supplements.