



November 17, 2014

VIA ELECTRONIC SUBMISSION

Food and Drug Administration,
Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-800)
5100 Paint Branch Pkwy
College Park, MD 20740

RE: Authorized Health Claim Petition: Eicosapentaenoic and Docosahexaenoic Acids and Reduction of Blood Pressure in the General Population

CRN¹ is the leading trade association for the dietary supplement and nutritional products industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements, many of which include long-chain polyunsaturated omega 3 fatty acid(s) (Eicosapentaenoic Acid (EPA), Docosahexaenoic Acid (DHA), and/or marine and/or plant based oils such as fish oil, krill oil, flax seed oil, etc.). The CRN members are responsible companies that sell high quality and efficacious products, and they rely on the most current and substantiated research on health and nutrition for their ingredients and products, including the information and conclusion in the petition submitted by the Global Organization

¹ The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

for EPA and DHA Omega-3s (GOED)² on an authorized health claim for EPA and DHA (EPA+DHA) and the reduction of blood pressure in the general population³.

A health claim characterizes the relationship between a substance and a disease or health-related condition. Such a claim explains that a food or food component may reduce the risk of a disease or a health-related condition and must contain the elements of (1) a substance and (2) a disease or health-related condition. Further, health claims are limited to claims about disease risk reduction, and cannot be claims about the diagnosis, cure, mitigation, or treatment of disease. Importantly, health claims provide an excellent opportunity to increase consumer awareness of diet and disease relationships, and so direct thoughtful and public health responsive choices. Approval of health claim language regarding EPA+DHA and blood pressure reduction would help policy-makers, healthcare professionals, educators, and consumers recognize the benefit of these nutrients and subsequently reduce U.S. morbidity and mortality from coronary heart disease (CHD) and stroke.

The public health burden of high blood pressure is extensive. Thirty-one percent of Americans are hypertensive, 30 percent are considered pre-hypertensive, and approximately 20 percent are hypertensive yet unaware of their status (“silent”).^{4,5} Of those with hypertension, the blood pressure of only 47 percent is adequately controlled.⁴ Prior research shows that diet and lifestyle modifications, including physical activity, sodium reduction, and fish oil supplementation, can reduce blood pressure and decrease cardiovascular disease (CVD) risk.⁶

The relationship between hypertension and CVD, the leading cause of death in the U.S., is well-documented and supported by multiple lines of biological evidence. As small as a 2

² GOED is an association of the world’s finest processors, refiners, manufacturers, distributors, marketers, retailers and supporters of products containing EPA and DHA omega-3 fatty acids. The organization's objectives are to promote and protect the category, educate consumers about the health benefits of EPA/DHA, and work with government groups, the healthcare community and the industry, while setting high standards for its business sector. GOED and its members are committed to personal integrity, ethical corporate behavior, public safety and quality assurance.

³ GOED to FDA, ONPLDS (HFS-800) dated April 21, 2014; Additional Information---Authorized Health Claim Petition: Eicosapentaenoic and Docosahexaenoic Acids and Reduction of Blood Pressure in the General Population. www.regulations.gov/#!docketDetail;D=FDA-2014-Q-1146.

⁴ Centers for Disease Control and Prevention. Vital signs: prevalence, treatment, and control of hypertension--United States, 1999-2002 and 2005-2008. *MMWR*. 2011;60:103-108.

⁵ Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics--2012 update: a report from the American Heart Association. *Circulation*. 2012;125:e2-e220.

⁶ Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA*. 2003;289:2560-2572.

mmHg reduction in blood pressure may reduce death from stroke, CHD, and total mortality by 6%, 4%, and 3%, respectively.⁷

GOED’s petition supports a role for EPA+DHA in blood pressure reduction using a comprehensive meta-analysis of randomized clinical trials (RCTs) and systematically reviews the observational epidemiologic literature on EPA+DHA (“O-3 rich intake”) and blood pressure. The following table provides the high level results of the meta-analysis. Additional results are included in the GOED petition, as well as the published meta-analysis which is freely available (link in footnote).⁸

Status	SBP⁹ Reduction (mm Hg)	DBP¹⁰ Reduction (mm Hg)
O-3 rich intake in subjects with High BP	4.51	3.05
O-3 rich intake in subjects with Normal BP	1.25	0.62
O-3 rich intake in all subjects	1.52	0.99

The findings are even more dramatic when compared with reductions achieved through commonly recommended lifestyle changes, as indicated in the chart below.

Lifestyle Intervention	SBP⁹ Reduction* (mm Hg)
Consuming EPA and DHA omega-3s	4.56 ⁸
Reduced dietary sodium	3.67 ¹¹
Increased physical activity	4.67 ¹¹
Decreased alcohol consumption	3.87 ¹¹

Conclusion

⁷ Stamler R. Implications of the INTERSALT study. *Hypertension*. 1991;17:116-20.

⁸ Miller PE, Van Elswyk M, Alexander DD. Long-chain omega-3 fatty acids eicosapentaenoic acid and docosahexaenoic acid and blood pressure: a meta-analysis of randomized controlled trials. *Am J Hypertens*. 2014;27:885-96. <http://ajh.oxfordjournals.org/content/early/2014/03/06/ajh.hpu024.full.pdf+html>

⁹ Systolic blood pressure.

¹⁰ Diastolic blood pressure.

¹¹ Dickinson HO, Mason JM, Nicolson DJ, et al. Lifestyle interventions to reduce raised blood pressure: a systematic review of randomized controlled trials. *J Hypertens*. 2006;24:215-233.

CRN agrees with the statement that appears in the final report and recommendations of the Food and Drug Administration's (FDA) "Task Force on Consumer Health Information for Better Nutrition"¹² which echoes the best available science put forth by GOED in their "Authorized Health Claim Petition for Eicosapentaenoic and Docosahexaenoic Acids and Reduction of Blood Pressure in the General Population:

"We believe that the work of this Task Force provides a credible and effective framework ***for the agency and the food and dietary supplement industry to begin to use immediately, to provide more and better information to consumers about the health and nutritional benefits of their products*** [emphasis added]. The Task Force believes that ***significant public health benefits will result when consumers have access to, and use, more and better information to aid them in their purchases, information that goes beyond just price, convenience, and taste, but extends to include science-based health factors*** [emphasis added]. Armed with more scientifically based information about the likely health benefits of the foods and dietary supplements they purchase, ***consumers can make a tangible difference in their own long-term health by lowering their risk of numerous chronic diseases*** [emphasis added]. With millions of citizens making use of such information for their own health benefit, a great deal will be gained when this type of information is provided in food labeling."¹³

Respectfully submitted,



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¹² The Task Force was announced on January 16, 2003, as part of the Consumer Health Information for Better Nutrition Initiative, and included representatives from FDA, the Federal Trade Commission and the National Institutes of Health.

¹³ Consumer Health Information for Better Nutrition Initiative: Task Force Final Report
<http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm096010.htm>