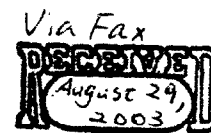


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August 29, 2003

**VIA FACSIMILE**  
**AND OVERNIGHT MAIL**

Dr. Tomoko Shimakawa

FDA

Office of Nutritional Products, Labeling and Dietary Supplements

HFS-830

5100 Paint Branch Parkway

College Park, MD 20740

***Re: June 23, 2003 Petition for Amended Health Claim: Omega-3 Fatty Acids and Coronary Heart Disease***

Dear Dr. Shimakawa:

This letter follows our meeting of July 25, 2003 with the ONPLDS staff and supplies the staff with the additional information on omega-3 fatty acids safety requested at that time. In the ONPLDS staff meeting we were asked to address three points: (1) the position of NHLBI on omega-3s as reported in the National Cholesterol Education Program report; (2) bleeding tendencies associated with omega-3 supplementation; and (3) evidence of the safe upper limit and optimum range for omega-3 supplementation. Dr. William Connor, author of the scientific report accompanying the above referenced petition, addresses those points in his attached letter. The following summarizes his conclusion:

- The NHLBI report is dated. In particular 15 peer-reviewed studies have been published since the NHLIB report was completed (Ref. 2-16). NHLIB's statement that more definitive clinical trials are required is satisfied by those fifteen studies.
- While there is a mild anti-thrombotic action of omega-3 fatty acids, there is no evidence that amounts of EPA plus DHA per day (1 gram) recommended for coronary heart disease prevention give rise to bleeding or other significant side effects. (Ref. 18-21). There is widespread agreement that bleeding is not a problem as a result of consuming the amounts of fish or fish oil needed to prevent cardiac arrhythmias and sudden death.

2003 Q-0401

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- The optimum range for EPA plus DHA in fish and fish oil supplements is one gram per day. (Ref. 2-16, 21). That relatively low amount of omega-3 fatty acids can be safely consumed without danger of any bleeding or other side effects and is only one-third of the upper limit specified by FDA as safe. No additional benefit for prevention of coronary heart disease would be expected by exceeding the one gram of EPA plus DHA per day. Dr. Connor finds no basis to question FDA's present 3 gram daily safe upper limit for omega-3 fatty acids.

Please do not hesitate to call us if you have any questions regarding this letter.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. W. Emord', with a stylized flourish at the end.

Jonathan W. Emord  
Andrea G. Ferrenz  
Kathryn E. Balmford

Attachments