American Stroke Association. A Division of American Heart Association

American Heart Association. Learn and Live.

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Office of Public Advocacy

About the American Heart Association

- Since 1924 the American Heart Association has helped protect people of all ages and ethnicities from the ravages of heart disease and stroke.
- These diseases, the nation's No. 1 and No. 3 killers, claim more than 930,000 American lives a year.
- The association invested more than $348 million in fiscal year 2002-03 for research, professional and public education, and advocacy so people across America can live stronger, longer lives.

TO:	301-436-2636	FAX:	
FROM:	BRIAN WILLIAMS	PHONE: 202.785.7900	
DATE:		TIME:	

NUMBER OF PAGES INCLUDING COVER SHEET:

MESSAGE:
AMERICAN HEART ASSOCIATION'S RESPONSE TO THE EMORD PETITION.

American Heart Association
1150 Connecticut Avenue, NW
Suite 300
Washington, DC 20036
Phone: 202-785-7900
Fax: 202-785-7950

If you did not receive this entire fax or have problems, please contact us at 202-785-7900.

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American Heart Association's Mission:
To reduce disability and death from cardiovascular diseases and stroke.

AMERICAN HEART ASSOCIATION'S RESPONSE TO THE EMORD PETITION FOR A CLASS A HEALTH CLAIM FOR OMEGA-3 FATTY ACIDS

The American Heart Association (AHA) is-supportive of the efforts by the Food and Drug Administration (FDA) to inform the consumer of the potential health benefits of specific food products that provide significant amounts of nutrients proven to be cardioprotective. In that light, we are happy to respond to the FDA's request for comments on the petition submitted by Emord & Associates, P.C. on behalf of Wellness Lifestyles, Inc. and Life Extension Foundation Buyers Club, Inc. which requests an amended health claim for foods and dietary supplements (June 23, 2003). While the AHA is anxious to encourage American consumers to increase their intake of omega-3 fatty acids, we have serious reservations about this particular petition. Our concerns are outlined below:

First, the Emord petition does not distinguish between the short chain alpha-linolenic acid (ALA) and the long-chain omega-3 fatty acids. EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid). The AHA believes that any health claim related to omega-3 fatty acids must, at this point in time, be restricted to EPA and DHA since the evidence for a cardioprotective effect of these two fatty acids (taken, as they appear in nature, in combination) is far stronger than the evidence for a beneficial effect of ALA. While ALA is converted to the longer chain fatty acid, the conversion rate in humans is low, and it is yet to be established that adequate amounts of EPA and DHA derived from ALA result in cardioprotective effects. Failing to distinguish between the short and long-chain omega-3 fatty acids will allow products containing ALA as the only omega-3 fatty -acid to carry the cardioprotective claim when convincing evidence for such a claim is still wanting.

Secondly, the Emord petition contemplates allowing claims for both whole foods as well as supplements. The Association prefers that health claims be made only for whole foods. While the AHA has acknowledged that in some cases (i.e., under a physician's care) supplements of EPA and DHA may have a place, obtaining these nutrients from foods is -preferable. This is because a beneficial food contributes to the total nutrition profile, adding beneficial nutrients and decreasing the less desirable nutrients. In this particular case, fish consumption (the principal source of EPA and DHA) helps the consumer achieve two important dietary goals: reducing saturated fat and increasing EPA and DHA intakes (when fish is substituted for meat).

Third, the Emord petition does not follow a standardized format and is decidedly deficient in supporting documents. The failure of this petition to present, in an organized and systematic manner, the evidence supporting the claim makes it impossible for those wishing to evaluate and comment on the petition to do so with any scientific rigor. We would strongly encourage the FDA to require a proper and complete document from all petitioners.

Fourth, the Emord petition proposes no Daily Value for long-chain omega-3 fatty acids. It would thus not be possible to decide whether any specific food contained sufficient EPA and DHA to warrant exhibiting the claim.

Finally, <u>the Emord petition includes no consumer research to prove that the wording of the proposed claim is actually perceived and understood by those individuals most likely to purchase the products to be labeled</u>. Without such information, the proposed claim may not achieve its intended purpose.

The AHA does agree with Emord & Associates, however, that a claim for EPA and DHA should be a Class A claim. --- While the AHA strongly prefers that health claims for food based dietary recommendations be Class A (unqualified), claims other than Class A should be considered only if the claim in conjunction with the accompanying qualification is correctly understandable by consumers as substantiated by consumer marketing research.

The American Heart Association is eager to offer its assistance to the FDA in creating health claims that are credible, informative, and actually lead to a beneficial change in consumer behavior. We share the FDA's goal of helping the American people adopt more healthful diets.