



SFP 3 2003

5886 '03 SEP -4 P1:54

Jonathan W. Emord, Esq.  
Emord and Associates, P.C.  
5282 Lyngate Court  
Burke, VA 22015

Re: Petition for omega-3 fatty acids and coronary heart disease health claim (Docket No. 2003Q-0401)

Dear Mr. Emord:

This letter acknowledges receipt on August 12, 2003 by the Food and Drug Administration (FDA) of your faxed letter regarding the health claim petition that you submitted on June 23, 2003 on behalf of Wellness Lifestyles, Inc. and Life Extension Foundation Buyers Club, Inc. We understand that both petitioners have agreed to have their health claim petition reviewed under the new process for qualified health claims rather than under the standard health claim review process described in Section 403(r)(4) and 403 (r)(5)(D) of the Federal Food Drug and Cosmetic Act (FFD&C Act)( 21 U.S.C. § 343(r)(4) and 21 U.S.C. § 343(r)(5)(D)). We will follow the interim procedures for qualified health claims described in the July 10, 2003 FDA publication of "Consumer Health Information for Better Nutrition Initiative" Task Force Final Report (<http://www.cfsan.fda.gov/~dms/nuttftoc.html>).

Accordingly, today we are filing your health claim petition for conventional foods and dietary supplements relating consumption of omega-3 fatty acids (specifically eicosapentaenoic acid ("EPA") and docosahexaenoic acid ("DHA")) to reduced risk of coronary heart disease. The petition is posted on our website and we are requesting comment on it. Interested persons may submit comments until November 2, 2003. Within 225 days of the filing date, we will notify you of our final decision regarding the requested qualified health claim. We have calculated this date to be April 15, 2004.

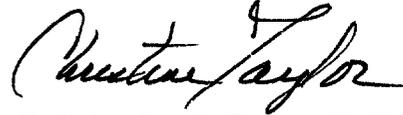
2003Q-0401

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Please feel free to contact Dr. Tomoko Shimakawa at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Christine Taylor". The signature is fluid and cursive, with a large initial "C" and "T".

Christine Lewis Taylor, Ph.D.

Director

Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety

and Applied Nutrition