

**VIA HAND DELIVERY**

April 13, 2004

Julie Schrimpf, Ph.D.  
Food and Drug Administration  
Office of Nutritional Products, Labeling  
And Dietary Supplements (HFS-800)  
5100 Paint Branch Parkway  
College Park, Maryland 20740



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Suite 500  
Rockville, Maryland 20855-2765  
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RE: Petition for Qualified Health Claim for Xangold® Lutein Esters Comprised of 93% Lutein Diesters (Principally Dipalmitate) and 7% Zeaxanthin Diesters): Request for English Translation of German Reference Article

Dear Dr. Schrimpf:

This is a follow-up to your letter of March 24 to Dr. Stanley M. Tarka, Jr. acknowledging receipt on March 12, 2004 by the Food and Drug Administration on the above referenced petition requesting a qualified health claim for the relationship between Xangold® lutein esters and age-related macular degeneration and cataract formation.

In this correspondence, you noted the following referenced article in a foreign language and requested that we submit two copies of an accurate and complete English translation for FDA's review:

Reference 108. Schweitzer, D, Lang, GE, Beuermann, B, Remsch, H, Hammer, M, Thamm, E, Spraul, CW, Land, GK. Objective Determination of Optical Density of Xanthophyll after Supplementation of Lutein. Ophthalmologie. 2002: 99(4): 270-275. [in German].

Enclosed, please find two complete and accurate copies of the English translation. This publication was translated by Ms Gisela Leon, an AAC Consultant who is a native German. She holds both a German Master of Science degree in Food Technology from the Technical University of Munich and additionally, a Master of Business Administration from George Mason University, Fairfax, Virginia. Ms. Leon also has held previous scientific and technical positions in German food processing companies.

2004Q-0180

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If you have any additional questions, please contact Stanley M. Tarka, Jr., Ph.D. at AAC Consulting Group, Inc. We look forward to the Agency's review and decision on this Petition. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward A. Steele", written over a horizontal line.

Edward A. Steele  
Vice President  
Food, Dietary Supplement & Cosmetic Consulting

Enclosure