



MAR 24 2004

Stanley M. Tarka, Jr., Ph.D.  
AAC Consulting Group  
7361 Calhoun Place  
Rockville, MD 20855-2765

RE: Qualified Health Claim Petition – Xangold® Lutein Esters and  
development of certain eye diseases

Dear Dr. Tarka:

This letter acknowledges receipt on March 12, 2004 by the Food and Drug Administration (FDA) of the petition you submitted, on behalf of the Cognis Corporation, pursuant to Sections 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 343(r)(5)(D)) and in accordance with the July 10, 2003 Task Force Final Report on the Consumer Health Information for Better Nutrition Initiative. The petition requests a qualified health claim for the relationship between Xangold® lutein esters and age-related macular degeneration and cataract formation.

The petition is undergoing initial FDA review. In accordance with interim procedures set forth in the aforementioned Task Force Final Report (<http://www.cfsan.fda.gov/~dms/nuttftoc.html>), within 45 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by either FDA action within the initial 45-day period, which ends on April 26, 2004, or by a lack of action by FDA within the initial 45-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

In our preliminary review of your petition, we found the below referenced article in a foreign language without an accompanying accurate and complete English translation (21 CFR 101.70(a)). Please provide us two copies of the complete and accurate English translation of this article for our review.

2004Q-0180

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Reference 108. Schweitzer, D, Lang, GE, Beurmann, 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]

Please feel free to contact me at 301-436-2031 if you have any questions concerning this petition.

Sincerely yours,



Julie Schrimpf, Ph.D.  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition