



APR 26 2004

Food and Drug Administration  
College Park, MD 20740

020 04 MAY 2 1 56

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:

On March 12, 2004, the Food and Drug Administration (FDA) acknowledged receipt 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)). You submitted the petition as a qualified health claim petition 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.

In accordance with the FDA's guidance, "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements," (<http://www.cfsan.fda.gov/~dms/nutftoc.html>), FDA is to determine, within 45 days of receipt of a qualified health claim petition, whether the petition is complete and can be filed for further review. The 45-day period for the filing review of your petition is April 26, 2004. Consequently, today we are filing the qualified health claim for lutein esters and its relationship to age-related macular degeneration and cataract formation. The petition is posted on Dockets web page (<http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>) and we are requesting comment on it for 60 days. Interested persons may submit comments until June 25, 2004. Within 225 days of the filing date, we will notify you of our final decision regarding the requested qualified health claim. We have calculated that date to be December 7, 2004.

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Page 2 - Stanley M. Tarka, Jr., Ph.D.

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

Sincerely yours,

A handwritten signature in black ink that reads "Laura M. Tarantino". The signature is written in a cursive style with a large, stylized initial "L" and "M".

Laura Tarantino, Ph.D.  
Acting Director  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition