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**March 5, 2004**

**PETITIONER**

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Subject: Petition for a qualified health claim for Xangold® lutein esters comprised of 93% lutein diesters (principally dipalmitate) and 7% zeaxanthin diesters

Petition submitted to:

Food and Drug Administration  
Office of Nutritional Products, Labeling and Dietary Supplements  
HFS-800  
5100 Paint Branch Parkway  
College Park, MD 20740

**INTRODUCTION AND PURPOSE**

The undersigned, Cognis Corp., submits this qualified health claim petition pursuant to section 403(r)(4) or 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act, and in accordance with the guidelines of the Task Force on the Consumer Health Information for Better Nutrition, with respect to consumption of Xangold® lutein esters and their relationship to reducing the risk of certain diseases of the eye. Attached hereto, and constituting a part of this petition, is the information required by 21 CFR §101.70(f).

On December 18, 2002, FDA launched the "Consumer Health Information for Better Nutrition" initiative and stated that it would develop a process to allow qualified health claims (QHC) on both conventional foods and dietary supplements. A Task Force was established to develop recommendations for implementing the QHC process. In July 2003, FDA issued recommendations provided by the Task Force on Consumer Health Information for Better Nutrition for implementation of this new program beginning September 2003. The intent of this initiative is to help consumers make informed choices about their diet and nutrition in order to improve the overall health of the American public. The stated goals of the FDA initiative are to 1) allow for more understandable and science-based information in labeling of foods and

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