

March 5, 2004

PETITIONER

Cognis Corporation, 5325 South Ninth Avenue, La Grange, IL 60525-3602

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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

nutritional supplements; 2) better inform the consumer on how dietary choices affect their health and 3) encourage companies to compete based on the health and nutritional consequences of their ingredients, in addition to non-health related features like taste and convenience.

The petitioner, Cognis Corp., believes that the FDA's qualified health claim program is a positive step, which can greatly benefit the health of consumers in making informed decisions regarding their diet. The petitioner is requesting that FDA authorize a qualified health claim for reduction of risk of age-related macular degeneration of the eye (AMD) and the onset of cataract formation from ingestion of Xangold® lutein esters in foods fortified with this ingredient or in dietary supplements. Suggested wording for the claim is below in Section D.

The petitioner uses the term "lutein esters" as the common name for the substance that is the subject of this petition. This substance is a mixture of xanthophyll esters, including esters of both lutein (>93 %) and zeaxanthin (<7 %). The major chemical entity of the substance is lutein dipalmitate. For clarity, the term lutein esters is used to describe the mixture of xanthophyll esters that is the subject of this petition.

The petitioner has developed the technology to manufacture three lutein ester products – i.e., a concentrate, and two products that are prepared by diluting this concentrate. The concentrate is manufactured from marigold (*Tagetes erecta*) flowers that are dried, milled, and subjected to solvent extraction, filtration and purification. The resulting concentrate is a granular, dark orange-brown solid containing a minimum of 60 percent lutein/zeaxanthin esters. Esterified lutein constitutes more than 93 percent of the total lutein esters in the concentrate and esterified zeaxanthin constitutes less than 7 percent of the total lutein esters in the concentrate.

The petitioner provides two commercial products from the concentrated form of its Xangold® lutein ester product. One commercial product is a microencapsulated powder containing a minimum of 10 percent xanthophyll esters based upon the Xangold® lutein ester concentrate. The second commercial product is prepared by diluting the Xangold® lutein ester concentrate with vegetable oil and is a liquid that contains a minimum of 15 percent xanthophyll esters. The petitioner's substance in powder or liquid form can be used in dietary supplements and in a variety of food products as described in Table 1.

Table 1. Intended Use of Lutein Esters

Food Category	Maximum Level of Use (milligrams (mg) of lutein ester per serving)
Baked goods and baking mixes	4.0
Soy milk	3.0
Beverages and beverage powders	4.0
Frozen dairy desserts and mixes	2.0
Processed fruit and vegetable products	4.0
Egg products and egg substitutes	4.0
Breakfast cereals (ready-to-eat) and hot	4.0
Fats and oils	3.0
Hard candy	2.0
Fruit snacks	2.0
Dairy products	6.0
Medical foods intended as the sole item of the diet (21 CFR 101.9(j)(8))	Not to exceed 40 mg per day

This petition has been prepared according to the requirements for health claim petitions in 21 CFR §101.70 and the guidance documents for qualified health claims provided by the Task Force on Consumer Health Information for Better Nutrition in July 2003 (<http://www.fda.gov/oc/mcclellan/chbn.html>). As part of this petition, the petitioner is presenting a comprehensive evaluation of the scientific basis for its claim including biological hypotheses by which lutein esters as a source of lutein are thought to reduce the risk of age-related macular degeneration (ARMD) and cataract formation. The petition presents the rationale for preferentially using Xangold[®] lutein esters either in a dietary supplement or a fortified food form as part of a balanced diet. The petition also includes scientific reports, human clinical, and epidemiological studies on the relationship between intake of lutein and/or lutein esters as the source of lutein, and reduction in risk of specific diseases of the eye including age-related macular degeneration (ARMD) and cataract formation. We believe that the petition presents far more than just credible evidence that the scientific data support the proposed claim. As this petition also shows, there is an abundance of scientific evidence, general acceptance by the

scientific community and increasingly, a recognition by various expert bodies and private institutions, that an increased dietary intake of lutein (in either the esterified or non-esterified form) may result in a decrease in the risk of ARMD and cataract. The scientific evaluation presented herein and the proposed claim have been reviewed and approved by consensus of an expert panel qualified to evaluate the scientific evidence. The signatures of the expert panel agreeing to the summary consensus statement, as well as attached curriculum vitae, are included as part of this petition in Section J of this binder.