



United Egg Producers

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2004Q-0180

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June 21, 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

Dear Dr. Schrimpf:

Ref: 2004Q-180 – Qualified Health Claim (QHC): Lutein and Eye Disease

United Egg Producers (UEP) representing more than 90 percent of the shell eggs produced nationwide, appreciates this opportunity to comment on the petition submitted by Cognis Corporation, 5325 South Ninth Avenue, La Grange, IL 60525-3602 (the petitioner) for a qualified health claim for an esterified lutein or lutein esters. Lutein reduces the risk of age-related macular degeneration (ARMD) and cataract formation. A copy of these comments will also be submitted to the Division of Dockets, FDA, 5630 Fishers Lane, Room 1061 (HFA-305), Rockville, MD 20852.

Lutein esters only one form of lutein.

The development by FDA of the Consumer Health Information for Better Nutrition initiative to allow qualified health claims (QHC) on conventional foods and dietary supplements is applauded by UEP. This will help consumers make informed choices about their diet and nutrition in order and thus improve the overall health of the American public. The petitioner is promoting lutein ester products with a concentrate containing 60 percent lutein/zeaxanthin esters promoting a relationship in the reduction of specific diseases of the eye including ARMD from the consumption of 12 mg of Xangold lutein esters per day. Lutein ester is just one source of lutein and is molecularly different from actual free lutein itself.

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Eggs are rich in free, non-esterified lutein.

UEP does not object to the petitioner asking to add esterified lutein to the reduction of ARMD, but if the petitioner hopes to restrict the claim to only lutein esters, it would be a disservice to consumers by limiting the claim on packaging of many common lutein-rich foods like eggs and spinach from a lutein/ARMD. Lutein, in its free, non-esterified form, is the core molecule producing bioactivity in the body when foodstuffs rich in lutein are consumed. Lutein, in its free, non-esterified form should be the primary ingredient in the claim for the reduction of diseases of the eye including ARMD.

Lutein and eye health

UEP supports the recognition of the connection between lutein and eye health and therefore support the establishment of a QHC for lutein as an ingredient that may reduce the risk of ARMD. However, UEP strongly urges that health claims involving lutein should be for the free, non-esterified forms since the free form is the key bioactive agent in foods rich in lutein. The lutein in the free form is more widely available in the diet than lutein esters. Published research by Handelman et al. *Am J Clin Nutr* 1999; 70:247-51 and Richer et al. *Optometry*, 2004, 75:4, 216-30 supports the connection between lutein present in blood serum following consumption of foods containing lutein and the reduction of chronic eye disease.

UEP appreciates this opportunity to comment on the petition on a QHC for lutein.

Yours sincerely,


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