Jean Mayer  
United States Department of Agriculture  
Human Nutrition Research Center on Aging  
At Tufts University  

June 23, 2004  

U.S. Food and Drug Administration  
Dockets Management Branch (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  

Re: Docket 2004Q-0180  
QHC: Lutein and Eye Disease  

Dear Sir or Madame:  

I submit this letter to comment on the proposed qualified health claim (Docket 2004Q-1080) that “consumption of 12 mg of Xangold lutein esters per day may reduce the risk of age-related macular degeneration (AMD) and cataract formation.” Lutein (often present with zeaxanthin) is present in a wide variety of plant foods especially dark-green leafy vegetables such as kale, spinach, turnip greens, and collards [1]. Lutein is also highly concentrated in egg yolks [2]. Research involving cell cultures, animal models, and human studies has been directed to the potential role of lutein in protecting against several chronic diseases, particularly AMD and cataract. Lutein is uniquely concentrated in the macular region of the retina [3-5] with zeaxanthin being the dominant component in the central macula and lutein distributed throughout the retina [4-6]. Lutein and zeaxanthin are the only carotenoids reported to be present in eye lens [7]. Possible biologic mechanisms of the protective role of lutein in the eye have been reviewed by Krinsky et al. [8] and include their ability to: [a] filter harmful short-wave blue light, [b] function as antioxidants, and [c] stabilize membrane integrity.

Increased consumption of foods rich in lutein [9,10] or ingestion of lutein supplements [11-13] have been reported to increase macular pigment density in healthy adults. In patients with inherited retinal degeneration, lutein supplementation augmented the macular pigment in many but not all patients, though central vision was unchanged after the supplementation [14]. The preservation of visual sensitivity in older people has been associated with macular pigment density [15]. Positive associations have been reported between dietary intakes of lutein vs. macular pigment density [32] and between serum concentrations of lutein vs. macular pigment density [16-18].

AMD is the most common cause of visual impairment and irreversible blindness among elderly Americans and a number of investigations have examined the relationship between lutein and AMD. In a case-control study, Bone et al [19] found that lutein concentrations in the fovea were lower in AMD donors than controls. Data from the Eye...
Disease Case-Control Study [20,21] are consistent with the hypotheses that a reduced risk of neovascular AMD is inversely associated with lutein intake and status. Snellen et al. [22] found that the prevalence rate of AMD in subjects with low lutein intake was more than twice that in subjects with high intake. In contrast, some results the Beaver Dam Eye Study in Wisconsin [23-25] and the Blue Mountains Eye Study in Australia [26] fail to show any significant association of lutein and the development of AMD.

In an examination of the relationship between lutein and cataract in the Nurses Health Study, Chasan-Taber et al. [27] found women with the highest intakes of lutein plus zeaxanthin had a significant reduction in relative risk of cataract severe enough to require extraction as compared to those with poorest intakes. A similar relationship was noted in men from the Health Professionals Follow-up Study by Brown et al. [28]. In contrast, associations of lutein and age-related cataract in the Beaver Dam Study were inconsistent with an inverse association between dietary lutein and cataract, but not between serum lutein and cataract [29,30]. However, in England, Gale et al. [31] found that the risk of posterior subcapsular cataract was lowest in those with higher concentrations of plasma lutein. Interestingly, in a small trial of people with cataract, lutein supplementation has been shown to improve visual acuity and glare sensitivity [32].

Thus, a compelling body of scientific evidence supports encouraging Americans to consume more lutein to reduce their risk of AMD and cataract formation. However, restricting a qualified health claim to only one form of lutein esters would prohibit similar statements on common lutein-rich foods and other forms of lutein in dietary supplements, including the bioactive free, non-esterified form of the molecule. In conclusion, I feel a qualified health claim that lutein (in any bioavailable form) may reduce the risk of AMD and cataract formation is substantiated by the totality of available scientific evidence and may assist Americans in better helping themselves promote their health.

Sincerely,

[Signature]

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References


