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Technical Literature

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HUMAN CLINICAL TRIALS WITH FLORAGLO® LUTEIN

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KEY CONCLUSIONS

- *FloraGLO® brand lutein is the most clinically researched lutein brand worldwide with over 70 human clinical trials published in peer-reviewed journals.*
- *FloraGLO is the only lutein used in infant supplementation trials.*
- *Clinical trials have evaluated visual function, macular pigment optical density levels, serum lutein concentrations, skin health and cognitive function following supplementation doses of 1.7 to 40 mg FloraGLO Lutein per day for periods of up to five years.*
- *These studies have been conducted in both healthy subjects and patients with eye conditions such as age-related macular degeneration, cataract and retinitis pigmentosa.*
- *No serious adverse events were reported in any of these trials.*

INTRODUCTION

Naturally sourced from marigolds, FloraGLO® Lutein is the most clinically researched lutein brand worldwide and the one used in the National Institutes of Health (NIH) National Eye Institute (NEI) prestigious Age-Related Eye Disease Study II (AREDS2). FloraGLO is selected by leading reasearchers, supplement and food manufacturers for its unparalleled science, as well as its quality and established safety profile.

Over 70 trials published in peer-reviewed journals have been completed in humans using FloraGLO Lutein. It is critical for manufacturers to formulate with an ingredient that has clinical evidence to substantiate their claims and manufacturers using FloraGLO Lutein are guaranteed an ingredient with strong scientific support.

The majority of the research has focused on eye health, as lutein is known to be deposited in the macula and lens. However, emerging research also supports lutein's beneficial role in skin health, cognition, maternal and infant nutrition. A review of the scientific literature available through PubMed[1] as of July 7, 2015 revealed 22 trials evaluating visual function, 28 trials assessing macular pigment optical density (MPOD) levels, 30 trials measuring serum lutein concentrations, four trials assessing parameters of skin health, and one trial evaluating cognitive function, all following supplementation with FloraGLO Lutein. These trials have supplemented with FloraGLO Lutein at doses ranging from 1.7 to 40 mg per day for time periods of up to five years (see the following tables for details). FloraGLO Lutein is the only brand of lutein that has Generally Recognized As Safe (GRAS) status for use in infant formula. Therefore, it should not be surprising that FloraGLO Lutein has been used as the sole source of lutein in all 12 supplementation trials conducted in infants.

In addition to the health-related benefits, a number of human clinical trials have also evaluated the effect FloraGLO Lutein on the parameters of oxidative stress, safety and intestinal absorption (*1-10*). The majority of these trials support the eye protective benefits of supplementation with FloraGLO Lutein. This protection is suggested to stem from the ability of lutein to act as "internal sunglasses" by absorbing short wavelengths of light in the blue region of the visible light spectrum (*11*) and as an antioxidant to neutralize free radicals. These short wavelengths of

[1]Pubmed is maintained by the United States National Library of Medicine® (NLM) at the National Institutes of Health and is considered to be the most comprehensive (with more than 22 million references to journal articles) for searches of this kind.

visible light are particularly damaging because they are high energy and can pass through outer structures of the eye such as the lens and cornea, which absorb ultraviolet wavelengths of light. In addition, these damaging visible wavelengths of high-energy blue light are efficient at generating reactive oxygen species (a principal type of free radical). Hence, both the visible light filtering and antioxidant properties of lutein reduce damage to ocular tissues that occurs from daily exposure to sunlight, indoor lighting, and environmental pollutants.

The more recent FloraGLO Lutein supplementation trials have utilized a dose of 10 mg lutein per day. However, the average daily intake of lutein in the United States from diet alone is estimated to be less than 2 mg (*12*), far below intakes shown to improve visual function, skin health and cognitive function. Lutein and zeaxanthin concentrations in the macula naturally deplete as people age (*13*), so daily maintenance with adequate levels of these important nutrients through diet or supplementation is critical. Supplementation trials, including many listed in the subsequent tables, have shown that the bioavailability of the FloraGLO lutein brand obtained from supplements and fortified foods is similar to that obtained from foods that naturally contain these nutrients (*9, 10*). Thus supplements and food fortified with the FloraGLO lutein brand can provide the same benefits for eye and skin health and function, cognition and infant nutrition as those provided by foods containing these nutrients.

EYE HEALTH

Visual Function

Table 1. Published trials examining the effect of FloraGLO Lutein supplementation on visual function.

Trial	Cohort[a]	Protocol[b]	Effect on Visual Function[c]
Bovier *et al*. 2015 (*14*)	25 healthy young adults	8mg FloraGLO and 26mg zeaxanthin/day for 4 months	Significant increase in temporal contrast sensitivity as compared to placebo
Sabour-Pickett *et al*. 2014 (*15*)	17 adults with early age-related macular degeneration (AMD)	20mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in contrast sensitivity at low spatial frequencies as compared to placebo
Hammond *et al.* 2014 (*16*)	57 healthy young adults	10mg FloraGLO and 2 mg zeaxanthin/day for 1 year	No impact on glare disability (p=0.21) as compared to placebo
Bovier *et al.* 2014 (*17*)	25 healthy young adults	8mg FloraGLO and 26mg zeaxanthin/day for 4 months	Significantly improved motor reaction time and critical flicker fusion threshold as compared to placebo
AREDS 2, 2013 (*18*)	2107 adults (age 50-85) with AMD	10mg FloraGLO and 2 mg zeaxanthin/day for 5 years	No change in visual acuity (p = 0.50) as compared to placebo
Chew (AREDS2 Report #4) 2013 (*19*)	2107 adults (age 50-85) with AMD	10mg FloraGLO and 2 mg zeaxanthin/day for 5 years	No change on the rates of cataract surgery (p=0.54) or vision loss (p=0.20) as compared to placebo
Chew (AREDS2 Report#3, 2014 (*20*)	2107 adults (age 50-85) with AMD	10mg FloraGLO and 2 mg zeaxanthin/day for 5 years	Significant reduction in AMD disease progression as compared to placebo
Dawczynski *et al.* 2013 (*21*)	105 AMD patients	10 mg FloraGLO and 1 mg zeaxanthin/day or 20 mg FloraGLO and 3 mg zeaxanthin/day for 1 year	Significant increase in visual acuity as compared to placebo

Pescosolido *et al.* 2012 (*22*)	24 healthy males	18 mg FloraGLO/day for 45 days	Improved Visual Evoked Potentials (VEP) by showing a significant decrease of latency increase of amplitude as compared to placebo
Loughman *et al.* 2012 (*23*)	12 healthy adults	20 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Significant improvement in mesopic contrast sensitivity at 6.0 cycles per degree (cpd) as compared to baseline
Piermarocchi *et al.* 2011(*24*)	103 AMD patients	10 mg FloraGLO and 1 mg zeaxanthin/day for 2 years	Significant increase in visual acuity, contrast sensitivity and National Eye Institute Visual Function Questionnaire score as compared to placebo
Sasamoto *et al.* 2011 (*25*)	43 Japanese subjects (5 normal, 5 with central serous chorioretinopathy and 33 with AMD); Only healthy eyes included in study	6 mg FloraGLO/day for 12 months	Significant increase in contrast sensitivity and retinal sensitivity as compared to baseline
Berson *et al.* 2010 (*26*)	110 retinitis pigmentosa patients	12 mg FloraGLO/day for 4 years	Significant reduction in the loss of midperipheral field sensitivity as compared to placebo
Parisi *et al.* 2008 (*27*)	15 AMD patients	10 mg FloraGLO/day for 12 months	Significant increase in multifocal electroretinogram response amplitude densities as compared to placebo
Stringham *et al.* 2008 (*28*)	40 healthy young adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Significant increase in glare tolerance and photostress recovery time as compared to baseline
Aleman *et al.* 2007 (*29*)	8 Stargardt disease and 3 cone–rod dystrophy patients	20 mg FloraGLO/day for 6 months	No change in foveal sensitivity ($p > 0.05$) as compared to baseline
Bahrami *et al*. 2006 (*30*)	34 retinitis pigmentosa patients	10 mg FloraGLO/day for 3 months followed by 30 mg FloraGLO/day for 3 months	Significantly improved visual field as compared to placebo. Non-significant increase in visual acuity ($p=0.58$) and contrast sensitivity ($p=0.34$)
Kvansakul *et al.* 2006 (*31*)	15 healthy males	10 mg FloraGLO and/or 10 mg zeaxanthin/day for 6 months	Significant improvement in contrast acuity as compared to placebo. Non-significant, decreasing trend in light scatter and wavefront aberrations as compared to placebo.
Morganti *et al.* 2004 (*32*)	20 healthy smokers	6 mg FloraGLO/day for 2 months	Significant increase in global visual activity as compared to placebo
Richer *et al*. 2004 (*33*)	59 AMD patients	10 mg FloraGLO/day for 12 months	Significant improvements in contrast sensitivity, visual acuity, glare recovery, and photostress recovery as compared to baseline
Falsini *et al.* 2003 (*34*)	17 AMD patients and 4 healthy subjects	15 mg FloraGLO/day for 6.5 months	Significant increase in macular focal electroretinogram parameters amplitude and modulation threshold as compared to baseline
Aleman *et al.* 2001 (*35*)	23 patients with retinal degeneration and 8 healthy subjects	20 mg FloraGLO/day for 6 months	Non-significant increase in visual acuity and foveal sensitivity ($p=0.33$) as compared to baseline
Dagnelie *et al.* 2000 (*36*)	13 retinitis pigmentosa patients and 3 with other retinal degenerations	40 mg FloraGLO/day for 9 weeks followed by 20 mg FloraGLO/day for 17 weeks	Significant improvement in mean visual acuity and central visual field as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients or placebo. [c]Statistical significance defined as $p < 0.05$

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Macular Pigment Optical Density (MPOD)

Table 2. Published trials examining the effect of FloraGLO Lutein supplementation on MPOD

Trial	Cohort[a]	Protocol[b]	Effect on MPOD[c]
Bovier *et al*. 2015 (*14*)	25 healthy young adults	8mg FloraGLO and 26mg zeaxanthin/day for 4 months	Significant increase in MPOD as compared to placebo
Akuffo *et al. 2015 (37)*	13 AMD patients	20mg FloraGLO and 0.86mg zeaxanthin/day for 3 weeks	Significant increase in MPOD as compared to baseline
Sabour-Pickett *et al*. 2014 (*15*)	17 adults with early age-related macular degeneration (AMD)	20mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in MPOD for 1.75° eccentricity as compared to baseline. Non-significant increases for all other eccentricities ($p>0.05$).
Hammond *et al.* 2014 (*16*)	57 healthy young adults	10mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in MPOD as compared to placebo
Bovier *et al.* 2014 (*17*)	25 healthy young adults	8mg FloraGLO and 26mg zeaxanthin/day for 4 months	Significant increase in MPOD as compared to placebo
García-Layana *et al. 2013 (38)*	23 AMD patients	12mg FloraGLO/day for 1 year	Significant increase in MPOD as compared to placebo
Dawczynski *et al.* 2013 (*21*)	105 AMD patients	10 mg FloraGLO and 1 mg zeaxanthin/day or 20 mg FloraGLO and 3 mg zeaxanthin/day for 1 year	Significant increase in MPOD as compared to placebo
Arnold *et al.* 2013 (*39*)	104 age-related macular degeneration (AMD) patients	10 mg FloraGLO and 1 mg zeaxanthin/day or 20 mg FloraGLO and 2 mg zeaxanthin/day for 12 months	Significant increase in MPOD at both doses as compared to baseline
Loughman *et al.* 2012 (*23*)	12 healthy adults	20 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Non-significant increase in MPOD with respect to baseline ($p>0.05$ for all measured eccentricities)
Nolan *et al.* 2012 (*40*)	11 healthy adults	20 mg FloraGLO/day for 8 weeks	No change in MPOD with respect to baseline ($p>0.05$)
Tanito *et al.* 2012 (*41*)	11 healthy adults	10 mg FloraGLO and 0.8 mg zeaxanthin/day for three months	Significant increase in MPOD with respect to baseline
Hammond *et al.* 2012 (*42*)	322 healthy female twins	18 mg FloraGLO and 2.4 mg zeaxanthin per day for 6 months	Significant increase in MPOD with respect to baseline
Sasamoto *et al.* 2011(*25*)	43 Japanese subjects (5 normal, 5 with central serous chorioretinopathy and 33 with AMD); Only healthy eyes included in study	6 mg FloraGLO/day for 12 months	No change in MPOD with respect to baseline ($p=0.261$ at the end of 12 months)
Berson *et al.* 2010 (*26*)	110 retinitis pigmentosa patients	12 mg FloraGLO/day for 4 years	Significant increase in MPOD as compared to placebo

Johnson *et al.* 2008 (*43*)	25 healthy older women	12 mg FloraGLO/day for 4 months	Significant increase in MPOD as compared to baseline
Stringham *et al.* 2008 (*28*)	40 healthy young adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Significant increase in MPOD as compared to baseline
Aleman *et al.* 2007 (*29*)	8 Stargardt disease and 3 cone–rod dystrophy patients	20 mg FloraGLO/day for 6 months	63% of patients experienced a significant increase in MPOD as compared to baseline
Richer *et al.* 2007 (*44*)	59 AMD patients	10 mg FloraGLO/day for 12 months	Significant increase in MPOD with no plateau as compared to baseline
Schalch *et al.* 2007 (*45*)	13 healthy males	10 mg FloraGLO/day for 6 months followed by 20 mg FloraGLO/day for additional 6 months or 10 mg FloraGLO/day and 10 mg zeaxanthin/day for 6-12 months	Significant increase in MPOD as compared to baseline
Franciose *et al.* 2006 (*46*)	32 healthy adults	4-6 mg FloraGLO/day for 12 weeks	No change in mean MPOD with respect to baseline ($p>0.05$)
Kvansakul *et al.* 2006 (*31*)	13 healthy males	10 mg FloraGLO/day for 6 months followed by 20 mg FloraGLO/day for additional 6 months or 10 mg FloraGLO/day and 10 mg zeaxanthin/day for 6-12 months	Significant increase in MPOD as compared to baseline
Rodriguez-Carmona *et al.* 2006 (*47*)	13 healthy males	10 mg FloraGLO/day for 6 months followed by 20 mg FloraGLO/day for additional 6 months or 10 mg FloraGLO/day and 10 mg zeaxanthin/day for 6-12 months	Significant increase in MPOD as compared to baseline
Morganti *et al.* 2004 (*32*)	20 healthy adults	6 mg FloraGLO/day for 2 months	Significant increase in MPOD as compared to baseline
Richer *et al*. 2004 (*33*)	59 AMD patients	10 mg FloraGLO/day for 12 months	Significant increase in mean MPOD as compared to baseline
Cardinault *et al.* 2003 (*48*)	12 healthy young and 17 healthy elderly	9 mg FloraGLO/day for 5 weeks	No change in MPOD with respect to baseline ($p>0.05$)
Duncan *et al.* 2002 (*49*)	7 choroideremia (form of retinal degeneration) patients	20 mg FloraGLO/day for 6 months	Significant increase in mean MPOD as compared to baseline
Schweitzer *et al.* 2002 (*50*)	10 healthy adults	6 mg FloraGLO/day for 40 days	Non-significant increase in MPOD with respect to baseline
Aleman *et al.* 2001 (*35*)	23 patients with retinal degeneration and 8 healthy subjects	20 mg FloraGLO/day for 6 months	Significant increase in MPOD as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$

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SERUM LUTEIN CONCENTRATION

Table 3. Published trials examining the effect of FloraGLO Lutein supplementation on serum lutein concentration.

Trial	Cohort[a]	Protocol[b]	Effect on Serum Lutein Level[c]
Akuffo *et al. 2015(37)*	13 AMD patients	20mg FloraGLO and 0.86mg zeaxanthin/day for 3 weeks	Significant increase in serum lutein as compared to baseline
Hammond *et al.* 2014 (*16*)	57 healthy young adults	10mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in serum lutein as compared to placebo
Borel *et al.* 2014 (*51*)	40 healthy adults	15mg FloraGLO single dose	Significant increase in serum lutein as compared to baseline
Sherry *et al.* 2014 (*52*)	89 post-partum women	6 or 12 mg FloraGLO daily for 6 weeks	Significant increase in serum lutein for both mothers and breast fed infants as compared to baseline and placebo
AREDS 2, 2013 (*18*)	2107 adults (age 50-85)	10mg FloraGLO and 2 mg zeaxanthin/day for 5 years	Significant increase in serum lutein as compared to baseline and placebo
Arnold *et al.* 2013 (*39*)	104 age-related macular degeneration (AMD) patients	10 mg FloraGLO and 1 mg zeaxanthin/day or 20 mg FloraGLO and 2 mg zeaxanthin/day for 12 months	Significant increase in serum lutein levels at both doses as compared to baseline
Meagher *et al.* 2013 (*53*)	11 healthy adults and 10 AMD patients	20 mg FloraGLO and 2 mg zeaxanthin/day for 8 weeks	Significant increase in serum lutein as compared to baseline
Loughman *et al.* 2012 (*23*)	12 healthy adults	20 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Non-significant increase in serum lutein as compared to baseline (p=0.14)
Evans *et al.* 2012 (*54*)	48 healthy adults	20 mg FloraGLO single dose	Significant increase in serum lutein as compared to baseline
Hammond *et al.* 2012 (*42*)	322 healthy female twins	18 mg FloraGLO and 2.4 mg zeaxanthin per day for 6 months	Significant increase in serum lutein as compared to baseline
Berson *et al.* 2010 (*26*)	110 retinitis pigmentosa patients	12 mg FloraGLO/day for 4 years	Significant increase in serum lutein as compared to baseline
Li *et al.* 2010 (*55*)	40 healthy adults	12 mg FloraGLO/day for 4 months	Significant increase in serum lutein as compared to baseline
Romagnoli *et al.* 2010 (*56*)	10 preterm infants	0.5 mg/kg body weight (one dose)	Increase in serum lutein as compared to baseline (statistics not run)
Nakagawa *et al.* 2009 (*57*)	6 healthy adults	9.67 mg FloraGLO/day for 4 weeks	Significant increase in serum lutein as compared to baseline
Huang *et al.* 2008 (*58*)	21 AMD patients and 19 healthy adults	10 mg FloraGLO/day and 2 mg zeaxanthin/day for 6 months	Significant increase in serum lutein as compared to baseline

Johnson *et al.* 2008 (*43*)	25 healthy older women	12 mg FloraGLO/day for 4 months	Significant increase in serum lutein as compared to baseline
Aleman *et al.* 2007 (*29*)	8 Stargardt disease and 3 cone–rod dystrophy patients	20 mg FloraGLO/day for 6 months	Significant increase in serum lutein as compared to baseline
Schalch *et al.* 2007 (*45*)	37 healthy adults	10 mg FloraGLO/day for 6 months followed by 20 mg FloraGLO/day for additional 6 months or 10 mg FloraGLO/day and 10 mg zeaxanthin/day for 6-12 months	Significant increase in serum lutein as compared to baseline
Franciose *et al.* 2006 (*46*)	32 healthy adults	4-6 mg FloraGLO/day for 12 weeks	Significant increase in serum lutein as compared to baseline
Khachik *et al.* 2006 (*59*)	45 healthy adults	2.5, 5, 10 mg FloraGLO per day for 6 months	Significant increase in serum lutein as compared to baseline
Tanumihardjo *et al.* 2005 (*60*)	9 healthy adults	18 mg FloraGLO/day in one dose	Increase in mean serum lutein following supplementation (statistics not run on magnitude of increase)
Thurmann *et al.* 2005 (*61*)	16 healthy adults	4.1 mg or 20.5 mg FloraGLO/day for 42 days	Significant increase in serum lutein as compared to baseline
Molldrem *et al.* 2004 (*62*)	9 healthy adults	1.7 mg FloraGLO/day for 7 days	Significant increase in serum lutein as compared to baseline
Cardinault *et al.* 2003 (*48*)	12 healthy young and 17 healthy elderly	9 mg FloraGLO/day for 5 weeks	Significant increase in serum lutein as compared to baseline
Bowen *et al.* 2002 (*63*)	18 healthy adults	20.7 or 24.5 mg FloraGLO/day in one dose	Significant increase in serum lutein as compared to baseline
Duncan *et al.* 2002 (*49*)	7 choroideremia (form of retinal degeneration) patients	20 mg FloraGLO/day for 6 months	Significant increase in serum lutein as compared to baseline
Aleman *et al.* 2001 (*35*)	23 patients with retinal degeneration and 8 healthy subjects	20 mg FloraGLO/day for 6 months	Significant increase in serum lutein as compared to baseline
Castenmiller *et al.* 1999 (*9*)	12 healthy adults	6.6 mg FloraGLO/day for 3 weeks	Significant increase in serum lutein as compared to baseline
van het Hof *et al.* 1999 (*10*)	10 healthy adults	9 mg FloraGLO/day for 4 weeks	Significant increase in serum lutein as compared to baseline and placebo
Kostic *et al.* 1995 (*64*)	8 healthy adults	0.5 mmol/kg body weight FloraGLO/day in one dose	Significant increase in serum lutein as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$

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INFANT AND MATERNAL HEALTH

Table 4. Published trials examining the effect of FloraGLO Lutein supplementation on maternal and infant health.

Trial	Cohort[a]	Protocol[b]	Effect on Infant Health[c]
Kon *et al.* 2014 (*65*)	23 full term infants age 10 days - 2 months	Formula with 11.4 µg FloraGLO/100mL supplemented for 28 days	Growth equivalence to control formula and no significant differences in formula tolerance
Perrone *et al. 2014 (66)*	103 healthy newborn infants	0.28 mg FloraGLO (two doses: one each at 6 and 36 hours of life)	Significantly higher biological antioxidant potential (BAP) as compared to control
Sherry *et al.* 2014 (*52*)	89 post-partum women	6 or 12 mg FloraGLO daily for 6 weeks	Significant increase of lutein in breast milk in mothers and plasma lutein in infants as compared to placebo
Lorenzoni *et al* 2013 (*67*)	12 pregnant women with gestational diabetes	10mg FloraGLO and 2 mg zeaxanthin for 12-14 weeks	Significantly lower total hydroperoxides in infants at 2 hours old as compared to control
Costa *et al.* 2013 (*68*)	38 infants with gestational age ≤ 34 weeks + 7 days	0.5 mg FloraGLO + 0.02 mg zeaxanthin/kg/day until 40th week post-menstrual age (PMA) or discharge	No significant effect on total antioxidant status (TAS) as compared to placebo (p>0.05). Significant linear correlation between plasma lutein concentration and TAS.
Mackey *et al.* 2012 (*69*)	41 full term infants between age 14 and 35 days	Formula with 32.6 µg FloraGLO/L or 52.6 µg FloraGLO/L	Significant increase in serum lutein as compared to placebo for high dose formula. Non –significant increase for low dose formula.
Manzoni *et al.* 2012 (*70*)	113 infants with gestational age <32 weeks + 6 days (mean 30 weeks)	0.14 mg FloraGLO + 0.6 µg zeaxanthin/day from birth until 36 weeks corrected gestational age	Non-significant reduction in threshold retinopathy of prematurity (p=0.18), necrotizing enterocolitis (p=0.15), and bronchopulmonary dysplasia (p=0.07) as compared to placebo
Romagnoli *et al*. 2011 (*71*)	31 preterm infants with gestational age ≤32 weeks	0.5 mg FloraGLO/kg/day and 0.02 mg zeaxanthin/kg/day from seventh day of life until 40 weeks PMA or until discharge	Not effective in preventing or reducing severity retinopathy of prematurity (ROP) as compared to placebo
Dani *et al.* 2011 (*72*)	58 infants gestational age <32 weeks (mean 28 weeks)	0.14 mg FloraGLO + 0.006 mg zeaxanthin/day from day 1-7 (mean 5.5 days) until discharge (mean 47 days).	Not effective in preventing retinopathy of prematurity (ROP) as compared to placebo
Rubin *et al.* 2011 (*73*)	92 infants > 33 weeks gestational age	Formula containing 211 µg/L FloraGLO until discharge at 40 weeks post-menstrual age (PMA) and 68.7 µg/L FloraGLO from 40 to until 50 weeks PMA.	Significant increase in plasma lutein and rod photoreceptor sensitivity as compared to placebo. Significant decrease in plasma C-reactive protein (CRP) at 40 weeks as compared to placebo. Significant correlation between plasma lutein concentrations and saturated response amplitude in rod photoreceptors at 50 weeks PMA. No group differences in growth, feeding tolerance or adverse events.
Capeding *et al.* 2010 (*1*)	115 infants > 14 days	Formula with 200 µg FloraGLO Lutein per liter for 16 weeks	Growth equivalence to control formula
Romagnoli *et al.* 2010 (*56*)	10 preterm infants	Single dose of 0.5 mg FloraLGO/kg	Increase in serum lutein as compared to baseline (statistics not run)

Perrone *et al.* 2010 (*3*)	10 healthy term newborns	0.28 mg FloraGLO orally at 12 and 36 hr after birth.	Significantly lower total hydroperoxides (TH) and significantly increased biological antioxidant potential (BAP) as compared to placebo.
Bettler *et al.* 2009(*74*)	20 healthy term (37 to 42 weeks gestation) formula-fed infants between 9 and 16 days of age	Formula with 45, 120, or 225 µg FloraGLO/L	Significant increase in serum lutein and normal growth was observed as compared to unfortified, control formula.

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$.

SKIN HEALTH

Table 5. Published trials examining the effect of FloraGLO Lutein supplementation on skin health.

Trial	Cohort[a]	Protocol[b]	Effect on Skin Health[c]
Morganti *et al.* 2008 (*75*)	20 healthy females	Unspecified dose of FloraGLO Lutein for 3 months applied topically	Significant decrease in transepidermal water loss; significant increase in hydration, skin lipids, elasticity and clinical scores of wrinkling, hyperpigmentation, roughness and laxity as compared to placebo
Palombo *et al.* 2007 (*76*)	30 healthy females	10 mg FloraGLO/day orally alone or in combination with 100 ppm FloraGLO/day topically for 3 months	Significant decrease in skin lipid peroxidation; significant increase in skin lipids, hydration, and elasticity as compared to placebo
Morganti *et al.* 2004 (*32*)	20 healthy smokers	6 mg FloraGLO/day orally for 2 months	Significant increase in skin lipids as compared to baseline
Morganti *et al.* 2002 (*77*)	20 healthy females	6 mg FloraGLO/day orally for 2 months	Significant decrease in skin lipid peroxidation; significant increase in skin lipids and hydration as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$.

COGNITIVE HEALTH

Table 6. Published trials examining the effect of FloraGLO Lutein supplementation on cognitive health.

Trial	Cohort[a]	Protocol[b]	Effect on Cognitive Health[c]
Johnson *et al*. 2008 (*78*)	25 healthy women	12 mg FloraGLO/day for 4 months (with & without DHA)	Significant improvement in verbal fluency scores in DHA, lutein and combined groups; memory scores and rate of learning improved significantly in the combined treatment group as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined ast $p < 0.05$.

CONCLUSIONS

By its very nature, the vitamin and dietary supplement market relies upon claims backed by clinical evidence in order to differentiate products in the marketplace. Many of the claims that are made by dietary supplement manufacturers for products containing lutein come from clinical studies actually conducted on formulations containing FloraGLO brand Lutein. Therefore, it makes good business sense to use the lutein brand shown to actually provide such differentiating

benefits. No wonder FloraGLO Lutein is the brand of lutein chosen by so many scientists and researchers. You should definitely consider making the same choice. FloraGLO brand Lutein – the most clinically researched lutein brand worldwide.

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