DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

'03 APR 18 P1:59

APR 10 2003

Ms. Barbara H. Bauschka
Regulatory Associate
Novartis Ophthalmics
P. O. Box 930761
Atlanta, Georgia 31193-0761

Dear Ms. Bauschka:

This is in response to your letter of April 1, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Novartis Ophthalmics is making the following claims for the product Vitalux™ Eye Vitamin and Mineral Supplement:

> "...contains...found to be beneficial to eye health by the Age-Related Eye Disease Study...;"
> "...the leader in the fight against Age-Related Macular Degeneration (AMD). Novartis Ophthalmics continues to research treatments for AMD..."
> "From the leaders in the fight against AMD."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease, namely, macular degeneration. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET689

Please contact us if we may be of further assistance.

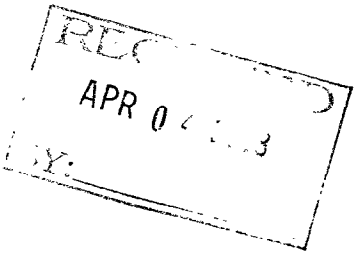
Sincerely yours,

Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Atlanta District Office, Office of Compliance, HFR-SE140

Novartis Ophthalmics, Inc.
P.O. Box 930761
Atlanta, Georgia 31193-0761

NOVARTIS
OPHTHALMICS



April 1, 2003

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park MD 20740

Re: Vitalux™ Eye Vitamin and Mineral Supplement

Dear Sir or Madam:

Pursuant to 21 CFR §101.93 Novartis Ophthalmics, Inc. is providing marketing notification as required for the product, Vitalux™ Eye Vitamin and Mineral Supplement.

On behalf of Novartis Ophthalmics, Inc. I certify that the information presented and contained in the notice is complete and accurate, and that Novartis Ophthalmics has substantiation that the statement is truthful and not misleading.

If there are any questions, or further information is required, please contact the Regulatory Affairs department at the above address, or by telephone at 770-905-1666.

Sincerely,

Barbara H. Bauschka

Barbara H. Bauschka
Regulatory Associate

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Distributor:	Novartis Ophthalmics, Inc 11695 Johns Creek Parkway Duluth GA 30097-1523
Text of Statement:	Promotes Eye Health
Dietary Ingredient(s):	Vitamin A (as beta-carotene) Vitamin C (as ascorbic acid) Vitamin E Zinc (zinc gluconate) Selenium Copper Lutein Zeaxanthin
Brand name:	Vitalux™ Eye Vitamin and Mineral Supplement

Directions: Two (2) tablets, twice daily with food.

Inactive ingredients: microcrystalline cellulose, hypromellose, methylcellulose, purified stearic acid, vegetable magnesium stearate, titanium dioxide, calcium silicate, hydroxypropyl cellulose, silicon dioxide, polyethylene glycol, caramel color, polysorbate 80, carnauba wax, ethyl vanillin, acetylated monoglycerides, xanthan powder.

Store in a dry place at room temperature.

For your protection do not use if printed seal under cap is broken or missing.

Keep out of reach of children.

L4165-A

†This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

NOVARTIS

Vitalux™

Eye Vitamin and Mineral Supplement

AREDS Formula Plus Lutein

PROMOTES EYE HEALTH†

From the leaders in the fight against AMD

120 Tablets

Supplement Facts

NOVARTIS

Serving Size: Two tablets, twice daily

Contents	Two tablets		Daily Dosage (4 tablets)	
	Amount	% Daily Value	Amount	% Daily Value
Vitamin A (as beta-carotene)	12500 IU	250%	25000 IU	500%
Vitamin C (as ascorbic acid)	250 mg	415%	500 mg	830%
Vitamin E	200 IU	667%	400 IU	1333%
Zinc (zinc gluconate)	40 mg	270%	80 mg	540%
Selenium	50 mcg	72%	100 mcg	143%
Copper	1 mg	50%	2 mg	100%
Lutein (FloraGLO®)	3 mg	*	6 mg	*
(contains approximately 0.2% Zeaxanthin)				

*Daily value not established.

®FloraGLO is a registered trademark of Kemin.

Made in Canada for: Novartis Ophthalmics, Duluth, GA 30097

Do not use if
under cap is

Vitalux™

Eye Vitamin and Mineral Supplement

AREDS Formula Plus Lutein

Tablets

NOVARTIS

Vitalux™

Eye Vitamin and Mineral Supplement

Vitamin & Coupon Inside

AREDS Formula Plus Lutein

EYE HEALTH

120 Tablets

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Copper	1 mg	50%	2 mg	100%
Lutein (FloraGLO®) (contains approximately 0.2% Zeaxanthin)	3 mg	*	6 mg	*

NOVARTIS

Take with food

methylcellulose,
stearate,
propyl
caramel
vanillin,