



JUL 11 2003

Mr. Harry August Shippy
President
Nutritional Specialties, Inc.
1456 E. Katella Avenue
Anaheim, California 92805

Dear Mr. Shippy:

This is in response to your letter of June 5, 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 Nutritional Specialties, Inc. is making the following claims for the product Brite Eyes™ With Lutein® Eye Health Formula:

“Results of the 10 year age related eye disease study (AREDS)...”
“...may reduce increase in age related lens problems.
“...help to improve vision clarity...”

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

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', written in a cursive style.

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, Los Angeles District Office, Office of Compliance, HFR-PA240

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June 5, 2003

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., S.W.
Washington, DC 20204

RE: Dietary Supplement Statement of Support Notification

To: Whom It May Concern:

Nutritional Specialties, Inc., 1456 E. Katella Ave. Anaheim, CA 92805, the distributor of the following dietary supplement products, intends to make the following statement of support: "Results of the 10 year age related eye disease study (AREDS) were published in October 2001. The results show that taking supplements providing high potencies of antioxidant vitamins and zinc helped preserve eye health. Lutein and Zeaxanthin may reduce increase in age related lens problems. Eye Bright and Billberry herbal extracts help to improve vision clarity and night vision."

This claim is being made for Beta Carotene (D-Salina Algae), Vitamin C (Ascorbic Acid), Vitamin E (D-Alpha Tocopheryl Acid Succinate), Zinc (Oxide), Copper (Gluconate), Lutein (FloraGLO®), Zeaxanthin (D-Salina Algae), Billberry Extract (Vaccinium Myrtillus), Eye Bright Extract (Euphrasia Officinalis).

Which is contained in LifeTime® Brite Eyes™ with Lutein Eye Health Formula Capsules. This submission is being made in compliance with the requirements of 21 CFR 101.93.

The undersigned is an authorized representative of Nutritional Specialties, Inc. and certifies that the information contained in this notice is complete and accurate, and that Nutritional Specialties, Inc. has substantiation that the above statement is truthful and not misleading.

Signature

Full Name

Title

Harry G. Shippy
HARRY AUGUST SHIPPY
PRESIDENT

NUTRITIONAL SPECIALTIES, INC.
1456 E. Katella Avenue • Anaheim, CA 92805
1-800-333-6168 • 714-634-9340
Fax 714-634-9347
Email: lifetime@sbcglobal.net

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with **Flora GLO®** LUTEIN

Brite Eyes™
With Lutein®
Eye Health Formula
Zeaxanthin, Bilberry, Eye Bright,
Beta carotene, Vitamins & Minerals
Dietary Supplement

60 Capsules

Supplement Facts

Serving Size: 2 Capsules
Servings Per Container: 30

Amount Per Serving	%Daily Value
Beta Carotene (D-Salvia Algae)	25,000 I.U. 500%
Vitamin C (Ascorbic Acid)	500 mg. 300%
Vitamin E (D-Alpha Tocopheryl Acid Succinate)	400 I.U. 1,333%
Zinc (Oxide)	15 mg. 100%
Copper (Gluconate)	2 mg. *
Lutein (Flora GLO®)	10 mg. *
Zeaxanthin (D-Salvia Algae)	1 mg. *
Bilberry Extract (Vaccinium Myrtillus)	100 mg. *
Eye Bright Extract (Euphrasia Officinalis)	100 mg. *

*Daily Value not established

Other Ingredients: Magnesium Stearate, Gelatin, Water.

Suggested Use: As a dietary supplement, Take 2 capsules daily.

Contains no Gluten, sugar, yeast, wheat, dairy, starch, artificial coloring, artificial flavoring or preservatives.

Result of the 10 year age related eye disease study (AREDS) were published in October 2001. The results show that taking supplements providing high potencies of antioxidant vitamins and zinc helped preserve eye health. Lutein and zeaxanthin may reduce increases in age related lens problems. Eye Brite and Bilberry herbal extracts help to improve vision clarity and night vision.

This statement has not been evaluated by the Food & Drug Administration (FDA). This product is not intended to diagnose, cure or prevent any disease.

LifeTime® products are manufactured to meet strict quality control standards and formulated using only quality industry acceptable materials. An environmentally concerned company.

Formulated and Distributed by:
LifeTime®, Nutritional Cosmetics, Inc.
Anaheim, CA 92805
www.lifetimevitamins.com