

CYANOTECH CORPORATION

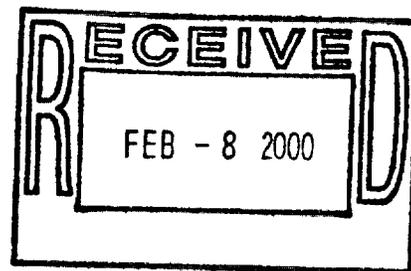
ISO 9002-94 CERTIFIED
QUALITY MANAGEMENT SYSTEM

64 '00 FEB 29 P2:14

Wednesday, February 02, 2000

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

69113



RE: Notification of statements of nutritional support (Spirulina Pacifica)

Dear Administrator,

This letter is notification of a statement of nutritional support for the dietary supplement, Spirulina Pacifica per 21 CFR section 101.93.

Description of Product:

The trade name of the product is Spirulina Pacifica, which is a spray-dried powder of *Spirulina platensis* algae. The microalgae is classified by The Bergey's Manual of Determinative Bacteriology (Ninth Edition) as follows:

<u>Group 11</u>	<u>Oxygenic Phototropic Bacteria</u>
Family	Cyanobacteria
Order	Oscillatoriales
Genus	Spirulina
Species	Platensis
Strain	Pacifica

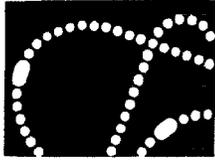
Spirulina Pacifica is sold as a powder or tablet and is produced under GMP conditions. The product has been marketed worldwide for over twenty years and has had a long history of safe use in the human diet.

Statement of Nutritional Support:

The statements: "Helps maintain healthy eyes" and "Helps support immune function" are proposed for future labels of Spirulina Pacifica. The company has reviewed the scientific evidence supporting the statements of nutritional support and has concluded that they are truthful, scientifically valid, and not misleading. A symbol will be linked to the disclaimer, "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".

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The statement "Helps maintain healthy eyes" already appears on Centrum multivitamins based on it containing 250 micrograms of lutein per dosage.

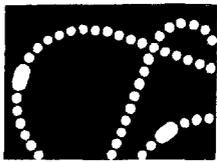
Ingredients:

Spirulina Pacifica contains approximately 0.25% beta-carotene and 0.1% zeaxanthin and is the subject of the first statement being made (see attached chromatogram). Humans cannot produce these carotenoids and they must be obtained from the diet. The carotenoid, zeaxanthin, is an isomer of lutein and essential component within the macula of the eye. Beta-carotene is converted to vitamin A and subsequently incorporated into the eye as rhodopsin. Scientific evidence indicates that consumption of foods rich in these carotenoids may decrease the risk of developing macular degeneration (Seddon *et al.*, 1994. Dietary carotenoids, vitamins A, C, and E, and advanced age-related macular degeneration. *JAMA* 272:1413-1420). Spirulina Pacifica contains a higher concentration of both beta-carotene and zeaxanthin than 100 grams of the richest vegetable sources (Pratt, 1999. Dietary prevention of age-related macular degeneration. *J. Amer. Optom. Assoc.* 70:39-47). Numerous studies implicate the necessity of rhodopsin and zeaxanthin for proper function of the eye.

Spirulina Pacifica also contains approximately 6% c-phycoyanin, sulfated polysaccharides, and glycolipids that have been implicated in antiviral, hematopoiesis and immunomodulation (Hayashi *et al.* 1996. Calcium Spirulan, and inhibitor of enveloped virus replication, from a blue-green algae Spirulina. *J. Natural Products.* 59:83-87; Mishima T. *et al.* 1998. Inhibition of tumor invasion and metastasis by calcium spirulan (Ca-SP), a novel sulfated polysaccharide derived from a blue-green alga, Spirulina platensis. *Clin. Exp. Metastasis.* 16:541-550; Babu, M. *et al.* 1995. Evaluation of chemoprevention of oral cancer with Spirulina. *Nutr. and Cancer.* 24:197-202.; Baojiang G. April 1994. Study on effect and mechanism of polysaccharides of Spirulina on body immune function improvement. *Proc. Second Asia Pacific Conf. Algal Biotech. Univ. Malaysia.* pp. 33-38; Hayashi *et al.* 1994. *J. Nutr. Sci. Vitaminol.* Numerous published papers have also linked healthy immune function to dietary carotenoids such as beta-carotene and zeaxanthin found in Spirulina Pacifica.

Intended Use:

The recommended daily dosage of Spirulina is 3 grams per day. Thus, this would provide approximately 3 milligrams of zeaxanthin, 7.5 milligrams of beta-carotene, and 180 milligrams of c-phycoyanin. The product does not present a significant or unreasonable risk of illness or injury under the conditions of use suggested in the labeling. There are no known contraindications or warnings that need to be stated.



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The firm believes it has substantiation that the statements "Helps maintain healthy eyes" and "Helps support immune function" are appropriate, truthful and not misleading for the ingredients of Spirulina Pacifica. If you have any questions or concerns, please do not hesitate to contact me.

Kind regards,

R. Todd Lorenz, Ph.D.
Scientific Director