R. Todd Lorenz
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Thursday, October 25, 2001

Office of Special Nutritionals (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street SW Washington, DC 20204

RE: Notification of statements of nutritional support for Haematococcus algae (BioAstin)

Dear Administrator,

This letter is notification of statements of nutritional support for the dietary supplement, *Haematococcus* algae per 21 CFR section 101.93. The notifying company is Nutrex Hawaii, Inc., a marketing subsidiary of Cyanotech Corporation (Kailua-Kona, HI).

Description of Product:

The algae used for the product is a spray-dried powder of *Haematococcus pluvialis* algae. The microalgae is classified as follows:

Phylum: Class: Order: Family: Genus: Species:	Chlorophyta Chlorophyceae Volvocales Haematococcaceae Haematococcus pluvialis
 species.	Piaviano

Haematococcus algae is extracted by supercritical carbon dioxide extraction, suspended into safflower oil and manufactured into gelcaps. All production processes follow cGMP conditions. The trade name for the product is BioAstin.

Statement of Nutritional Support:

The statements: "Supports joint function after heavy exercise" and "Supports skin structure during sun exposure" are proposed for future labels of BioAstin dietary supplement. Nutrex Hawaii, Inc. has substantiation from clinical trials that support these statements. The notifying 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".

Ingredients:

BioAstin contains 4 milligrams of astaxanthin per gelcap suspended in high oleic safflower oil. Humans cannot produce carotenoids and they must be obtained from the diet. Astaxanthin cannot be converted to vitamin A or other carotenoids.

Intended Use:

The recommended daily dosage of BioAstin is 1 gelcap per day, which is equivalent to 4 milligrams of astaxanthin per day. The product has been marketed worldwide for over 2 years and has had a history of safe use without adverse reaction reports. A Food Additive petition has recently been filed with the Food and Drug Administration and has been given the designation, 1A4732.

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.

Manufacturer:

Cyanotech Corporation (distributed by Nutrex Hawaii, Inc.) 73-4460 Queen Kaahumanu Highway #102 Kailua-Kona, HI 96740

Tel: 808-326-1353 Fax: 808-329-3597 The information in this notice is complete and accurate. Nutrex Hawaii, Inc. believes it has sufficient substantiation that the statements "supports joint function after heavy exercise" and "supports skin structure during sun exposure" are appropriate, truthful and not misleading for the ingredients of BioAstin. If you have any questions or concerns, please do not hesitate to contact me.

Sincerely,

R. Todd Lorenz, Ph.D.

Agent for Nutrex Hawaii, Inc. and

Cyanotech Corporation