A.F.A., Inc

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Dockets Management Branch
Food and Drug Administration
12420 Parklawn Dr. Room 1-23
Rockville, MD 20857

5-7-97

Dear Dockets Manager:

Regarding: Docket # 96N-0417) Federal Register Vol. 62, No 25- Part IV Department of Health and Human Services- Food and Drug Administration 21 CFR Ch 1-

A.F.A. Inc. is a harvester of Blue Green Algae on the Upper Klamath Lake in Oregon. We are a small business with per annum sales of over 1.5 million dollars, in the food supplement industry. A.F.A. has both Current Good Manufacturing Practices, and Good Harvesting Practices which provide for assurances of a safe and healthy food supplement.

A.F.A. supports the Industry Draft of the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplement: Proposed Rule. The contents of the rule are well designed. A.F.A. has modelled our revised Current Good Manufacturing Practices under the proposed standards and integrated these practices in the A.F.A. Policy Manual and the Health and Safety Plan.

There are refinements in this law that need to be worked on. In theory these are good ideas. A.F.A. Inc. wants to address the F.D.A.'s concerns as expressed in points 1-9 (pages 5707 & 5708) of the proposed points for consideration. A.F.A. is concerned that the law will integrate the points 1-9 (pages 5707 & 5708) of this law without the necessary inclusion of essential and key points outlined below that will protect industry from potential misinteruptation. Regardless of how this proposed law is applied- each industry must be consulted in developing the application to this standard in processing and quality control.

A.F.A. Inc, has comments to the following issues and concerns brought by the F.D.A. Points #1-9:

1. As a responsible company we believe that a reasonable standard be met for the development of defect action levels(DAL). This standard should be set in consultation with industry. A.F.A. Inc. has incorporated series of procedures for harvesting of a high quality product. Along with the harvest of the product can come unwanted cyanobacterias that have toxins in them. We aggressively test for these toxins in our product and have incorporated methodologies for the quality assurance in our product. We have been working with the Oregon Dept of Health toxicologist who is considering implementing the Canadian drinking water standard to be applied to the food

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supplement. The scientific studies he uses to base this level are from cyanobacteria with significantly differing strains from those our company harvests on the Upper Klamath Lake. The letter and intent of the food supplement law is to extend existing food industry practices into the food supplements. We request that drinking water standards not be used in application DAL. It is further requested the DAL action levels not be applied without specific quantified analysis of the problem with a standardised analytical methodology, *on the specific strain of the botanical in question.* (Attachment #1)

2. A.F.A. believes that there must be a generally available ***standardised*** analytical methodology for testing, that does not register false positives (Attachment #1). This testing methodology must be standardised by the AOAC. It is important to provide quality control of the product, a reasonable interim standard agreed upon by industry and health officials, using current methodologies might serve as an acceptable alternative.

4. A.F.A. believes that self regulating industries and associations of food supplement manufacturers or handlers, establishing internally high standards for their product, be allowed to submit their CGMP to the FDA, for acceptance. Industries that have incorporated safeguards and precautions known to the industrial community must be responsible for following through with the Good Manufacturing Practice, on a daily basis. The terminology on a day to day basis should not mean that a batch is indicative of a day. In the blue green algae industry, a batch may the harvest from the 10:00 pm through two days of harvest until 5000 gallons is harvested. This product is stored, chilled and homogeneously mixed. The monitoring of this product through the production and handling should be tracked and tested as established in the CGMPs on a day to day basis. A.F.A. Inc is concerned about placing into law a redefinition of a batch, as a daily figure.

4. If there is no counterpart in part 110 in the section 402(g), specific studies to determine these levels should be conducted by the National Institute of Health to arrive at the acceptable standard. It is our concern that as pointed out in item one- the water standard might be applied. It appears to be the responsibility of the Office of Dietary Supplement within the National Institutes of Health:

> (2). TO PROMOTE SCIENTIFIC STUDY OF THE BENEFITS OF DIETARY SUPPLEMENTS IN MAINTAINING HEALTH AND PREVENTING CHRONIC DISEASE AND OTHER HEALTH RELATED CONDITIONS.

6. A.F.A. Inc. promoted and assisted in sponsoring an event on April 26, 1997, at the Shilo Inn in Klamath Falls where we heard two of the leading national experts in Toxicology: Dr. Wayne Carmichael and Dr. Donald Anderson state that we should conduct very costly daily tests for toxins that have never seen in our product. Different strains of cyanobacteria have differing levels of toxins in differing locations. Item #6 on page 5709 Vol 62, No 25 requests comments on whether GMP should identify evaluate and respond to potential safety concerns with dietary ingredients. If we were to listen to the recommendations of these experts we would be conducting over $80,000.00 of testing per annum for toxins never found in our product to date after 14 years of testing. Testing for proven safety concerns is the responsibility of each company.

8. We need to be able to work with the FDA in developing the CGMP, for our industry. A.F.A. wants to work with the F.D.A. in developing acceptable standards. The Oregon Dept. of Agriculture and the Oregon Dept. of Health embargoed our entire inventory of product based upon a felonious report by a former disgruntled employee that have essentially the same product, same harvest, same lake same area The product tested out as clear of the contaminant- Microcystin- See attachments #3 (copies of the release of embargo and the testing results)- however due to the action of the Oregon Food Safety Division in applying a rule very similar to that proposed in item #8, we have suffered a financial burden. A.F.A. Inc., because of our first hand experience, believes that whenever the FDA declares any product an action item or consider applying the Hazard Analysis and Critial Control Points (HACCP), they must work with manufacturers of these companies. From our own experience, it was very difficult to hear the FDA was asking distributors questions, when we were not contacted to provide the information.

- Both the FDA- Mr. Nichols Duy(Special Nutritionals FDA) and Mr. Duncan Gilroy(Oregon Dept. of Health) have taken the liberty to call many of our large active accounts asking them directly if they sell our blue green algae product to children. These questions were not levelled to any distributor of competitors products. A.F.A. Inc. has wanted to see uniform treatment. With the official titles and positions these men have, it is important for them not to represent themselves to our marketplace in this manner. If a market survey is called for, it should be conducted by a third party marketing research firm in a professional manner. The design of the market survey should be developed so the information is gathered in a way that the industry is not hurt. If a retailer is placing product on the shelf, he may not know who is purchasing this product. These major retailers and resellers who are purchasing our algae are becoming alerted and have an extra level of concern because of the manner in which they were contacted.

- We have lost a major account because of the statements made by the Oregon Food Safety Division to account representatives, prior to the low clean test results in our product.

The FDA requests comment on how costly it would be to conform to the industry submission. To comply with the Industry draft of the proposed ruling should be considered the cost of doing business, for all food supplement businesses. Needless testing, as identified in item #5 of the above, and the cost of the FDA conducting market surveys to individually identified corporate accounts however, is very costly, to targeted businesses.

In conclusion, we support the Industry draft of the Proposed rules for Good Manufacturing Procedures. Thank-you for your time and thoughtful consideration. A.F.A. is requesting to be on the mailing list to recieve copies of any proposed regulations issued through this process.

Sincerely,

Susan Blevins, QAQC
A.F.A. Inc.

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FAX TRANSMITTAL

DATE: _____

TIME: _____
(Pacific)

A.F.A., inc.

(Aphanizomenon Flos Aquae)
Supplier of Upper Klamath Lake Algae

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Total # pgs. sent ___ (including this page) 1-202-260-9957

TO: Sharon Ross - FDA

FROM: _____ FAX # (503) 783-3360

MESSAGE: Attached are ammended comments

(... FAX in its entirety.)

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