DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
REGION VI

December 12, 1986

REF: 87-DAL-06

OFFICE OF THE REGIONAL
FOOD AND DRUG DIRECTOR
3032 BRYAN STREET
DALLAS, TEXAS 75204-6191
TELEPHONE: 214-767-0317

REGULATORY LETTER

HAND DELIVERED

Mr. Robert M. Adler, II, Chairman
United Sciences of America, Inc.
2724 Realty Road
Carrollton, Texas 75006

Dear Mr. Adler:

An inspection conducted in May 1986 of your facility at the above address and subsequent investigation by the Food and Drug Administration (FDA) has disclosed that your firm is marketing the products Master Formula, Formula Plus, Calorie Control Formula and Fiber Energy Bar. The promotional materials such as printed brochures and a video tape which we have reviewed represent and suggest that these products are useful in preventing and treating serious disease conditions.

Although you refused to provide specific product formulations at the time of our inspection, we conclude, based on our review ot other materials, that your products contain in part: Master Formula - vitamins A, C, E, beta carotene, selenium and cysteine, calcium, magnesium, mixed tocopherols, L-glutathione, selenomethionine, L-taurine, PABA (Para Aminobenzoic Acid), Allium Sativum (garlic extract), and bioflavonoids; Calorie Control Formula - protein from various sources, "Ultraprotein" blend; fiber from various sources and fructose; Fiber Energy Bar - fiber from various sources, and Formula Plus - eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), Allium sativum (garlic extract), d-alpha-tocopherol and ascorbyl palmitate.

A brief review of the labeling available to us indicates that these products are offered as safe and effective for the prevention and/or treatment of conditions such as (examples only):

Master Formula - protects against cellular toxins and pollutants through use of anti-oxidants, antithrombotic effect, eliminates chronic degenerative diseases, reduces blood pressure, protects from cancer, protects from free radicals, reduces risk of rheumatoid arthritis, lowers uric acid levels, utilizes blood sugar better, converts insulin to its active form, stimulates collagen production, has toxic effect against rhinovirus, shortens duration and severity of colds, prevents AIDS, stimulates and strengthens immune system, reduces frequency and severity ot asthmatic attacks, helps colitis, reduces the negative effects of estrogen, improves acne, prevents cancer, reduces dangerous free radical diseases such as alcoholism,

protects lungs from smoke and reduces risk of emphysema, reduces risk of kidney stone formation.

Formula Plus - helps lower blood pressure, provides antithrombotic activity, inhibits breast tumors (in mice), protects tissues from inflammation, won't increase your risk of cancer, has beneficial effects on vision, raises immunity, has beneficial effect on PMS symptoms, prevents cancer.

Calorie Control Formula - reduces insulin response.

Fiber Energy Bar - lowers cholesterol, reduces risk of diabetes, treats diabetes, helps blood sugar, controls hyperglycemia, delays the deterioration of the immune system, prevents AIDS, lowers incidence of heart disease, and stabilizes blood sugar.

Because such labeling includes statements which represent and suggest that the articles are intended to be used in the cure, mitigation, treatment or prevention of disease, or are intended to affect the structure or any function of the body of man, these products are drugs as defined in section (§) 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Further, we are unaware of any substantial evidence which demonstrates that these drugs are generally recognized as safe and effective for their intended uses. Accordingly, continued marketing of these drugs constitutes serious violations of the Act as follows:

SECTION	BRIEF DESCRIPTION
502(a)	The articles are misbranded in that their labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the articles are safe and effective for the prevention or treatment of those conditions specified above, or for any other drug uses.
502(f)(1)	The articles are misbranded in that their labeling fails to bear adequate directions for the uses for which they are represented or suggested, as described above, and they are not exempt from this requirement under regulation 21 CFR 201.115 since the articles are new drugs within the meaning of § 201(p) and no approvals of applications filed pursuant to § 505(b) are effective for the drugs. The articles are further misbranded in that their labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5 since most of the conditions for which they are offered are not amenable to self-diagnosis and treatment by the laity; therefore, adequate directions for use cannot be written under which the layman can use these drugs safely and for the purposes for which they are intended.

505(a) The articles are drugs within the meaning of § 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under § 505(a) of the Act, since they are new drugs within the meaning of § 201(p) of the Act and no approvals for applications filed pursuant to § 505(b) are effective for such drugs.

Removal of all statements which represent and suggest that the articles are intended to be used in the cure, mitigation, treatment or prevention of disease, or are intended to affect the structure or any function of the body of man or other animals would transfer your products into the category of foods as defined by § 201(f) of the Act, and the products would then be in violation of Chapter Four of the Act as follows:

SECTION	DESCRIPTION
402(b)(1)	"Fiber Enegy Bar" coded 81396 is adulterated in that our analysis revealed that the product contained less protein per serving (55.2% on original and 63.9% on check analysis) than declared.
403(a)(1)	The products are misbranded in that their labeling bears numerous false and misleading claims regarding alleged properties and functions of vitamins, minerals, other nutrients, and substances (e.g., "vitamin E and selenium have an enhancing or synergistic effect on each other when precisely balanced", "ultra protein blend... provides the highest protein efficiency (P.E.R.) of any plant or seafood source", "calcium may be assimilated almost twice as efficiently in the body if taken in a combined multivitamin form than if taken alone"). There is no scientific evidence to support such claims and no such dietary efficacy has been demonstrated for these nutrients and substances.
403(a) and (j)	The product "Calorie Control Formula" is falsely represented as a "low calorie" drink in that it fails to comply with the requirements of Title 21 CFR 105.66(c) which defines a low calorie food as one which provides no more than 40 calories per serving and no more than 0.4 calories per gram.
403(j)	The products "Calorie Control Formula" and "Master Formula" are represented as hypoallergenic foods, however, their labels fail to bear the information required by Title 21 CFR 105.62.

In addition to these more serious violations our review also shows the following label violations which should receive prompt attention.

Fiber Energy Bar, carton label

1. The term "Fiber Energy Bar" is not an appropriate identity statement for the product. We would not object to the name "A Sweetened Oat, Rice, Barley and Cottonseed Bar" or another sufficiently descriptive name which explains the basic nature of the food, its characterizing properties or ingredients.

2. The nutrition labeling must be declared in the complete format prescribed by Title 21 CFR 101.9.

   The declarations of percentage of U.S. RDA's required by § 101.9(c)(7) and the number of servings per container required by § 101.9(c)(2) are not declared on the label.

3. The specific form of the "cottonseed protein" and "chickpea protein" should be declared in the ingredient statement (e.g., "cottonseed protein isolate", "chickpea protein concentrate", or "cottonseed flour").

4. The declaration of dietary fiber content per serving should not be a part of the nutrition labeling but may be declared as a separate statement elsewhere on the label.

5. "Carrot fiber" and "yucca fiber" and "apple bran" are not common or usual names of any food ingredient.

6. Guar gum is permitted to be added to foods under the provisions of Title 21 CFR 184.1339. Guar gum may be used as an emulsifier, a stabilizer, thickener and formulation aid at the specific levels stated in the regulation. There is no provision for its use as a source of fiber.

   The specific form of the cellulose used is not declared in the ingredient statement however, sodium carboxymethylcellulose is regulated by Title 21 CFR 182.1745 and methycellulose is regulated by Title 21 CFR 182.1480. Although there are no explicit restrictions on their uses in foods, the data which formed the basis for these regulations did not include its use as a source of fiber.

   We therefore, conclude that the addition of guar gum, and methycellulose or sodium carboxymethylcellulose (if they are being used in the product) for the purpose of adding fiber is not in compliance with the applicable regulations. If you wish to pursue this matter, you may wish to submit a petition under Title 21 CFR 170.35 or 171.1 for the use of these substances as sources of fiber.

7. The specific source of the lecithin should be declared in the ingredient statement as required by Title 21 CFR 101.4(b) (e.g. "soy lecithin").

8. The type size of the ingredient statement, manufacturer's name, and nutrition information fail to meet the minimum 1/16 inch height requirements of Title 21 CFR 101.2(c).

9. The type size of the quantity of contents statement fails to meet the minimum 1/8 inch height requirement of Title 21 CFR 101.105(i)(2).

Formula Plus

1. Eicosapentanoic acid (EPA) and docosahexaenoic acid (DHA) are not deemed to be generally recognized as safe nor are there present food additive regulations which prescribe conditions for their safe use in foods.

2. You should be aware that we expect to soon publish a proposal regarding the use of health claims on food labels in the Federal Register. The present claims on the label regarding the usefulness of EPA and DHA in the diet may need to be revised in accord with the provisions of the proposed policy statement.

3. The EPA, DHA, and allium sativum (garlic) should not be declared in terms of potency (milligrams) because they are not essential and therefore, are not dietary supplements. They should be declared only in the ingredient statement in descending order of predominance by weight.

4. Carob is not presently permitted for use in foods as a color. In addition, the statement "colored naturally with carob" is incorrect. Since all added colors result in an artificially colored food, we object to the declaration of any added color as natural.

Calorie Control Formula

1. The percentage of U.S. RDA of phosphorus in the nutrition labeling is not declared to the nearest 5 percent increment as required by Title 21 CFR 101.9(c)(7)(i).

2. The individual ingredients of the "surimi" must be declared in the ingredient statement, either parenthetically or separately in descending order of predominance by weight as required by Title 21 CFR 101.4(b)(2).

3. The terms "Apple Fiber" and "Yucca Fiber" are not appropriate common or usual names for food ingredients. The common or usual name of the specific ingredients used must be declared in the ingredient statement.

4. The specific source of the lecithin should be declared in the ingredient statement (e.g. "soy lecithin").

5. The term "French Vanilla" is an inappropriate flavor designation for the product.

6. The declaration of fiber per serving should not be a part of the nutrition labeling format, but may be declared as a separate statement on the label.

Master Formula

1. The principal display panel fails to bear an identity statement (e.g. "Dietary Supplement of _____" or "Multivitamin - Multimineral Supplement").

2. Bioflavonoids, PABA (para aminobenzoic acid), and allium sativum (garlic) are not essential nutrients and therefore should not be declared in terms of potency (milligrams) but should be declared in the ingredient statement in descending order of predominance.

3. Taurine is not deemed to be generally recognized as safe, nor is there a present food additive regulation which prescribes conditions for its safe use in foods. If you have information which demonstrates its safety, this information should be submitted in the format of a food additive petition, Title 21 CFR 171.1, or a petition for generally recognized as safe status, Title 21 CFR 170.30.

The violations listed above are not intended to be all-inclusive. It is your responsibility to market products which are in full compliance with the Act.

We request that you schedule a meeting with Daniel L. Michels, Director, Office of Compliance, Center for Drugs and Biologics, Rockville, MD 20855, telephone number 301-295-8054, within ten (10) days of your receipt of this letter to inform us of what action you intend taking to bring your products into compliance with the law. If corrective action is not undertaken promptly, FDA is prepared to initiate legal action to enforce the law. The Act provides for seizure of violative products or injunction against the manufacturer or distributor of these products (21 USC 332 and 334).

Sincerely yours,

Donald C. Healton

DONALD C. HEALTON
Regional Director
Food and Drug Administration

cc: Jerris Leonard, President