

WNG 7-13-88



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
50 United Nations Plaza, Room 526
San Francisco, California 94102
Telephone: 415-556-2062

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 24, 1988

Our Reference No. 29-36080

Proteus Corporation
dba Earthrise Company
830 Fifth Street
San Rafael, CA 94901

SAN 88-19

Attention: Robert W. Hendrikson, President

REGULATORY LETTER

Dear Mr. Henrikson:

On January 21, 1988, FDA Investigator Kathryn D. Macropol conducted an inspection of your facility at 75 Pelican Way, Units F & G, San Rafael, California. The inspection revealed that you are distributing a number of products which are manufactured and labeled to your specifications by several contract firms. Review of the labeling and promotional materials for Imun-N-Sure Colds & Flu Season Protection Formula, Step Ahead PMS Nutritional Supplement Plus Spirulina, Super-Beta Beta Carotene and Anti-Oxidants With Spirulina & Herbs has revealed that the products are drugs as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

These products are in serious violation of the Act, as follows:

SECTION

BRIEF DESCRIPTION

502(a)

Misbranded in that the labeling for:

- (1) Imun-N-Sure Colds & Flu Season Protection Formula represents and suggests that the product raises "the body's protective system with perfectly balanced herbs and potent superfoods" when a cold or flu feels imminent, when resistance is low, or when one is at risk; that the product "insures against depletion of any of the critical deficiencies that may impair the work of the body's protective system"; prevents zinc deficiencies which lead to weakened thymus glands and reduction in the body's

resistance; "enlarges blood vessels for easier circulation"; and protects against germs;

(2) Step Ahead PMS Nutritional Supplement Plus Spirulina represents and suggests that the product is effective for pre-menstrual stress without the use of drugs; and that the product, through the presence of spirulina, helps to regulate prostaglandins, the hormone-like substances in women;

(3) Super-Beta Beta Carotene and Anti-Oxidants represents and suggests that the product protects against free radicals, which come from stress caused by pollution, toxic chemicals, drugs, poor dietary habits, infections, physical and emotional stress, and which lead to illness, cancer and accelerated aging; that the product helps the body produce more anti-oxidants internally, thereby reinforcing the immune system; and that the product stimulates white blood cells which are essential factors in the immune system, and normalizes the balance of prostaglandins and hormones;

which statements are false and misleading or otherwise contrary to fact since the drugs are not adequate and effective for such purposes.

502(a)

Futher, the articles are misbranded in that promotional literature, entitled "The Purity of Earthrise Spirulina", claims that "Earthrise Farms Spirulina meets all current USA Food and Drug Administration guidelines for spirulina . . .", which statement is false and misleading.

502(f)(1)

Misbranded in that the labeling for Imun-N-Sure Colds & Flu Season Protection Formula, Step Ahead PMS Nutritional Supplement Plus Spirulina, Super-Beta Beta Carotene and Anti-Oxidants With Spirulina & Herbs fails to bear adequate directions for use for the purposes for which the drugs are intended, and no such directions can be written.

505(a)

Imun-N-Sure Colds & Flu Season Protection Formula, Step Ahead PMS Nutritional Supplement Plus Spirulina, and Super-Beta Beta Carotene and

Anti-Oxidants With Spirulina & Herbs are new drugs within the meaning of section 201(p) of the Act, and may not be introduced into interstate commerce since no approval of an application filed pursuant to section 505(b) is effective for such drugs.

Furthermore, all of your spirulina-containing products, including any not specified above, are misbranded by newsletters and promotional literature, some of which bear your by-line, distributed by Earthrise Company. Examples of such literature include: "Discover the Benefits of Earthrise Spirulina"; "New Clinical Research with Spirulina"; "Three billion year old expert shares secrets"; "Ancient Algae, Spirulina, Yields New Medical Discoveries".

These promotional materials are replete with claims that spirulina: reduces the incidence of cancer; supports the body's natural defenses against diseases; aids in the production of prostaglandins (master hormones that control many body functions); aids women in building bone mass and in combating osteoporosis; accelerates wound healing; contains phycocyanin which stimulates the immune system; contains gamma-linolenic acid which prevents degenerative diseases and other health problems, and helps conditions of heart disease, premenstrual stress, obesity and arthritis; contains beta-carotene which decreases the risk of cancer, and reduces the number and size of tumors or causes them to disappear; decreases the levels of cholesterol, triglyceride, and LDL (low density lipoproteins); contains antibiotic substances (unidentified) which inhibit the growth of bacteria, yeast, and fungi, and provides extra energy, stamina and mental alertness.

We request that you take immediate action to correct these violations. If such action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions provided under the law. These include seizure and injunction.

We request that your reply include:

- (1) An estimate of the quantities of the drugs manufactured or received within the past twelve (12) months.
- (2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.
- (3) An estimate of the amounts of the drugs that are in inventory under your control and your estimate of the amounts in distribution channels outside your control.
- (4) The date of discontinuance in the event that you have already discontinued marketing these drug products.
- (5) Your intention with respect to the disposition of your inventories and outside stocks in trade channels.

Please advise us within ten (10) days as to the specific actions taken, or intended to be taken, including measures to prevent the recurrence of the violations, and an explanation of any foreseen delays in correcting the violations. Your response should be directed to Mr. Rod Chu, Compliance Officer.

The violations listed above are not intended to be all inclusive. It is your responsibility as a drug manufacturer/distributor to ensure that all of your products are the subject of approved new drug applications wherever appropriate, and that the products are properly labeled for their intended uses.

Sincerely, _____



Ronald M. Johnson
District Director
San Francisco District

cc: [REDACTED]
[REDACTED]
[REDACTED]