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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 206-486-8788

August 29, 1989

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to: Regulatory Letter SEA 89-18

Harold and Ellen Wilfley, Owners
Bio Water Products
16532 S. Union Mills Road
Mulino, Oregon 97042

REGULATORY LETTER

Dear Mr. and Mrs. Wilfley:

This letter is written in reference to the marketing of Bio Ge Oxy 132, and Bio Co-Q10 by your firm.

Promotional literature (labeling) distributed with Bio Ge Oxy 132 states or suggests that the product is useful in treating or preventing AIDS, cancer, cardiovascular disease, heart disease, diabetes, leukemia, epilepsy, arthritis, in restoring sexual function, preventing miscarriages, restoring eyesight and hearing, pain, angina pectoris, stroke, hepatitis, psoriasis, anemia, wounds, hypertension, depression, headaches, mercury and cadmium poisoning, cataracts, asthma and that it helps repair immune responses.

Promotional literature (labeling) distributed with Bio Co-Q10 states or suggests that the product is useful in treating or preventing congestive heart failure, cardiac arrhythmias, heart attack, high blood pressure, ischemic or hypoxic injury, periodontal disease, drug toxicity, in increasing resistance to bacterial, viral, and yeast infections including Candida Albicans, extending the lifespan and stimulating Immunologic responses.

Because such labeling includes statements which represent and suggest that Bio Ge Oxy 132, and Bio Co-Q10 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 within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act. Further, we are unaware of any substantial scientific evidence which documents that these drugs are generally recognized as safe and effective for the previously mentioned disease conditions or any other disease conditions. The drugs are therefore new drugs

within the meaning of Section 201(p). Accordingly, marketing of these drugs is a violation of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION	BRIEF DESCRIPTION
502(a)	The articles of drug are misbranded in that their labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that these articles are safe and effective for the treatment of the diseases or medical conditions listed in the labeling for each drug.
502(f)(1)	The articles of drug are misbranded in that their labeling fails to bear adequate directions for use in the treatment of the diseases or medical conditions for which each article is represented or suggested, and they are not exempt from this requirement under Regulation 21 CFR 201.115 since each article is a new drug within the meaning of Section 201(p) and no approval of any application filed pursuant to Section 505(b) is effective for each drug. Each article of drug is further misbranded in that its labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5 since 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, Bio Ge Oxy 132, and Bio Co-Q10 are drugs within the meaning of Section 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Federal Food, Drug,

and Cosmetic Act, since they are new drugs within the meaning of Section 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) is effective for each such drug.

Furthermore the articles, Bio Ge Oxy 132 and Bio Co-Q10 are labeled and represented as dietary supplements, foods within the meaning of Sections 201(f), 411(a)(2) and 411(c)(1) of the Federal Food, Drug, and Cosmetic Act, and are in serious violation of the Act as follows:

402(a)(2)(C) — In that the articles are adulterated within the meaning of the Act since they bear or contain food additives which are unsafe within the meaning of Section 409(a) since their presence in the articles are not in conformity with any regulation or exemption in effect under Section 409(b) as follows:

Bio Ge Oxy 132 is labeled to contain 25 mg Ge Oxy 132 (99% Organic Germanium Bio Carboxyethyl (Germanium Sesquioxide)) yielding 10.67 mg of Germanium.

Bio Co-Q10 is labeled to contain Coenzyme Q10 50 mg.

Germanium Bio Carboxyethyl (Germanium Sesquioxide) and Coenzyme Q10 are each unsafe food additives within the meaning of Section 409(a) since it and its intended use are not in conformity with a regulation or exemption in effect pursuant to Section 409(b).

403(a)(1) and 201(n)
21 CFR 101.9(i)(1) — In that the accompanying literature (labeling) misbrands the articles by falsely representing, suggesting, or implying that these foods are adequate or effective in the prevention, cure, mitigation, or treatment of the labeled conditions as previously listed in this letter.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the

marketing of these products. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 U.S.C. 332 and 334).

Your response should include:

1) An estimate of the quantity of the products 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 amount of the products that are in inventory under your control and your estimate of the amount in distribution channels outside your control.

4) The date of discontinuance in the event that you have already discontinued marketing these products.

5) Your intention with respect to the disposition of your inventories and outside stocks in trade channels.

Your reply should be directed to Donald E. Peterson, Compliance Officer at this address.

Sincerely yours,

Roger Lowell
District Director

Enclosures: