



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Wax 3-26-
Public Health Service

March 20, 1990

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

Telephone: 206-486-8788

In reply refer to: Regulatory Letter SEA 90-16

Kenneth D. Scott, President
Highland Laboratories, Incorporated
110 South Garfield Street
Mt. Angel, Oregon 97362

REGULATORY LETTER

Dear Mr. Scott:

This letter is written in reference to the marketing of Immune Plus, Ge Oxy 132 Capsules, Co Q10 Capsules, Cholesterol Reducer Tablets, Pure Gamma Oryzanol Capsules, Fat Burner Tablets, Smilax Extract Plus, Smilax Officinalis Extract, Women's Smilax with Royal Jelly, B-12 Folic Acid Drops, and Colonic Rinse Capsules by your firm.

Promotional material ("labeling" as the term is defined in Section 201(m) of the Federal Food, Drug, and Cosmetic Act) distributed with Immune Plus states or suggests that your product is useful in enhancing the immune system, preventing cancer, and combating angina pectoris.

Promotional material (labeling) distributed with Ge Oxy 132 states or suggests that germanium strengthens the immune system and controls and reverses chronic allergies, hepatitis, cancer, leukemia, cataracts, cardiovascular disease, asthma, and heavy metal poisoning, and removes toxins and poisons from the system.

Promotional material (labeling) distributed with Co Q10 (Coenzyme Q10) states or suggests that Coenzyme Q10 is useful in treating or preventing congestive heart failure, cardiac arrhythmias, heart attacks, lowering blood pressure, reducing ischemic or hypoxic injury, periodontal disease, for extending the lifespan, and preventing toxicity from drugs.

Promotional material (labeling) distributed with Cholesterol Reducer states or suggests that the product is useful in preventing cholesterol absorption and reducing serum cholesterol in the total absence of dietary cholesterol. In addition, the product name, "Cholesterol Reducer," implies reduction of cholesterol levels.

Promotional material (labeling) distributed with Pure Gamma Oryzanol Capsules states or suggests that the product is useful in increasing muscle growth, strength, fat burning, and as an anti-oxidant.

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Promotional material (labeling) distributed with Fat Burner Tablets states or suggests that the product is useful for reducing cholesterol, burning off fat, and adding extra choline for the synapses of brain cells. In addition, the product name, "Fat Burner," implies reduction of body fat levels.

Promotional material (labeling) distributed with Smilax Extract Plus states or suggests that the product is a substitute for steroids and is an aphrodisiac, and is useful for treating impotence, low back pain, low sexual energy, weakness, dizziness, weak legs, tendon and muscle soreness, premature ejaculation, infertility, frequent urination, tiredness, and most "male" problems. It further claims to increase strength levels, quicken recuperative power, increase muscle hardness, treat cuts, increase aggressiveness, increase energy, and increase oxygen utilization.

Promotional material (labeling) distributed with Smilax Officinalis Extract states or suggests the product increases strength levels, quickens recuperative power, increases muscle hardness, and increases aggressiveness.

Promotional material (labeling) distributed with Women's Smilax with Royal Jelly states or suggests the product is useful in treating or preventing muscle fatigue and soreness, increasing energy, endurance, and muscle strength, alleviating symptoms of PMS, irritability, menopause, menstrual irregularity, pain, and soreness, and enhancing sexuality and creativity.

Promotional material (labeling) distributed with B-12 Folic Acid Sublingual Drops states or suggests usefulness in preventing lung cancer.

Promotional material (labeling) distributed with Colonic Rinse states or suggests the product is useful in treating or preventing heavy metal absorption, soothing irritations, and hastening the closure of lesions that have begun to weep or bleed.

Because such labeling includes statements that 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 within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Further, we are unaware of any substantial scientific evidence documenting that these drugs are generally recognized as safe and effective for

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the above-referenced 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 Act as follows:

<u>SECTION</u>	<u>BRIEF DESCRIPTION</u>
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 the articles are safe and effective for the treatment of the above-listed diseases or conditions.
502(f)(1)	<p>The articles of drug are misbranded in that their labeling fails to bear adequate directions for use in the treatment of the above-listed diseases or conditions in its promotional material, and they are not exempt from this requirement under <u>Code of Federal Regulations</u>, Title 21, Part 201.115 (21 CFR 201.115), since the articles are new drugs within the meaning of Section 201(p) and no approval of any application filed pursuant to Section 505(b) is effective for these drugs.</p> <p>The articles of drug, Immune Plus, Ge Oxy 132 Capsules, Co Q10 Capsules, Cholesterol Reducer Tablets, Pure Gamma Oryzanol Capsules, Fat Burner Tablets, Smilax Extract Plus, Smilax Officinalis Extract, Women's Smilax with Royal Jelly, B-12 Folic Acid Drops, and Colonic Rinse Capsules, 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 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 purpose for which they are intended.</p>
505(a)	The articles, Immune Plus, Ge Oxy 132 Capsules, Co Q10 Capsules, Cholesterol Reducer Tablets, Pure Gamma Oryzanol Capsules, Fat Burner Tablets, Smilax Extract Plus, Smilax Officinalis Extract, Women's Smilax with Royal Jelly, B-12 Folic Acid Drops, and Colonic Rinse Capsules, are drugs within the meaning of Section 201(g) of the Act which may not be introduced or delivered for introduction into

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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 any applications filed pursuant to Section 505(b) are effective for such drugs.

In addition, the labels for the Immune Plus and Ge Oxy 132 Capsules state that the products are dietary supplements and, as such, are in serious violation of the Act as follows:

<u>SECTION</u>	<u>BRIEF DESCRIPTION</u>
402(a)(2)(C)	In that the articles are adulterated within the meaning of the Act since they bear or contain the food additives germanium sesquioxide and/or germanium bis-carboxyethyl sesquioxide which are unsafe within the meaning of Section 409(a) since their presence in the articles is not in conformity with any regulation or exemption in effect under Section 409.

This agency has not reviewed your entire product line. It is your responsibility to ensure that all of your products are in compliance with the Federal Food, Drug and Cosmetic Act.

We request that you take prompt action to correct these violations. If such action is not taken, 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 and/or injunction against the manufacturer or distributor of illegal products (21 U.S.C. 332 and 334).

In addition, during review of the labels for B-12 Folic Acid Drops and Co Q10 Capsules by the Center for Food Safety and Applied Nutrition, they commented that in their view that folic acid at greater than 400 mcg (800 mcg for pregnant women), and coenzyme Q10 are not sanctioned by a regulation nor are they deemed to be Generally Recognized As Safe (GRAS).

Please advise us in writing within ten (10) days of your receipt of this letter stating the actions you have taken or intend to take, including measures to prevent the recurrence of the

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violations, and an explanation of any potential delays in correcting the violations that may occur. Your reply should be sent to Donald B. Peterson, Compliance Officer, at the above address.

Sincerely,

Joseph R. Baca
Director, Compliance Branch

Enclosure:
Federal Food, Drug and Cosmetic Act

