DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015-2
Telephone (213) 252-7583

REGULATORY LETTER

June 14, 1989

Bala B. Patel, President
Nutritional & Biological
Research Company
21424 North 7th Avenue, #3
Phoenix, AZ 85027

LA 32-9

Dear Mrs. Patel:

During an inspection of your firm between January 24 and February 14, 1989 our investigator documented that you are engaged in the own-label distribution of food supplements which contain orotic acids. We consider these products, containing magnesium orotate and calcium orotate, to be in serious violation of the Federal Food, Drug, and Cosmetic Act.

Furthermore, promotional material (labeling) distributed by your firm, states or suggests that VITALI-T affects the immune system and is useful in the prevention or treatment of cancer and acquired immunodeficiency syndrome (AIDS); PRO GEST (aka BIO GEST), as a stomach acidifier, will treat such diseases as diabetes, epilepsy, mental disturbances, arthritis, anemia, allergies, and constipation as well as achlorhydria; VASCU PLEX (aka BIO VAS) will treat such diseases as circulatory/heart related problems; and calcium orotate tablets (NUTRI CAL aka ORO CAL) are effective in the treatment of decalcification diseases, psoriasis, arthritis, arteriosclerosis, retinitis, chronic hepatitis and colitis.

Because such labeling includes statements which represent and suggest that these products 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 above referenced disease conditions or any other disease conditions. 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 the articles are safe and effective for the treatment of the above listed disease conditions.
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 above listed disease conditions for which the articles are represented or suggested, and they are not exempt from this requirement under Regulation 21 CFR 201.115 since the articles are new drugs within the meaning of Section 201(p) and no approval of any applications filed pursuant to Section 505(b) are effective for the drugs. The articles of drug Orotate Tablets and Betaine Hydrochloride Tablets 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 purposes for which they are intended.
505(a)	The articles, Orotate Tablets and Betaine Hydrochloride Tablets, 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 any applications filed pursuant to Section 505(b) are effective for such drugs.
402(a)(2)(C)	The products, containing magnesium orotate and calcium orotate, are adulterated within the meaning of Section 402(a)(2)(C) in that they are food additives which are unsafe within the meaning of Section 409(a), since their use and intended use are not in conformity with a regulation or exemption in effect pursuant to Section 409.

For your information, in U. S. v. Article of Food...Orotic Acid, 414F Supp. 793 (E.D. Mo. 1976), a U. S. District Court found that orotic acid and its salts are not generally recognized among experts qualified by scientific training and experience to evaluate their safety, as having been shown through scientific procedures or experience based on common use in food, to be safe under the conditions of intended use. The Court further found that knowledgeable nutritionists and physicians do not accept orotic acid as having either nutritional or therapeutic properties and there is no evidence that it is needed in the human diet to supplement the body's synthesis of orotic acid.

We are unaware of adequate data to establish the effectiveness of the ingredients found in products like PRO GEST aka BIO GEST (betaine hydrochloride, pepsin and raw stomach substance) for treating achlorhydria and hypochlorhydria, and because such conditions are asymptomatic, any OTC drug product that is labeled, represented or promoted for use as a stomach acidifier is not generally recognized as safe and effective. For more details refer to the enclosed copy of the Federal Register of August 17, 1988 (effective date February 17, 1989) which contains the final rule for stomach acidifier drug products for over-the-counter human use. Therefore, PRO GEST aka BIO GEST is considered to be a new drug and misbranded and is in violation of Sections 505 and 502 of the Federal Food, Drug, and Cosmetic Act respectively as discussed above.

The above enumeration of deficiencies should not be construed as an all inclusive list of violations which may be in existence with your products and product labeling. It is your responsibility to ensure that all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder are being met.

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 food and drug products and use of the misbranding labeling. 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 and/or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

Your response should be directed to:

Mr. Thomas L. Sawyer
Director, Compliance Branch
U.S. Food and Drug Administration
1521 West Pico Boulevard
Los Angeles, CA 90015

Sincerely,

George J. Gerstenberg
District Director
Los Angeles District Office

Enclosure

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