DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE
BROOKLYN, NEW YORK 11232-1593

CABLE ADDRESS: NYFOODRUG

REGULATORY LETTER

OCT 19 1988

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: 1-NYK-89

Joseph Ashkin
Chairman of the Board
Barth-Spencer Co., Inc.
865 Merrick Avenue
Westbury, New York 11790

Dear Mr. Ashkin:

This letter is in reference to the marketing of the products "Beta Carotene" capsules (6mg. and 15mg.), "Sea Beta-Carotene" capsules, "Dry Beta Carotene" capsules, "Imunoplex" tablets, "Coenzyme Q10" capsules, "Rivital-A Cellular Reactivator Cream", "Revitalcreme Skin Revitalizing Treatment", "Eye-Vites" capsules, "Feverfew" tablets and "Anti-Yeast Complex" tablets, by your firm. Promotional material in the form of a catalog (labeling) distributed with your products represent or suggest the following intended usages:

Labeling for the Beta-Carotene products contains the statements "Helps stimulate your body's immune system *** helps repair tissues. *** important to the health of the lungs and respiratory system".

Labeling for the "Revital-A" product contains the statements: *** help ... prevent premature skin aging at the cellular level *** stimulates skin cell growth ***".

Labeling for the "Revitalcreme" product contains the statements: "*** activating skin cells to renew themselves, stimulating skin respiration *** skin-renewing effect ***".

Labeling for the "Eye-Vites" product contains the statements: "*** helps strengthen the immune system. This may help your eyes resist disease *** help brighten and strengthen the eyes *** exclusive formula designed specifically to nourish and promote the health of the eyes ***".

Labeling for the "Feverfew" tablets product contains the statements: *** for temporary relief from migraine and minor arthritis pain *** has remarkable powers for relieving pain and accompanying stress ***" I attribute my long life to the good care I have received from Barth's "M.H., Ala."

Labeling for the "Anti-Yeast Complex" product contains the statements: "*** helps diminish harmful yeast infections, promotes a healthier intestinal tract and colon. *** Caprylic Acid *** found to have a strong antifungal effect and to help bring relief of intestinal yeast infections ***".

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

SECTION	BRIEF DESCRIPTION
502(a)	The articles of drugs 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 previously mentioned conditions and diseases.
502(f)(1)	The articles of drugs are misbranded in that their labeling fails to bear adequate directions for use 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 section 201(p) and no approval of any application filed pursuant to Section 505(b) are effective for these drugs. The articles of drug are further misbranded in that their labeling does not contain adequate directions for use as this term is defined in 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 the 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 Section 201(g) of the Act which may not be introducted 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.

The product "Imunoplex" name suggests the article has a therapeutic affect on the immune system. The labeling statements: "Natural Defense Formula *** herbs and plants and had marvelous powers that *** especially helpful in keeping the body in a healthy condition," and the name misbrand the product.

The labeling statements that "Coenzyme Q10" "is like a miniature engine that needs a spark to activate it"; is a "Fountain of Youth" "for your heart and body cells"; and "has shown a remarkable ability to boost the performance of the heart, nerve, impulses, muscles and other body organs ***" misbrand the product.

The charges and the products contained in this letter are not meant to be all-inclusive. It is your responsibility as a drug distributor to ensure that all your present products as well as any similar drug products intended for future distribution are the subject of approved new drug applications when appropriate and that the products are properly labeled for their intended uses.

We request that you take prompt action to correct these violations. If such action is not taken, the Food Drug Administration is prepared to invoke regulatory sanctions such as seizure and/or injunction. Please advise us within (10) days of receipt of this letter as to the specific actions taken and intended to be taken, including measures to prevent the recurrence of the violations. Your response should be directed to Mr. Fredric J. Richman, Compliance Officer, at the address above.

Sincerely,

JOSEPH J. FALINE
District Director
Food and Drug Administration

JJF:FJR:dl

[redacted]