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

PREVIOUSLY SENT BY
FACSIMILE TRANSMISSION

May 4, 1990

Martin J. Brooks
President and Chief Executive Officer
Phoenix International Marketing Corporation
1395 Greg Street, Suite 111
Sparks, Nevada 89431

REGULATORY LETTER

Dear Mr. Brooks:

This letter is written in reference to the marketing of the Phoenix Nutritious Beverage, the Phoenix Fiber Cookie, the Phoenix Fizzie, and the Phoenix Vitamins and Minerals Capsules, all of which are component products of the Phoenix for Life Program, a.k.a. "Cookies and Cream" Program.

Promotional material (labeling) distributed with the above mentioned articles state or suggest the products are useful for, among other examples, weight control, cardiovascular disease, diuresis, lowering blood pressure, heart disease, irritable bowel syndrome, colon cancer, diabetes, and diverticulitis.

Because such labeling includes statements which represent and suggest that these articles are intended to be used in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or 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 demonstrates that these drugs are generally recognized as safe and effective for any of the aforementioned conditions. Accordingly, marketing of these drugs is a serious violation of the Act as follows:

SECTION	Brief Description
502(a)	The aforementioned 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 prevention or treatment of the conditions identified above.

502(f)(1) The articles of drug are misbranded in that their labeling fails to bear adequate directions for use for the conditions for which they are being offered 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 an application filed pursuant to Section 505(b) is 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 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 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 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) is effective for such drugs.

We also consider the Phoenix Fiber Cookie to be in further violation of the food misbranding provisions of the Act as follows:

403(a) The article is misbranded in that the labeling (leaflet entitled "Introducing...The Phoenix Cookie") represents and suggests that this product has special dietary properties to replace medication for a diabetic and "decreases the amount of calories, fats, sugars, etc., that are normally absorbed" because it "speeds the elimination of digested foods" by reason of its fiber content, which representations and suggestions are false and misleading because they are contrary to fact.

403(j)	The label statement "For weight control" and statements in the product labeling (leaflet entitled "Introducing ... The Phoenix Cookie") including "Lose Up to 14 Pounds in 14 Days," "healthy weight loss," and "The Diet Cookie" represent and suggest that this product is useful in reducing or maintaining caloric intake or body weight; however, the label fails to bear complete nutrition information in accordance with 21 CFR 101.9 and does not bear any of the label statements required by 21 CFR 105.66, and is not a "Low calorie" food as defined in 21 CFR 105.66. Further, the label statement "New Fiber" and the numerous references to fiber in the promotional material require complete nutrition information as per 21 CFR 101.9.
403(f)	The list of ingredients on the label fails to appear in letters all of which are at least one-sixteenth inch in height as required by 21 CFR 101.2(c).
403(i)(2)	The label fails to bear the common or usual name of each ingredient since "100% organic cane juice" is not the common or usual name of a food, and all ingredients in the fabricated foods "vegetable margarine" and "baking powder" are not listed on the label. Further, "citrus fiber, apple fiber, prune fiber, and fig fiber" are not the common or usual names for "pulp" or "spent pulp", and ingredients are not listed on the label in descending order of predominance by weight as required by 21 CFR 101.4.
1453(a)(3)(C)(i) (Fair Packaging and Labeling Act)	The quantity of contents declaration on the label does not appear in letter and numerals of at least one-eighth inch in height as required by 21 CFR 101.105(i)(2).

This letter is not meant to represent a comprehensive listing of all violations which may be associated with Phoenix weight-control products, nor is it meant to represent that other violations may not exist with regard to other products distributed by your firm. It is your responsibility to ensure that all requirements of the Act, and regulations promulgated thereunder, are being met.

We request that you immediately cease distribution of all of these products and related promotional materials, and that you provide an immediate response to this request. We also request that you provide a written response to this letter within 5 days stating the corrective action you have taken or will take to correct the above violations. If significant stocks of these products and promotional materials remain in trade channels at this time, we request that they be immediately recalled to the wholesale level and direct consignee level (including "Phoenix Centers" and "counselor"/retail level). If distribution is not ceased immediately and corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law.

The 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).

We request that your written reply also include:

1. A report of the quantity of products manufactured or received within the past 12 months.

2. A listing of shipments of these products made by you in the past 12 months, including shipment size and frequency of shipment.

3. A report of the amount of products inventory under your control and an estimate of the amounts that remain in channels of distribution outside of your control.

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

5. A statement of your plan regarding the disposition of your inventories (product and promotional material) and the recall of stocks of products and promotional materials from trade channels.

Sincerely,

Dale E Cooper for

Alan L. Hoeting
Acting Associate Commissioner
for Regulatory Affairs