(OK) HLT-I-3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service 1-17-91

Food and Drug Administration
KANSAS CITY FIELD OFFICE
1009 CHERRY STREET
KANSAS CITY, MISSOURI 64106

TELEPHONE: (816) 374-6371

January 2, 1990

Robert A. Spicer, President
Pure Life Systems, Inc.
209 East Williams, Suite 300
Wichita, Kansas 67202

Dear Mr. Spicer:

An Inspection of Pure life Systems, Inc., Wichita Kansas May 16 and 17, 1990 by Food and Drug Administration (FDA) Investigator David A. Blevins and the samples, including labeling for The Cookie Diet cookies, collected during the inspection revealed serious violations of the Federal Food, Drug, and Cosmetic Act (Act), in relation to labeling and promotional claims for food, as follows:

SECTION	BRIEF DESCRIPTION
403(a)(1)	The labeling represents and suggests that this food will lessen PMS symptoms, lower serum triglycerides, lower blood pressure, assist in the balance of blood sugars and improve health which is false and misleading because it is contrary to fact.
	The labeling represents and suggests that this food, because of its level of fiber, is useful in reducing or maintaining calorie intake or body weight which is false and misleading because it is contrary to fact. The usefulness of a high fiber diet for weight control is not well established or supported by scientific data
	The labeling represents and suggests that this food has special value above the consumption of other food in reducing hunger which is false and misleading because it is contrary to fact.
	The labeling contains statements which represent and suggest that a balanced diet of ordinary foods cannot supply adequate amounts of vitamins and minerals for people who exercise or smoke, that vitamins are useful in the relief of stress and that because Life Formula 1 contains vitamin D-3 it is superior to other supplements of Vitamin D in the marketplace which are false and misleading because they are contrary to fact.

Your labeling statements, "The recommended dietary allowances aren't always enough. Remember, they're minimum allowance designed for the average person." and "It's no secret that the RDA's are grossly insufficient..." are false and misleading. RDA's are the level of intake of essential nutrients that, on the basis of scientific knowledge, are adequate to meet the known nutrient needs of practically all healthy persons.

The labeling statement, "The Cookie Diet gives you 100% of the U.S. Recommended Dietary Allowances" is misleading as applied to this product which declares 9% of the U.S.RDA for protein, 33% for vitamin A, 35% for vitamin C and calcium, 38% for riboflavin, 40% for iron, 42% for niacin, and 51% for thiamine per serving.

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

502(a) — The aforementioned article of drug is misbranded in that its labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the article is safe and effective for the prevention or treatment of the conditions identified above.

502(f)(1) — The article of drug is misbranded in that its labeling fails to bear adequate directions for use for the conditions for which it is being offered and it is not exempt from this requirement under regulation 21 CFR 201.115 since the article is a new drug within the meaning of section 201(p) and no approval of an application filed pursuant to section 505(b) is effective for this drug.

505(a) The article is a drug 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 Act and no approval of an application filed pursuant to Section 505(b) is effective for such a drug.

We have the following additional comments:

1. The immediate container label and labeling lack a declaration of nutrition information in accordance with Title 21 Code of Federal Regulations (CFR) 101.9. The nutrition information on the "30 Day" carton label is not in the format or increments specified in 21 CFR 101.9.

2. The nutrition information, manufacturer's name and address and ingredient statement are not located together on the information panel. [21 CFR 101.2]

3. The product labels lack an appropriate identity statement. [21 CFR 101.3]

4. "Oat fiber" and "vitamin supplement added" are not common or usual names for ingredients. If the ingredients declared as "whole wheat flour" and "unbleached white flour" contain optional ingredients they should be declared in accordance with 21 CFR 101.4(b)(15).

5. The declaration of the preservative ingredient "potassium sorbate" must include a separate description of its function in accordance with 21 CFR 101.22(j).

6. The declaration of "Dutch Cocoa" should be replaced by "cocoa processed with alkali" or "cocoa Dutch processed with alkali" and appear in the ingredient list in its order of predominance by weight for the chocolate cookie formulation. The "Peanut Butter and "Peanut Flavoring" should appear in the ingredient list in order of predominance by weight for the Peanut Butter cookie formulation. Optional ingredients in peanut butter must be declared in accordance with 21 CFR 164.150.

7. The brochure "The Pure Life Approach" dated May/June 1989 contains many statements regarding the benefits of "the Pure Life Cookie" which are false and misleading, such as; "Fiber speeds the transit time of food in your digestive system so fewer calories are absorbed.", "Fiber fights diseases by moving through your body quickly, removing toxins and poisons before your body can absorb them.", and "The special soluble and insoluble fiber blends of the cookie may help lower cholesterol, triglycerides, blood pressure and balance sugars."

The above enumeration of violations should not be construed as an all inclusive list of violations which may be in existence in relation to your products. It is your responsibility to ensure that all requirements of the Act and related regulations are being met.

Food labeling regulations are published in Title 21 CFR Parts 1 and 101. Drug labeling regulations are published in Title 21 CFR Parts 1 and 201. New drug regulations are published in CFR parts 310 though 361. These regulations are available at most major public libraries, and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

You should take prompt action to correct the violations and set up procedures whereby such violations will not recur. If such action is not taken, the FDA is prepared to invoke regulatory sanctions, such as seizure and/or injunction.

Please notify us in writing within ten (10) days of the steps you have taken to correct these violations. We request that your reply include:

1. An estimate of the quantity of each of the products, The Cookie Diet Cookie and Life Formula 1, manufactured or received within the past twelve months.

2. An estimate of the size and frequency of shipments made by you in the past twelve months.

3. An estimate of the amount of the above products that are in inventory under your control and 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 two products.

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

You may direct your written response to Ray Moore, Compliance Officer at the above address.

Sincerely

W. Michael Rogers
District Director
Kansas City District

[redacted]

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