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Food and Drug Administration  
KANSAS CITY FIELD OFFICE  
1009 CHERRY STREET  
KANSAS CITY, MISSOURI 64108

February 8, 1991

TELEPHONE: (816) 374-6371

REGULATORY LETTER

Certified Mail - Return Receipt Requested

Stanley A. Leitner, President  
Lifestyles U.S.A.  
18401 Edison  
Chesterfield, Missouri 63005

91-STL-003

Dear Mr. Leitner:

Inspection of your firm, Lifestyles U.S.A, Chesterfield, Missouri, on July 2 and 9, 1990, resulted in review of labeling and promotional materials and analyses of cookies. Serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) were found, that included:

<u>Section</u>	<u>Brief Description</u>
403(a) (1)	<p>Cookies collected at your firm are misbranded in that their labeling is false and misleading as follows:</p> <p>a. Chocolate Chip cookies stamped "Best Used By 12/23/90" were analyzed and found to contain 13% and 14% (10.5% on check analyses) of the declared 35% U.S. RDA of calcium per serving.</p> <p>b. Oatmeal cookies stamped "Best Used By 01/06/91" were analyzed and found to contain 64.4% (68.9% on check analyses) of the declared 35% of the U.S. RDA of Riboflavin; and 25 and 27% (24.9% on check analysis) of the declared 35% U.S. RDA of calcium per serving.</p>
403(a) (1)	<p>Representations of the usefulness of these products in weight loss, based on their fiber content, are false and misleading because they are contrary to fact. The effectiveness of fiber in promoting weight loss and satiety is not substantiated. There is no evidence that dietary fiber can "absorb" calories.</p>

Furthermore, promotional material (labeling) distributed by your firm for Lifestyles' Cookies (Oatmeal, Chocolate Chip and Peanut Butter) and Lifestyles' Cakes (French Vanilla, Chocolate Swiss Fudge, Hawaiian Banana Pecan, Dutch Chocolate Chocolate Fudge and Jamaican Spice) states or suggests that they are useful for, among other claims, weight control; prevent digestive tract disorders, appendicitis, diverticulosis, coronary artery disease and colon cancer; lower blood cholesterol of diabetics; reduce LDL cholesterol and increases HDL cholesterol; and resist disease by purging poisons and toxins.

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 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 demonstrates that these drugs are generally recognized as safe and effective for the above referenced conditions or for any disease conditions. Accordingly, marketing of these drugs is in violation of the Federal Food, Drug, and Cosmetic Act as follows:

<u>Section</u>	<u>Brief Description</u>
502(a)	The aforesaid 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 prevention or treatment of the conditions identified above.
502(f) (1)	<p>The articles of drugs are misbranded in that their labeling fails to bear adequate directions for use for the conditions for which they are being offered and 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 the drugs.</p> <p>The articles of drugs are further misbranded in that their labeling does not contain adequate directions for use as this time is defined in 21 CFR 201.5 since the conditions for which they are offered are not amendable 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.</p>
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 505(a) of the Act, since they are new drugs within the meaning of Section 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) is effective for such drugs.

We request that you take prompt action to correct the above violations. If such actions are not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions provided under law, which include seizure and/or injunction.

Other objectionable label deviations of the Act and regulations promulgated thereunder relating to your cookies (Oatmeal, Peanut Butter, Chocolate Chip) and cakes (French Vanilla, Swiss Fudge, Hawaiian Banana Pecan, Dutch Chocolate Chocolate Chunk, Jamaican Spice) include:

1. The net quantity of contents statement is not located in the lower 30% of the principal display panel; [21 CFR 101.105(f)]
2. The type size is too small for the size of the principal display panel label; i.e. the Oatmeal label (4" x 4") is 16 in <sup>2</sup> and should bear a net weight statement at least 1/8" in height. [21 CFR 101.105(h)]
3. The label does not qualify the association of your firm's name with the products, since you do not manufacture them; i.e. manufactured for \_\_\_\_\_, distributed by \_\_\_\_\_, etc. [21 CFR 101.5(c)]
4. The declaration for calories (all products except Jamaican Spice cake) are not stated in the increments specified in 21 CFR 101.9(c) (3).
5. The declaration for fat (Chocolate Chip Cookies) is not in the increments specified in 21 CFR 101.9(c) (6).
6. Dietary fiber is not a part of the current nutrition labeling format. This information may be provided elsewhere on the label.
7. The fruit juices must be declared individually in descending order of predominance by weight rather than under the collective term "CONCENTRATED FRUIT JUICES."
8. If the "soybean oil" ingredient is partially or completely hydrogenated it must be indicated as such in the ingredient statement.
9. The ingredient list includes a number of possible multi-component ingredients, e.g., wheat flour, chocolate chips and chunks, margarine. Ingredients which are themselves composed of two or more ingredients should be declared in accordance with 21 CFR 101.4.
10. The identity statement "cookies" and "cakes" are not a principal feature on the principal display panel.
11. These products which contain 10% of the U.S. RDA of protein should not be represented as a meal replacement.
12. In the Federal Register of July 19, 1990, FDA published a tentative final regulation governing cholesterol claims on foods. This regulation proposed to limit the claim "cholesterol free" to those foods that contain less than two (2) milligrams cholesterol per serving, and five (5) grams or less total fat per serving, and twenty (20) percent or less total fat on a dry weight basis, and two (2) grams or less saturated fatty acids per serving, and six (6) percent or less saturated fatty acids on a dry weight basis. If this regulation is finalized as proposed, these foods will not be permitted to bear "cholesterol free" claims.

There are a number of statements in the Lifestyle's manual and brochures which are misleading. They include:

1. There is no evidence that reducing fluid consumption will delay the onset of sensations of hunger. In addition, reducing fluid intake is not desirable when consuming products that contain added fiber.
2. There is no evidence that large meals deprive the brain and muscles of energy, thereby inducing drowsiness.
3. We question your statements regarding the findings established by Dr. Burkitt. Dr. Burkitt found that African populations with high fiber intakes had low incidence of certain diseases. He did not establish that the low incidence resulted from the high fiber intake. There may have been other components of the high fiber diets which were responsible for the effects, or other non-dietary factors may have been responsible.
4. There is no direct evidence that soluble fiber absorbs sugar, toxins, etc., in living animals or humans.
5. We question the statements regarding the effect of blood sugar swings on the immune system.
6. There is no evidence that consumption of polyunsaturated fats as the only dietary modification will effectively lower blood pressure.

Analyses of the Oatmeal cookies and the Chocolate Chip cookies revealed sodium at 117% of the declared 95 mg. per serving and 110% of the declared 140 mg per serving, respectively.

We request that you reply within ten days of your receipt of this letter stating the action you will take to discontinue the marketing of these drug products. Your response should be directed to Spencer L. Sorenson, Compliance Officer, at Food and Drug Administration, 808 N. Collins Alley, St. Louis, Missouri 63102 referenced in the letterhead.

We request that your reply include:

1. An estimate of the quantity of the drugs manufactured or received within the past 12 months.
2. An estimate of the size and frequency of shipments made by you in the past 12 months.
3. An estimate of the amount of the drugs that are in inventory under your control and 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 the drug products.

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

Sincerely,

A handwritten signature in black ink, appearing to read "W. Michael Rogers", with a long horizontal flourish extending to the right.

W. Michael Rogers  
District Director  
Kansas City District

WMR/SLS/sp