DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

9-11-91

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER

WL-28-1

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015-2486
Telephone (213) 252-7583

August 28, 1991

Armand Mingione
President
Armco Food Products Manufacturing
1553 Simpson Way
Escondido, California 92025

RE: Country Chocolate Jerzee Blend
Country White Jerzee Blend
Nutri-Tonic Q-10

Dear Mr. Mingione:

An inspection of your firm indicated that you market the above referenced products.

COUNTRY CHOCOLATE AND COUNTRY WHITE JERZEE BLEND

Our review of the product labels and promotional material (labeling) distributed with your products "Country Chocolate Jerzee Blend" and "Country White Jerzee Blend" reveals these products are in violation of the Federal Food, Drug and Cosmetic Act (the Act) as follows:

SECTION	BRIEF DESCRIPTION
403(a)(1)	The products identified as "Country Chocolate Jerzee Blend A Delicious Low Caloric Chocolate Beverage" are misbranded since the statement "low caloric beverage" represents these products to be low calorie foods meeting the requirements of Title 21, Code of Federal Regulations CFR 105.66(c), whereas, these products fail to comply with the requirements of a low calorie food in that a serving of these products provide more than 40 calories.
403(a)(1) 201(n)	The product names including "Jerzee Blend" and the labeling (Products Data Sheet and Technical Information) makes the statement "...that this nutritious formulation functions well in practically all cooking applications, where whole, 2%, or dry milk solids are necessary" and "Can be directly substituted for milk in recipes, usually with superior results..." these products (Country Chocolate Jerzee Blend and Country White Jerzee Blend) are misbranded since they represent and suggest that these products are or can substitute for whole milk and 2% milk which is contrary to fact and fails to reveal the material fact that they are nutritionally inferior to whole and 2% milk in product protein content.

Such representations made or suggested constitute misleading labeling. Further, because these products are nutritionally inferior to milk they must be labeled as "Imitation" immediately followed by the common or usual name of the specific milk product imitated.

403(f) The products identified as "Country Chocolate Jerzee Blend" and "Country White Jerzee Blend" are misbranded in that statements and other information required to appear on the label is not placed thereon as follows:

The nutrition labeling information for the Country Chocolate and Country White Jerzee Blend fails to bear a declaration of sodium.

The net quantity of content statements for the Country Chocolate and Country White Jerzee Blend labels fail to be declared in terms of pounds with the remainder in terms of ounces or common fraction of a pound.

All letters and numbers in the nutrition information and the ingredient statements for the Country Chocolate and Country White Jerzee Blend labels shall be declared in a size type of at least one-sixth of an inch in height.

In addition, the Country Chocolate Jerzee Blend contains aspartame and its label fails to bear the statement "PHENYLKETONURICS: CONTAINS PHENYLALANINE."

The ingredient listed as "vanilla (an artificial flavor)" for the Country Chocolate Jerzee Blend label should be declared as "vanillin (an artificial flavor)", if true.

NUTRI - TONIC Q-10

Our investigation disclosed that your firm prepares and distributes a printed promotional leaflet in conjunction with the sales of the product identified as "Nutri-Tonic Q-10". This leaflet is considered to be product labeling within the meaning of Section 201(m) of the Federal Food, Drug, and Cosmetic Act (the Act). Our review of the product label and promotional material (labeling) distributed with your product "Nutri-Tonic Q-10" reveals this product is in violation of the Act as follows:

SECTION	BRIEF DESCRIPTION
403(a)(1)	The product, "Nutri-Tonic Q-10" is misbranded in that the labeling (promotional material with the heading Spectra Marketing Company) makes statements and comments that falsely represent, suggest and imply that this food is adequate or effective in the prevention, cure, mitigation or treatment of conditions such as: "...can relieve the pain of arthritis, lower blood pressure, melt off ugly bulges and restore natural softness to your skin." This material also misbrands the product by claiming that the product "BOOSTS THE IMMUNE SYSTEM - INCREASES THE STRENGTH OF THE HEART MUSCLE - RELIEVES ANGINA - PROTECTS AGAINST HEART ATTACKS - LOWERS BLOOD PRESSURE - REDUCES WEIGHT NATURALLY - EXTENDS LIFE ITSELF - HELPS CURE PERIODONTAL DISEASE" since it is contrary to fact.
403(a)(1) 201 (n)	The product identified as "Nutri-Tonic Q-10" is misbranded since nutrients have been added but the label fails to bear nutrition labeling in the format and increments prescribed by 21 CFR, 101.9. Failure to reveal material facts constitutes misleading labeling.
403(i)(1)	The product identified as "Nutri-Tonic Q-10" is misbranded since its label fails to bear the common or usual name or an appropriately descriptive term or phrase as the identity statement for this food.

Because the labeling bears the above numerous claims such as "Boosts the Immune System...Lowers Blood Pressure...Extends Life Itself..." the statements represent and suggest that the product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of the referenced disease conditions. Because of the claims the product is regarded as a drug as defined in Section 201(g) of the Act. Also, we are unaware of any substantial scientific evidence that demonstrates the safety and effectiveness of this product for its intended uses. Nor are we aware that this drug is generally recognized as safe and effective for the intended uses. Therefore, the product is a new drug within the meaning of Section 201(p) of the Act. Accordingly, marketing of this drug is a violation of the Act as follows:

SECTION	BRIEF DESCRIPTION
505(a)	The article, "Nutri-Tonic Q10", is new drug within the meaning of Section 201(p) of the Act which may not be introduced or delivered for introduction into interstate commerce since no approval of an application filed pursuant to Section 505(b) is effective for such a drug.
502(f)(1)	The article of drug is misbranded in that its labeling fails to bear adequate directions for use in the treatment of the disease or medical conditions for which the article is represented or suggested, and the drug is not exempt from this requirement under 21 CFR 201.115 since this article is a new drug within the meaning of Section 201(p) and no approval of any application filed pursuant to Section 505(b) is effective for this drug. The article of drug is further misbranded in that its labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5, since the conditions for which it is 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 this drug safely and for the purpose for which this drug is intended.
502(a)	The article of drug is misbranded in that its labeling is false and misleading by representations and suggestions that there is substantial evidence to establish that this article is safe and effective for the treatment of the disease or medical conditions listed in the labeling for this drug.

The above listed deficiencies are not intended to be construed as all inclusive of those that exist in your firm. It is your responsibility to ensure that all requirements promulgated thereunder are being met.

We request that you reply within fifteen (15) days of your receipt of this letter stating the action you will take to discontinue the marketing of the these products or otherwise bring them into compliance. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure of illegal products and/or injunctive actions against the manufacturer or distributor of illegal products.

Your reply should be directed to:

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

Sincerely,

George J. Gerstenberg
District Director
Los Angeles District Office

[redacted]