NWW 12-12-8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

REGULATORY LETTER

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

December 1, 1989

Kinichi Torii, President
Whitney Industries, Inc.
dba Nutri-Action/Nutri-Health
15324 So. Western Avenue
Gardena, CA 90247

LA-08-0

Dear Mr. Torii:

A recent investigation by the Food and Drug Administration reveals that you distribute in interstate commerce drug products labeled as "Sweet Away", "Oyster Extract", "Renew-F", "Herbal Cleanse", "Organic Germanium" and "ORA-K PLUS".

Labeling for Sweet Away claims that it "May assist in the reduction of sugar intake ...", "... We are aware of the many problems that can arise from too much sugar consumption. Ailments such as diabetes, hypoglycemia, alcoholism, acne, hyperactive children's problems and obesity are just a few of the problems".

Claims in the Oyster Extract literature include, among other claims, cancer, heart disease, reduces inflammation, and loss of memory.

Promotional material distributed with Renew-F states, "... May assist the body to retain and maintain near normal functions after menopause or hysterectomy".

Promotional literature for Herbal Cleanse claims that it "May assist in symptoms where blood cleansing is needed".

Labeling for Organic Germanium contains claims, among other claims, for cancer, AIDS, and immune system functions.

Promotional material distributed with ORA-K PLUS states or suggests that it is useful for serious circulation problems including numbness in limbs, memory, plaque formation in the arteries, elimination of fat build-up in the circulatory system; and protects the body from harmful environmental substances like air pollution, chemical additives, radiation, and chlorinated water.

Additionally, because the promotional literature for these products represents and suggests that the articles are intended to be used in the diagnosis, 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 as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act. Further, we are unaware of any substantial scientific

evidence which demonstrates that the referenced products are generally recognized as safe and effective for their intended uses. Accordingly, marketing of these drugs is a serious violation of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

SECTION	BRIEF DESCRIPTION
502(a)	The aforesaid articles of drugs are misbranded in that the 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 conditions listed in the labeling.
502(f)(1)	The articles of drugs are misbranded in that their labeling fails to bear adequate directions for use 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 the drugs.
	The articles of drugs 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 505(a) of the Act, since they are new drugs within the meaning of Section 201(p) of the Act and no approvals of applications filed pursuant to Section 505(b) are effective for such drugs.

Further, we consider ORA-K PLUS to be in serious violation of the food adulteration provision of the Federal Food, Drug and Cosmetic Act as follows:

402(a)(1) The food is adulterated in that it contains an added poisonous or deleterious substance namely, Vitamin A at a level of 40,000 I.U. per day, which may render it injurious to health.

For your information:

1. The addition of the amino acids l-cysteine and dl-methionine to the product is not presently permitted by the provisions of 21 CFR 172.320. Amino acids may be used to significantly improve the biological quality of the total protein in a food containing naturally occurring primarily-intact protein that is considered a significant dietary protein source.

2. Marine lipids, in general, are not considered to be generally recognized as safe for use in dietary supplements nor is there presently a food additive regulation which prescribes conditions for the safe use of marine lipids in dietary supplements. If the manufacturer has information which demonstrates the safety of the use of marine lipids in dietary supplements, he should submit it in the form of a petition to establish Generally Recognized As Safe (GRAS) status under 21 CFR 170.35 or a food additive petition in the format of 21 CFR 171.1.

3. The term "Yeast Free" is a hypoallergenic claim which subjects the label to the requirements of 21 CFR 105.62 for hypoallergenic foods.

The violations listed above are not intended to be all inclusive. It is your responsibility as a food and drug distributor to market food and drug products which are in compliance with the Federal Food, Drug and Cosmetic Act. The labeling for all products you distribute, including formulations and claims contained in your catalogue, should be reviewed to assure compliance with the Federal Food, Drug and Cosmetic Act.

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 the drug products and food product. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug, and Cosmetic 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 reply include:

1. An estimate of the quantity of the food and 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 food and 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 of food and drug products.

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

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

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