DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

April 19, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

99-PHI-26

Mr. Henry Bartos, President
Sanapac Co.
Orange Road, RR 3, Box 236
Dallas, Pa 18612

Dear Mr. Bartos:

On February 11, 1999, Philadelphia District Investigator Ann Marie Karnick conducted an inspection of your repackaging and distribution facility located at Orange Road, RR 3, Dallas, PA. The products repacked and distributed by this facility are dietary supplements within the meaning of Section 201(ff) of the Federal Food, Drug, and Cosmetic (FD & C) Act and, as such, are subject to the requirements of Title 21 Code of Federal Regulations (21 CFR).

At the conclusion of the inspection, Mildred K. Bartos, Vice President, was presented with a Form FDA-483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR), Part 111. This section covers the Good Manufacturing Practices for Dietary Supplements. A copy of the FDA-483 is enclosed for your information. By virtue of these deficiencies, the products listed below that are packaged and distributed at your facility are adulterated within the meaning of Section 402(a)(4) and Section 402(g) of the Federal Food, Drug and Cosmetic Act (the Act) and are not in conformance with Current Good Manufacturing Practice (CGMP) regulations, codified at 21 CFR Part 111 as indicated below:

1. Products including Sanapac Rooster Brand Pills, Rooster Kings, Super Kings Inner Man, Sanapac Inner Man Gold and Super Queens Inner Woman are packaged in 30 to 70 count tablet containers with an iron content as follows: Sanapac Rooster Brand Pills- 300 mg (Ferrous Sulphate); Rooster Kings – 300 mg (Ferrous Sulphate); Super Kings Inner Man – 250 mg (Ferrous Sulphate); Sanapac Inner Man Gold – 250 mg (Ferrous Sulphate) and Super Queens Inner Woman – 300 mg (Ferrous Sulphate).

> Please be advised that the use of iron and iron salts as iron sources in dietary supplements offered in solid oral dosage form, and containing 30 milligrams or more of iron per dosage unit, is safe in accordance with current good manufacturing practice only when such supplements are packaged in unit-dose packaging [21 CFR Part 111.50].

In addition, further review of the products listed above revealed they are also misbranded based on the use of National Drug Code (NDC) listing numbers on the label. A dietary supplement label may not bear a National Drug Code (NDC) listing number because such information misbrands the dietary supplement under Section 403(a)(1) of the Act because it is false and misleading. The products, as presently labeled, may not be marketed as dietary supplements because the labels bear information (i.e., and NDC number) that misbrands them under Section 403(a)(1).

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

You should take prompt action to correct these violations. Failure to do so may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific actions you have taken or intend to take to correct these violations. Your reply should include each step that has or will be taken to completely correct the violations. If corrective action cannot be completed within fifteen (15) working days, please include in your reply the reason for the delay, the time within which the corrections will be completed and any documentation necessary to indicate correction has been achieved.

Your reply should be sent to the attention of Lynn S. Bonner, Compliance Officer, at the address noted above.

Sincerely,

Thomas D. Gardine

Thomas D. Gardine
District Director
Philadelphia District

cc: Pennsylvania State Department of Agriculture
Bureau of Foods and Chemistry
2301 North Cameron Street
Harrisburg, PA 17120-9408
Attention: Leroy C. Corbin, Jr., Chief
Division of Food Control

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