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Refer to: CFN 1125573

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

August 20, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gregg Barna, CEO
Health Thru Nutrition, Inc.
d.b.a. Health Technologies Network (HTN)
150 Research Drive
Hampton, Virginia 23666

Dear Mr. Barna:

The Food and Drug Administration (FDA) has reviewed labeling for "ALKA-LINE CORAL CALCIUM" and other products listed below that are marketed and distributed by your firm. Labeling for these products makes therapeutic claims, which cause the products to be drugs per Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Labeling is not limited to the immediate product container, but includes all promotional literature distributed in connection with your products, including the brochure entitled, "Complete Product Line."

Products and objectionable claims include the following:

ALKA-LINE Coral Calcium and Coral Calcium Gold	regulate blood pressure, arthritic conditions, heart disease, neutralize digestive reflux
DENTAL-MAX	anti-bacterial, fight gum disease, control pyorrhea and gingivitis, combat periodontal disease, desensitize teeth, fight bacteria, relieve pain caused by sensitivity to cold, heat, acids, and sweets
Metabolizer Health Aids	provide pain relief, act as an anti-bacterial
Metabolizer Lax-Max	parasite control, kill adult parasites
Pro-Max	Osteoporosis
HTN Superfood Children's CHEWABLES	hyperactivity, ADD/ADHD

Super C & P-Max	Candida Albicans (yeast infection), attack parasites, eliminate harmful bacteria, employs the same principle as all effective vaccines
Omega 3/50+ with Shark Liver Oil	reduce high blood pressure, reduce inflammation

Claims that your Coral Calcium products can "neutralize digestive reflux" cause these products to be subject to the final rule (monograph) on "Antacid Products for Over-the-Counter (OTC) Human Use." This monograph is found in Title 21, Code of Federal Regulations (21 CFR), Part 331. Neither the labeling nor the formulations for the products conform to this final regulation.

Further, Metabolizer Health Aids and Super C & P-Max are labeled as combination homeopathic and colloidal drugs. Pro-Max is also labeled as containing a homeopathic ingredient. FDA's Compliance Policy Guide (CPG) 7132.15 states that drug products containing homeopathic ingredients in combination with nonhomeopathic ingredients are not homeopathic drugs.

All of the above mentioned products are "new drugs" [Section 201(p) of the Act] and, therefore, may not be legally marketed in this country without approved New Drug Applications [Section 505(a)]. These drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [Section 502(f)(1)] and is false and misleading because it suggests that the products are safe and effective for their intended uses when, in fact, this has not been established [Section 502(a)].

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.

Therapeutic claims for additional products are included in the complete product list. Such claims may also cause these products to be misbranded. Products and claims include:

Assimilator	dissolve cholesterol deposits, reduce bacteria, reduce problems associated with sickle cell anemia, break up and dissolve uric acid crystals
ActiVin OPC 50	decrease insulin resistance, improve diabetic symptoms (several Internet distributor sites also promote this product for cancer)
Mind Set	depression, ADD/ADHD, reduce alcohol and drug cravings, lower blood pressure
Golden-Max	decrease alcohol and drug craving
Metabolizer M2000 Series M2000, M2000+, M2000xtra	decrease insulin resistance, improve diabetic symptoms

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Endura-Max	decrease insulin resistance, improve diabetic symptoms
Adult Super Food	ADD/ADHD

In addition, we are aware of a number of distributor web sites on the Internet that include similar or additional claims to those listed above.

We request that you take prompt action to correct these violations. Failure to do so may result in enforcement action being initiated by the FDA without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for an 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 steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, VA 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 378-1627, extension 14.

Sincerely,



Susan M. Setterberg
Acting Director, Baltimore District