



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

August 4, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David R Wimmer, Ph.D.,
President
Scientific Health Products, Inc.
dba Natural Wonders
351 West 6160 South
Salt Lake City, Utah 84124

Ref. # - DEN-99-17

Dear Dr. Wimmer:

During an inspection of your firm conducted on March 12, 1999, Consumer Safety Officer Elvin R. Smith determined your firm manufactures a variety of oral and topical products. This letter is in reference to the promotion, marketing, and distribution of these products by your firm.

Claims are made for some of your products through labels and promotional literature, including catalogs:

- “Prevent” claims include: “...Prevent Degenerative Disease...” and “...the development of many degenerative diseases...age-related health problems – most commonly, heart disease and cancer...”;
- “Life-Mate” claims include: “...colds, flu...health problems related to the diabetes, such as gout, failing eyesight...”;
- “Garden Greens” claims include: “...Reduces blood pressure...Helps prevent allergies and relieves allergic symptoms... Alleviates depression, stress,... and impotency...”;

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- “Aloe Wonder” claims include: “...irritated, damaged or infected skin...,” ...“Fights viral and bacterial infections; relieves pain and swelling of infections Inhibits gastric secretions and gastric lesions; reduces pain and promotes healing of gastric ulcers... Reduces symptoms caused by inhaled and food allergies Promotes healing of mouth and throat lesions (e.g. cold sores, infected gums, canker sores, sore throat, etc.)...Promotes rapid healing and repair of damaged skin tissue (e.g. cuts, scrapes, burns, sunburn, chemical burns, scalds, frostbite, etc.)...Relieves pain of cuts and burns almost instantly Promotes healing of other skin irritations such as psoriasis, rashes, pre-cancer and early cancer lesions, dermatitis...”;
- “Vein-Flex” claims include: “...fortifies against varicose veins, swelling and inflammation of the veins, swelling and inflammation of hemorrhoids, and hemorrhage potential...”;
- “Intimate-F” claims include: “...menstrual disorders and discomfort such as excessive bleeding and cramping...”;
- “Intimate-M” claims include: “...impotence...detoxifies the prostate gland and reduces swelling...”;
- “Pan-Balance” claims include: “...hypoglycemia is under control...”;
- “Barley-Gold” claims include: “...fortifies against arthritis...”;
- “Flex-Able” claims include: “...reduce aches and stiffness...uric acid to reduce swelling and inflammation...”;
- “S-E-T Free” claims include: “...strengthen them against infection...”;
- “Workout” claims include: “...promotes healing and repair for injury, sprains and bruises...”
- “Kleen-Sweep-I” claims include “...promotes the expulsion of parasites...”;
- “Kleen-Sweep-L” claims include: “...my doctor said to go off my cholesterol medicine...”;
- “Me Again” claims include: “...Alleviate mood swings, feelings of anxiety and depression...Reduce the risk of heart disease, strokes, endometrial and breast cancer...”; and,
- “Herb-A-Derm” claims include: “...Promotes rapid healing of cuts and burns (e.g. sunburns, chemical burns, scalds)...” .

Furthermore, the promotional literature “Natural Wonders Product Catalog” includes numerous disease claims in the form of testimonials. Examples of such claims include:

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- "...I have arthritis very badly, and it has helped my arthritis...";
- "...mother of an 18-month-old son... he was exposed to the RSV virus ... never seen such a healthy RSV baby...";
- "... My asthma has improved...";
- "... yeast infection..."; and
- "...my throat had cleared up and felt normal without further treatment... ."

Based on the claims for these products and their intended uses, these products are drugs as defined by Section 201 (g) of the Federal Food, Drug, and Cosmetic Act (the Act). They are also new drugs as defined by Section 201 (p) of the Act and may not be legally marketed in the United States without approved New Drug Applications as found in Section 505 of the Act.

These drugs are misbranded in that their labeling fails to bear adequate directions for use under Section 502 (f)(1) of the Act. These products are further misbranded under Section 502(a) of the Act in that their labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when this has not been established.

In addition, the following "Homeolixir" products are offered as homeopathic over-the-counter (OTC) drugs to treat or cure diseases which are neither self-limiting nor amenable to self diagnosis by the laity:

- "Depression" claims include "...depressive tendencies, mood swings, and feelings of depression..."; and
- "Inflammation-B" claims include "For relief of minor ear ache, sore throat, redness, swelling and other symptoms related to inflammation (bacterial infection)."

These "Homeolixir" products are misbranded as described in Sections 503 (b)(1) and (b)(4) of the Act because they are not dispensed under the supervision of a practitioner licensed by law and the labels of the drugs fail to bear, at a minimum, the symbol "Rx only."

Furthermore, Section 201 (ff)(2) of the Act provides that the term dietary supplement means, in part, an article intended for ingestion. The product "Aloe Wonder" (concentrated liquid Aloe Vera) is offered as a beverage and spray. Your catalog makes claims for benefits of these products when taken internally and/or externally. Since this product is represented for external (i.e., topical) use, it is excluded from the definition of a dietary supplement under Section 201 (ff)(2) of the Act because it is not "intended for ingestion."

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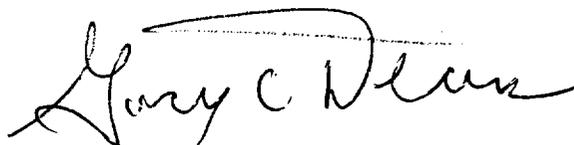
This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations 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 15 working days of your receipt of this letter, of the specific steps you have taken to correct the stated violations. You should also include 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, please state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to Ms. Shelly L. Maifarth, Compliance Officer, at the above letterhead address.

Sincerely,

A handwritten signature in cursive script that reads "Gary C. Dean". The signature is written in black ink and is positioned above the printed name and title.

Gary C. Dean
District Director

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