DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
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Denver, Colorado 80225-0087
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June 19, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Daniel P. Howells, President and CEO
Nature's Sunshine Products, Inc.
75 East 1700 South
Provo, Utah 84605

Dear Mr. Howells:

This letter concerns your firm's marketing and distribution of "Cholester-Reg," a product promoted as a cholesterol lowering agent. Labels collected during our inspection of your firm on February 6, 2001, bear your Internet website address www.naturessunshine.com. Claims found on your Internet site cause your product to be in violation of several provisions of the Federal Food, Drug, and Cosmetic Act (the Act). Our investigators noted that the name of the product "Cholester-Reg" was formerly "HongQu," and that some materials still use this name. For the purposes of this Warning Letter, the product "Cholester-Reg" will refer to both products.

The claims found for "Cholester-Reg (HongQu)" on your Internet website and the product label for "Cholester-Reg include "supports optimal balance of HDL to LDL levels..." and "This premier red rice extract is standardized to contain 3 mg of natural HMG-CoA reductase inhibitors (including mevinolin)." In addition, the product name, "Cholester-Reg" may be considered a drug claim in that it implies the product affects the structure/function of the body by regulating cholesterol levels.

"Cholester-Reg (HongQu)" contains lovastatin, a prescription drug that is not approved for Over-The-Counter (OTC) use and requires monitoring by a physician. The presence of lovastatin in your product is demonstrated by:

- Your label claim that this product "is standardized to contain 3 mg of natural HMG-CoA reductase inhibitors (including mevinolin),"

- The "RAW MATERIAL SPECIFICATION ANALYSIS Red Yeast Powder R27194" sheet states "The red rice extract is standardized to approximately 1.4% lovastatin (mevinolin)," and
- The "FINISHED PRODUCT SPECIFICATION ANALYSIS Cholester-Reg/HongQu (DIN) 555" sheet specifies a test for "Lovastatin (meninolin)" with a specification of "3.225 mg 2.9-4.03 (90-125%)."

In 1998, the Food & Drug Administration sought to regulate Cholestin, a red yeast rice product, containing lovastatin, as a drug. This product was marketed by Pharmanex, Inc., 203 Thomas Drive, Egg Harbor Twp., New Jersey 08234. The firm sued the Agency under the argument that their product, Cholestin, was a dietary supplement and was therefore not subject to regulation as a drug. Despite an initial ruling in favor of Pharmanex, the decision was remanded by the United States Court of Appeals and returned to the District Court in the District of Utah. In its dismissal of the law suit, the decision of the U.S. District Court for the District of Utah on March 30, 2001, case number 2:97CV262K, affirmed that red yeast rice products which contain lovastatin are subject to regulation as drugs and are not dietary supplements.

"Cholester-Reg" is a "drug" within the meaning of section 201(g) of the Act. Moreover, it is also a "new drug" [section 201(p) of the Act] because there is no evidence that this product is generally recognized as safe and effective for its intended use. Since this product is a "new drug", it may not be legally marketed in the United States without an approved new drug application [section 505(a) of the Act].

Furthermore, this drug is misbranded [section 502(f)(1) of the Act] because its labeling fails to bear adequate directions for use, for the conditions for which it is offered. The drug is also misbranded because the labeling is false and misleading as it suggests that the product is safe and effective for its intended use when this has not been established [section 502(a) of the Act].

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 & 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 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, state

the reason for the delay and the time within which the corrections will be implemented.

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

Sincerely,

Thomas A. Allison
Director, Denver District