



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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June 19, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Frank W. Gay, Chairman and CEO
Nutraceutical International Corporation
1400 Kearns Boulevard, Second Floor
Park City, Utah 84060

Dear Mr. Gay:

This letter concerns your firm's marketing and distribution of the products "KAL Cholesterol Defense," "Solaray Red Yeast Rice," and "Solaray Guggul & Red Yeast Rice." The label for "KAL Cholesterol Defense" claims the red yeast rice to be "...Supplying 3.6mg [0.3%] Lovastatin...;" the container closure for "Solaray Red Yeast Rice" has a sticker claiming "0.3% Lovastatin;" the label for "Solaray Guggul & Red Yeast Rice" claims "0.3% Lovastatin;" and the list of ingredients on the label claims the red yeast rice ingredient is "Guaranteed 1.2mg [0.3%] lovastatin..."

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 contention that the 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 the dismissal of the suit on March 30, 2001, the U.S. District Court for the District of Utah, case number 2:97CV262K, affirmed that red yeast rice products that contain lovastatin are subject to regulation as drugs within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act), and are not dietary supplements.

Moreover, they are also "new drugs" [section 201(p) of the Act] because there is no evidence that these products are generally recognized as safe and effective for their intended uses. Since these products are "new drugs", they may not be legally marketed in the United States without approved new drug applications [section 505(a) of the Act].

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Page 2 – Nutraceutical International Corp.
June 19, 2001

Furthermore, these drugs are misbranded {section 502(f)(1) of the Act] because their labeling fails to bear adequate directions for use for the conditions for which they are offered. These drugs are also misbranded because the labeling is false and misleading as it suggests that the products are safe and effective for their 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

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