



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration  
158-15 Liberty Avenue  
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

September 26, 2001

Mr. Saiful Kibria  
President  
Kabco, Inc.  
2000 New Horizons Blvd.  
Amityville, NY 11701

Ref: NYK-2001-127

Dear Mr. Kibria:

This letter is in reference to the inspection of your firm on July 23 & 25, 2001 regarding your firm's product, "Cholestrol Support Capsules", containing red yeast rice powder.

Your "Cholestrol Support" product contains lovastatin. The presence of lovastatin in your product is demonstrated by a certificate of analysis provided to you by one of your sources of the bulk red yeast rice powder used to make these capsules which shows the product to contain 1.4% lovastatin, the active ingredient in the prescription drug Mevacor. You have also provided this certificate to your contract customer, [REDACTED]. The drug Mevacor is dispensed solely by prescription for the treatment of diagnosed hypercholesterolemia and is marketed with an approved New Drug Application (NDA).

In 1998, the Agency 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 Township, 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 Court of Appeals and returned to the District Court. 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 significant amounts of lovastatin are subject to regulation as drugs and are not dietary supplements.

Your "Cholestrol Support" product 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 uses. 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].

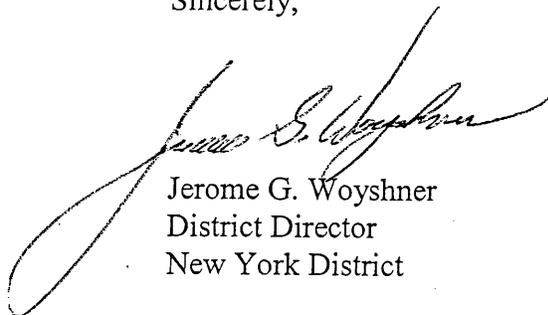
Furthermore, this drug is misbranded [502(f)(1) of the Act] because its labeling fails to bear adequate directions for use, for the conditions for which it is offered.

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 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 Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Lillian C. Aveta, Compliance Officer. If you have any questions regarding the content of this letter, Ms. Aveta can be reached at (718) 662- 5576.

Sincerely,



Jerome G. Woyshner  
District Director  
New York District