



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

9/24/92

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 8, 2001

Steve Yamada, President
Maypro Industries, Inc.
2700 Westchester Avenue
Purchase, NY 10577

Ref: NYK-2001-70

Dear Mr. Yamada:

This letter is in reference to our February 13, 2001, inspection of your firm regarding your firm's product, bulk red yeast rice powder.

According to the certificates of analysis provided to you by your sources of this product, and which you provide to your customers, the red yeast rice powder contains greater than 0.4% lovastatin, the active ingredient in the prescription drug Mevacor. The drug Mevacor is dispensed solely by prescription for the treatment of diagnosed hypercholesterolemia and is marketed with an approved New Drug Application (NDA). Due to potential side effects, drugs containing lovastatin may not be marketed over the counter because patients using this drug product require monitoring by a physician.

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.

This drug is misbranded within the meaning of section 502(o) of the Act because it was manufactured or prepared in an establishment not duly registered under section 510.

Maypro Industries, Inc.

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Your red yeast rice with lovastatin is also misbranded within the meaning of section 502(f)(1) of the Act because the labeling fails to bear adequate directions for its intended use. The drug is not exempt from this requirement under 21 CFR 201.122 because your product is intended for use in manufacture, processing, or repacking which causes the finished article to be a new drug and the drug does not have an approved NDA.

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: Bruce A. Goldwitz, Compliance Officer. If you have any questions regarding the content of this letter, Mr. Goldwitz can be reached at (718) 340-7000, ext. 5582.

Sincerely,



Robert L. Hart
Acting District Director

Maypro Industries, Inc.
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cc: HFR-NE1
cc: HFR-NE100
cc: HFR-NE140/QA file
cc: HFR-NE150
cc: HFR-NE1510/W. Eng
cc: HFR-NE340
cc: HFA-224
cc: HFC-210/CFN 2434717
cc: HFD-300
cc: HFD-310 (William Russell)
cc: HFI-35/redacted copy
cc: EF (Maypro Industries, Inc., CFN 2434717)
cc: warning letter file (NYK-2001-70)
cc: BAG

DCB approved
FACTS 6459-0

A handwritten signature in black ink, appearing to be 'S. J. ...', is written over the text 'DCB approved' and 'FACTS 6459-0'.