



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY 18 1999 4 09 6 '99 JUN 21 A9 53

Mr. Stephen L. Welling
President
Nature's Herbs
600 East Quality Drive
American Fork, Utah 84003

Dear Mr. Welling:

This is in response to your letter of May 1, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). In your letter, you state that you are making the claim "Helps maintain healthy cholesterol levels" for the product **Nature's Herbs Cholesterol-Power**. This product contains the ingredient red yeast fermented on rice (*Monascus purpureus*).

This letter is to advise you of the current status of products that contain red yeast rice. FDA announced its administrative decision on May 20, 1998 that a product named "Cholestin¹", manufactured by Pharmanex, Inc., which was promoted as a dietary supplement intended to affect cholesterol levels, is not a dietary supplement, but is instead an unapproved drug under the FD&C Act. This decision meant that Cholestin could not be legally sold in the United States.

On February 16, 1999, the United States District Court for the District of Utah "held unlawful and set aside" the FDA's administrative finding of May 20, 1998. FDA has appealed the District Court's decision to the United States Court of Appeals for the 10th Circuit. The future regulatory status of all red yeast rice products will depend, in part, on the decision of the courts on the merits of the Cholestin matter. At this time, FDA believes that products containing red yeast rice or *Monascus purpureus* that contain lovastatin are unapproved new drugs that are in violation of the FD&C Act.

¹Cholestin consists of the yeast *Monascus purpureus* when fermented on premium rice powder. The fermentation of the rice with this yeast, under certain conditions, produces a product that contains lovastatin, the active ingredient in the prescription cholesterol-lowering drug Mevacor.

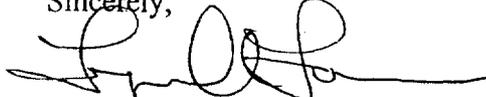
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Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lynn A. Larsen', with a long horizontal line extending to the right.

Lynn A. Larsen, Ph.D.

Director

Division of Programs and Enforcement Policy

Office of Special Nutritionals

Center for Food Safety

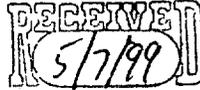
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240



May 1, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, D.C. 20204

Dear Sir or Madam

This letter will serve as a 30-day notification, pursuant to 403(r)(6) of the Federal Food, Drug & Cosmetic Act and regulations promulgated thereunder.

Product manufacturer: Nature's Herbs, 600 East Quality Drive, American Fork, UT 84003

Nutritional support claim being made: Helps maintain healthy cholesterol levels

Dietary supplement ingredient(s): Red Yeast fermented on rice (*Monascus purpureus*)

Product brand and name: Nature's Herbs Cholesterol-Power

As required, enclosed are two photocopies of this notification.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen L. Welling", written over a horizontal line.

Stephen L. Welling
President

Enclosures