



JUL 12 1999

2709 '99 JUL 19 P3:18

Mr. Neil Blechman
Executive Vice President
Twin Laboratories, Inc.
150 Motor Parkway
Suite 210
Hauppauge, New York 11788

Dear Mr. Blechman:

This is in response to your letter of June 21, 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 Twin Laboratories, Inc. is making the claim "Promotes a healthy blood lipid profile" for the product **Changes[®] Cardio Results[™]**. This product contains the ingredient red yeast rice, fermentation of *Monascus purpureus*(Went).

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.

975-0163

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Page 2 - Mr. Neil Blechman

Please contact us if we may be of further assistance.

Sincerely,

for Robert J. Moore

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

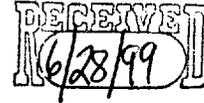
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140

"The Best of Nature through Nutritional Science"



June 21, 1999



Office of Special Nutritionals (HFS-450)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 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: **Changes International, a division of Twin Laboratories Inc.**
150 Motor Parkway
Hauppauge, NY 11788

Nutritional support claim being made: **Promotes A Healthy Blood Lipid Profile**

Dietary supplement ingredients: **Vitamin B6 (pyridoxine HCl)**
Folate (folic acid)
Vitamin B12 (cyanocobalamin)
Red yeast rice (fermentation of *Monascus purpureus* Went)
Purified soy phytosterols (45-55% beta-sitosterol)

Product brand and name: **Changes® Cardio Results™**

As required, enclosed are two photocopies of this notification.

Sincerely,

Neil Blechman
Executive Vice President
Twin Laboratories Inc.

Enclosures

63858



June 21, 1999

RECEIVED
6/28/99

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Executive Vice President
Twin Laboratories Inc.

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65858



June 21, 1999

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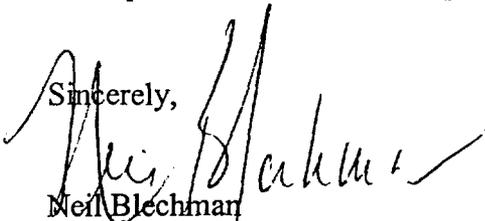
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