



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 10 1999

Mr. Harry A. Shippy
President
Nutritional Specialties, Inc.
1452 E. Katella Avenue
Anaheim, California 92805

Dear Mr. Shippy:

This is in response to your letter of October 19, 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 Nutritional Specialties, Inc. is making various claims for the product **LifeTime[®] Choles-Control Standardized Red Rice Yeast Extract** 600 mg. This product contains the ingredient red yeast rice.

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 "Cholestin", 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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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 flourish 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, Los Angeles District Office, Office of Compliance, HFR-PA240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0 163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-3 10 (B Williams)

HFD-3 14 (Aronson)

HFS-605

GCF- 1 (Dorsey, Barnett, Nickerson, Parker)

HFV-228 (SBenz)

f/t:HFS-456:rjm:11/10/99:docname:68003.adv:disc42

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 c St., S.W.
Washington, DC 20204

RECEIVED
10/18/99

RE: Dietary Supplement Statement of Support Notification

To: Whom It May Concern: ,

Nutritional Specialties, Inc., 1452 E. Katella Ave. Anaheim, CA 92805, the distributor of the following dietary supplement products, intends to make the following statement of support: "The natural ingredient in Choles-Control assists in normalizing the body's Cholesterol level. In China, this all natural ingredient has been used for over 1 .000 years as a traditional medicinal remedy and food."

This claim is being made for Red-Rice Yeast. Which is contained in LifeTime® Choles-Control Standardized Red Rice Yeast Extract 600 mg. This submission is being made in compliance with the requirements of 21 CFR 101.93.

The undersigned is an authorized representative of Nutritional Specialties, Inc. and certifies that the information contained in this notice is complete and accurate, and that Nutritional Specialties, Inc. has substantiation that the above statement is truthful and not misleading.

Harry A. Shippy
Signature
HARRY AUGUST SHIPPY
Full Name
RRS
Title

68003