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OCT 30 2001

Ms. Marjorie L. Fine
Senior Vice President
and General Counsel
Shaklee Corporation
Hacienda Campus
4747 Willow Road
Pleasanton, California 94588-2740

Dear Ms. Fine:

This is in response to your letters of September 28, 2001, 2001 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 (the Act)). Your submission states that Shaklee Corporation is making the following claim, among others, for the following products:

Garlic Dietary Supplement

“...may help retain normal blood cholesterol levels when taken daily as part of a low-fat, low-cholesterol diet...”

Energizing Soy Protein Dietary Supplement

“...as part of a low-fat, low-cholesterol diet, helps retain normal cholesterol levels.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate disease, namely, hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

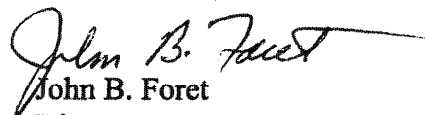
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Page 2 - Ms. Marjorie L. Fine

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Foret", with a long horizontal flourish extending to the right.

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling,
and Dietary Supplements

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-PA140

Shaklee Corporation
Hacienda Campus
4747 Willow Road
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Telephone 925/924-2586
Fax 925/924-2155

Marjorie L. Fine
Senior Vice President and
General Counsel

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September 28, 2001

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OCT 01 2001
BY: _____

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

Re: Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Shaklee Corporation hereby notifies FDA that it has begun using the following statements:

This unique Shaklee formula contains Garlic, which studies have shown may help retain normal blood cholesterol levels when taken daily as part of a low-fat, low-cholesterol diet, as well as Rosemary which has antioxidant properties, and Spearmint. Used daily, important phytochemicals in Shaklee Garlic may help promote cardiovascular health.

which contain the statutory statement, on the following product:

Garlic Dietary Supplement

I certify that the foregoing is complete and accurate, and that Shaklee Corporation has substantiation that the statements are truthful and not misleading.

Very truly yours,

Marjorie L. Fine (am)

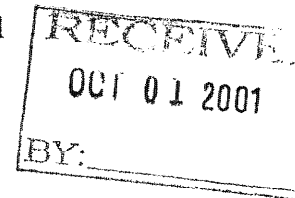
Marjorie L. Fine

MLF/mm

Shaklee Corporation
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Marjorie L. Fine
Senior Vice President and
General Counsel

September 28, 2001



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

Re: Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Shaklee Corporation hereby notifies FDA that it has begun using the following statements:

Research suggests that daily intake of soy protein as part of a low-fat, low-cholesterol diet helps retain normal cholesterol levels and promotes heart, breast, and prostate health. Studies have shown that soy helps regulate hormonal balance for women during the transitional period of menopause.

which contain the statutory statement, on the following product:

Energizing Soy Protein Dietary Supplement

I certify that the foregoing is complete and accurate, and that Shaklee Corporation has substantiation that the statements are truthful and not misleading.

Very truly yours,

Marjorie L. Fine

Marjorie L. Fine

MLF/mm

77967