



MAY - 3 2002

Curtis A. Spilburg, Ph.D.
President
Lifeline Technologies, Inc.
400 Chesterfield Center
Suite 120
Chesterfield, Missouri 63017

Dear Dr. Spilburg:

This is in response to your letter of April 18, 2002 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 Lifeline Technologies, Inc. is making the following claim for the product ChoLESStolife:

“ChoLESStolife lowers cholesterol absorption in the small intestine to help retain healthy cholesterol levels.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product contains no such clarification, however. Therefore, FDA considers it to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol.

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for

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use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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.

Please contact us if we may be of further assistance.

Sincerely,



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, Kansas City District Office, Office of Compliance, HFR-SW340

80233

Lifeline

Technologies

April 18, 2002

APR 6 5 2002
BY:

Office of Nutritional Products, Labeling and
Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

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BY:

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BY:

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, Lifeline Technologies, Inc. notifies FDA that it has begun using the following statement:

“ChoLESStolife lowers cholesterol absorption in the small intestine to help retain healthy cholesterol levels.”

This statutory statement will appear on a dietary supplement, and it is based on the consumption of 1.0 gm/day of soy stanols, the active ingredient in the tablet(s). This statutory statement will appear with the following product:

ChoLESStolife, a dietary supplement

I certify that the foregoing is complete and accurate, and that Lifeline Technologies, Inc. has substantiation that the statements are truthful and not misleading.

Very truly yours,

Lifeline Technologies
400 Chesterfield Center, Suite 120
Chesterfield, MO 63017

by 

Curtis A. Spilburg, Ph.D.
President

