DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN 28 2002

6379 '02 MAR 26 P2:20

Ms. Lisa J. Haskell
Manager, Domestic Labeling
Solgar Vitamin and Herb
500 Willow Tree Road
Leonia, New Jersey 07605

Dear Ms. Haskell:

This is in response to your letter of November 6, 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 Solgar Vitamin and Herb is making the claim "Cholesterol Support" for the product **Gold Specifics Cholesterol Support**.

Your claim (i.e., Cholesterol Support) implies that the product is intended to affect blood cholesterol levels, given the added context that the product is also for "circulatory" support. 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, namely that it is for "cholesterol support," 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 statements that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for 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.

975-0163 LET 567

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret

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, New Jersey District Office, Office of Compliance, HFR-MA240

78981

SOLGAR Since 1947

SOLGAR VITAMIN AND HERB
WORLD HEADQUARTERS

500 WILLOW TREE ROAD, LEONIA, NJ 07605 USA
PHONE 201-944-2311 FAX 201-944-2351

100% QUALITY PLEDGE

11-6-01

RECEIVED
JAN 16 2002
BY:

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
FOOD AND DRUG ADMINISTRATION
200 C Street, S.W.
Washington, D.C. 20204

RE: Notification for Statement on Dietary Supplement

Dear Sir/Madam:

In compliance with the Dietary Supplement Health and Education Act of 1994, Solgar Vitamin and Herb hereby makes its official notification under Section 101.93 that it has included a statement listed in Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act on its label. Accordingly, enclosed please find two (2) copies of this Notification. The following information is being provided:

The dietary supplement is being distributed by:

SOLGAR VITAMIN AND HERB
500 Willow Tree Road
Leonia, New Jersey 07605 USA

The text of the statement, the name of the dietary supplement and the name of the dietary ingredients contained in the product, which is the subject of the above statement, is listed on the attached sheet.

I hereby certify that the information presented and contained in this notice is complete and accurate, and my files contain substantiation that the statements made are truthful and not misleading.

Thank you for your time and attention to this matter. If you have any questions, please do not hesitate to contact the undersigned.

Very truly yours,
SOLGAR VITAMIN & HERB

Lisa J. Haskell
Manager, Domestic Labeling

Certified Mail – Return Receipt Requested
7000 0600 0024 1798 0336

November 6, 2001

Product Name	Structure Function Claim Or Statement	Dietary Ingredient (s)
Gold Specifics Cholesterol Support*	Cholesterol Support* Circulatory*	Guggulipids, Soy, Tocotrienols
Lutein Carotenoid Complex	Vision Support*	Lutein
Saw Palmetto Pygeum Lycopene Complex	Prostate Support*	Lycopene
Super Concentrated Isoflavones	Phytoestrogen Source*	Soy Isoflavones