



JAN 14 2002

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Mr. Christian Seyrig
Senior Vice-President
Health from the Sun
19 Crosby Drive
Suite 300
Bedford, Massachusetts 01730

Dear Mr. Seyrig:

This is in response to your letter of November 28, 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 Health from the Sun is making the following claims, among others, for the product **Basikol Capsules**:

- “Helps maintain healthy cholesterol levels;”
- “...maintain a healthy heart system;”
- “...beneficial effects to maintain a healthy heart and normal cardiovascular system;”
- “...supplying 800 mg phytosterols, shown to maintain healthy 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 this product suggest that it is intended to treat, prevent, cure, or mitigate diseases, namely, hypercholesterolemia¹ and coronary heart 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.

¹FDA discussed the circumstances when cholesterol maintenance claims may not be disease claims in the January 6, 2000 Federal Register final rule on structure/function claims (see 65 FR 1000 at 1018; discussion for comment 45).

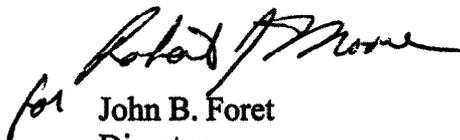
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While it is not clear from your submission, the statements being made for this product may be intended by you as statements about the relationship between plant sterols and stanols and the risk of coronary artery disease. Such claims are not subject to 21 U.S.C. 343(r)(6), but instead are claims subject to 21 U.S.C. 343(r)(1)(B). ~~FDA has authorized a health claim on the relationship between plant sterol esters and stanol esters and the risk of coronary artery disease (see 21 CFR 101.83).~~ A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between plant sterol esters and stanol esters and the risk of coronary artery disease in its labeling. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.83 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.83 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary artery disease. If your product meets the eligibility requirements to bear the health claim authorized in 21 CFR 101.83 in its labeling and the claims themselves meet the message requirements set forth in the regulation, it would qualify to bear the authorized health claim in its labeling.

Please contact us if you require further assistance.

Sincerely,



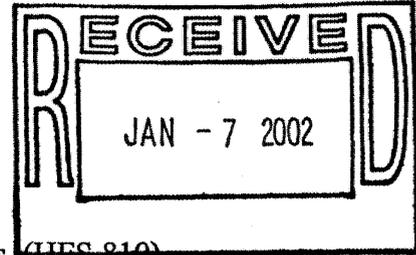
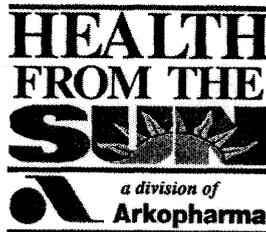
John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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, New England District Compliance, HFR-NE240



November 28, 2001

Food and Drug Administration
Office of Nutritional Products Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, D.C. 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Arkopharma/Health From The Sun, 22 N. Main St. Newport, NH 03773, within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or in the labeling:

Text of Claims:

1. Helps maintain healthy cholesterol levels
2. A natural way to help maintain a healthy heart system
3. Several studies have been carried out on these compounds showing their beneficial effects to maintain a healthy heart and normal cardiovascular system
4. Basikol completes the daily intake by supplying 800 mg phytosterols, shown to maintain healthy cholesterol levels

Name of Ingredients Subject to Claim: Phytosterols (extracted from soy, corn and canola)
Name of Supplement: Basikol Capsules

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma/Health From The Sun has substantiation that the statement is truthful and not misleading.

Sincerely,

Christian Seyrig
Senior Vice-President

SALES, MARKETING AND FINANCE OFFICE
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