



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT - 7 1999

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David M. Kulow, President
Health from the Sun, Division of Arkopharma
Sales, Marketing & Finance Office
53 Shore Road
Winchester, Massachusetts 0 1890

Dear Mr. Kulow:

This is in response to your letter of September 16, 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 (the Act)). Your submission states that Health from the Sun, a Division of Arkopharma, is making the following claims for the product "Health From The Sun EFA Glucose Formula:"

"maintains healthy blood sugar"

"promotes healthy blood sugar levels"

"provide nutritional support for those with impaired glucose/insulin function"

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, or mitigate disease, namely diabetes and disorders of glucose and/or insulin function and metabolism. 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-3 10, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET309

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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 Office, Office of Compliance, HFR-NE240

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 (Bowers)

HFV-228 (Benz)

GCF- 1 (Dorsey, Barnett)

f/t:HFS-456:rjm: 10/6/99:docname:67504.adv:disc41



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September 16, 1999

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

10/5/99

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 Health From The Sun, PO Box 179 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. maintains healthy blood sugar
2. promotes healthy blood sugar levels
3. provide nutritional support for those with impaired glucose/insulin function

Marketers of:

The Total EFA

Evening Primrose Oil

Borage Oil

Black Currant Oil

Flax Oil

FiProFLAX

Fish Oil

Rocket Fuel

*Bee Pollen
from England*

Sanhelios

Name of Ingredients Subject to Claim: vitamin C, vitamin E, chromium, borage seed oil, fish oil, gymnema sylvestre leaf extract, momordica charantia seed extract, alpha-lipoic acid, vanadium

Name of Supplement: Health From The Sun *EFA Glucose Formula*

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

Sincerely,

David M. Kulow
President

Sales, Marketing & Finance Office
53 Shore Road
Winchester, MA 01890
Tel: (781) 721-3303
Fax: (781) 290-5851

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