



AUG 18 1998

1840 '98 AUG 21 P12:45

Mr. John P. Venardos
Vice President, Regulatory Affairs
International Product Management
Herbalife International of America, Inc.
9800 La Cienega Boulevard
P.O. Box 80210
Inglewood, California 90301

Dear Mr. Venardos:

This is in response to your letter of August 4, 1998 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, responding to FDA's letter of June 25, 1998, states that Herbalife International of America, Inc. is making the following statements, among others, for the product "Woman's Choice Dietary Supplement:"

"...experience a variety of symptoms...

"...causes discomfort, including sleep disturbance."

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 prevent disease, namely disturbances associated with menopause. 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.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 211

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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, Los Angeles District Office, Compliance Branch, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file, OSN#60634)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:rjm:HFS-456:8/17/98:60634.adv:disc31



HERBALIFE INTERNATIONAL OF AMERICA, INC
9800 La Cienega Blvd., Inglewood, CA 90301
Mailing Address: P.O. Box 80210, Los Angeles, CA 90080-0210
(310) 410-9600 • FAX: (310) 258-7124

JOHN P. VENARDOS
Vice President, Regulatory Affairs
International Product Management

August 4, 1998



Office of Special Nutritionals (HFS-450)
Center For Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION
200 C Street, S.W.
Washington, D.C. 20204

Ref.: **Woman's Choice Dietary Supplement**

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. has begun commercializing Woman's Choice dietary supplement in the United States. This letter is intended to replace our June 15, 1998 notification letter to the FDA advising the agency of statements being made for the Woman's Choice product. It contains a revision of certain statements made in our June 15 notification letter, and reflects the Company's response to the FDA's comments on the statements made in our June 15 letter, as set forth by the agency in its June 25, 1998 courtesy letter to us.

Woman's Choice dietary supplement is labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

LABEL

Suggested Serving: One or two tablets per day.

Woman's Choice contains a special blend of isoflavones from Red Clover, Soy and Kudzu plus Black Cohosh which helps promote hormone balance in women.

PRODUCT LITERATURE

As women begin the perimenopausal period (about age 35), they experience a variety of symptoms, some of which are related to declining estrogen levels. This normal occurrence often causes discomfort, including sleep disturbance. Many studies suggest that isoflavones may help women meet nutritional needs during menopause. Isoflavones have a chemical structure similar to the body's natural estrogen, which may account for these effects. Additionally, isoflavones help maintain a healthy cholesterol level and preliminary studies show that soy isoflavones may increase bone mass. Woman's Choice is rich in natural sources of isoflavones, including Black Cohosh, Red Clover Extract and Kudzu Root. It also contains antioxidants that assist the body's defense against the effects of free radicals.

- Contains a special blend of isoflavones from Red Clover, Soy and Kudzu, along with antioxidant-rich Black Cohosh, that may promote hormone balance in premenopausal and menopausal women.

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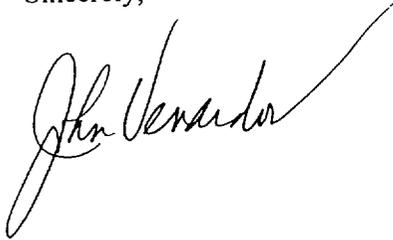
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August 4, 1998
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Product labeling prominently bears the required boxed statement, "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

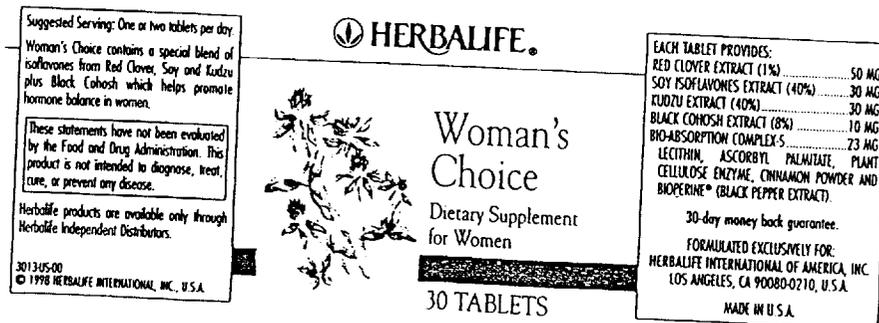
Herbalife International of America, Inc. certifies that the information contained in this notice is complete and accurate, and that the Company has substantiation that the foregoing statements are truthful and not misleading.

Please do not hesitate to advise should you have any questions.

Sincerely,



File: Woman's Choice Dietary Supplement



Suggested Serving: One or two tablets per day.
Woman's Choice contains a special blend of isoflavones from Red Clover, Soy and Kudzu plus Black Cohosh which helps promote hormone balance in women.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Herbalife products are available only through Herbalife Independent Distributors.

301345-00
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HERBALIFE.

Woman's Choice
Dietary Supplement
for Women

30 TABLETS

EACH TABLET PROVIDES:
RED CLOVER EXTRACT (1%) 50 MG
SOY ISOFLAVONES EXTRACT (40%) 30 MG
KUDZU EXTRACT (40%) 30 MG
BLACK COHOSH EXTRACT (8%) 10 MG
BIO-ABSORPTION COMPLEX 23 MG
LECTITHIN, ASCORBYL PALMITATE, PLANT CELLULOSE ENZYME, CINNAMON POWDER AND BIOPERINE® (BLACK PEPPER EXTRACT).

30-day money back guarantee.

FORMULATED EXCLUSIVELY FOR:
HERBALIFE INTERNATIONAL OF AMERICA, INC.
LOS ANGELES, CA 90080-0210, U.S.A.

MADE IN U.S.A.



Special Supplements For Women



Tang Kuei Plus*

Superior nutritional tonic especially for women.

Tang Kuei has been used for centuries in China as a general nutritional tonic, particularly beneficial for women. The root of the plant is preferred because it is a rich source of B vitamins, Calcium, Iron, Magnesium and essential oils. In the Chinese system, Tang Kuei is considered a "superior herb" that can be taken on a daily basis and is often added to soups and broths to increase the nutritional value of these dishes.

- Specially formulated to normalize the challenges associated with a woman's menstrual cycle.
- Includes the additional benefit of Chamomile. This multipurpose plant was used by the Ancient Greeks and was considered a sacred herb by the early Anglo-Saxons.
- Includes Calcium and Magnesium, as well as Vitamin A.

#1014 (case of 12)

#0003 (HAP or unit) \$12.50

Woman's Choice

Dietary supplement for women.

As women begin the perimenopausal period (about age 35), they experience a variety of symptoms, some of which are related to declining estrogen levels. This normal occurrence often causes discomfort, including sleep disturbance. Many studies suggest that isoflavones may help women meet nutritional needs during menopause. Isoflavones have a chemical structure similar to the body's natural estrogen, which may account for these effects. Additionally, isoflavones help maintain a healthy cholesterol level and preliminary studies show that soy isoflavones may increase bone mass. Woman's Choice is rich in natural sources of isoflavones, including Black Cohosh, Red Clover Extract and Kudzu Root. It also contains antioxidants that assist the body's defense against the effects of free radicals.

- Contains a special blend of isoflavones from Red Clover, Soy and Kudzu, along with antioxidant-rich Black Cohosh, that may promote hormone balance in perimenopausal and menopausal women.

#3013 (case of 12)

#0166 (HAP or unit) \$22.95

