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John P. Venardos
Vice President, Regulatory Affairs
Herbalife International of America, Inc.
1800 Century Park East
Century City, California 90067-1501

Dear Mr. Venardos:

This is in response to your letter of June 1, 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 Herbalife International of America, Inc. is making the following claims, among others, for the product **Herbalifeline with Omega-3 Fatty Acids DHA and EPA:**

- "...reduce fatty triglyceride levels in the blood, which can build up in the arteries and cause heart attacks"
- "Studies show that Eskimos and the Japanese, who for centuries have eaten fatty fish, have a very low rate of heart disease and circulatory disorders due in part to their diet"
- "...fish oil reduces the incidence of sudden death and cardiac death"
- "...reduction of stroke, particularly in women"
- "...reduced risk of blockage of vein grafts in people who have had coronary artery bypass surgery"
- "...reduces the risk of developing age-related macular degeneration"
- "...protective against the development of depression."

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 diseases. 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.

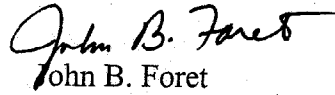
975-0163

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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, Los Angeles District Compliance, HFR-PA240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (file)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:6/6/01:docname:76205.adv:disc56



HERBALIFE INTERNATIONAL OF AMERICA, INC.
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(310) 203-7746 • FAX (310) 557-3916
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JOHN VENARDOS
Vice President, Regulatory Affairs
International Product Management

June 1, 2001

76205

Office of Nutritional Products
Labeling and Dietary Supplements
FOOD & DRUG ADMINISTRATION
200 C Street, S.W.
Washington, D.C. 20204

Ref: **Herbalifeline Softgels**

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. has begun commercializing Herbalifeline Softgels.

Herbalifeline Softgels are labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug and Cosmetic Act.

1. LABEL

This exclusive blend of highly refined marine lipids contains high quality Omega-3 fatty acids, especially eicosapentanoic acid (EPA) and docosahexanoic acid (DHA). Herbalife's exclusive combination of these highly refined fish oils and essential oils from thyme, peppermint and clove will minimize any unpleasant aftertaste.

Individuals taking prescription anticoagulants should consult with their physician prior to using this product.

2. HERBALIFE FACT SHEET

(Note: Immediately adjacent to the following copy, appears a ruled DSHEA disclaimer box.)

Herbalifeline® - Omega - 3 liquid marine source lipid complex (fish oil) with special nutritional factors.

Looking for a direct line to cardiovascular health? Call on Herbalifeline® with Omega - 3, a fatty acid which can help keep your heart-the most important muscle in your body-healthy. Omega - 3 fatty acids are required for normal growth and development as well as good vision. Researchers have found that Omega - 3 fatty acids can help reduce fatty triglyceride levels in the blood, which can build up in the arteries and cause heart attacks.

Omega - 3 is not made by the body and must come from the diet. Studies show that Eskimos and the Japanese, who for centuries have eaten fatty fish, have a very low rate of heart disease and circulatory disorders due in part to their diet. The average American diet, on the other hand, is high in saturated fats found in meats and dairy products and high in Omega - 6 fatty acid from corn oil. However, it is low in foods rich in Omega - 3 fatty acids, a combination that can lead to health challenges.

Herbalifeline® is an exclusive blend of highly refined marine lipids containing high - quality Omega - 3 fatty acids, especially eicosapentanoic acid (EPA) and docosahexanoic acid (DHA), so you can help improve your health without necessarily altering your diet. One of Herbalife's most popular products,

Herbalifeline® not only includes premium-grade, deodorized fish oil, it is also formulated with vitamin E, one of the most potent antioxidant vitamins, and selenium, a health-protecting mineral.

Discussion Points

Medical and nutritional experts agree that Omega-3 fatty acids play a significant role in good health, and some studies suggest it can help support the proper functioning of the heart. Herbalifeline® is rich in Omega-3 fatty acids and can be taken daily for optimum results.

- A sea of ingredients: Herbalifeline® includes other marine lipids, which offer powerful health-enhancing benefits direct from the sea.*
- Easy to digest: Low-reflux formula minimizes fish-oil taste during digestion.
- Stable: Essential oils of thyme, peppermint and clove help keep the oil fresh and pure.
- Combine with other products: Herbalifeline® can be used in conjunction with the Thermojetics® Weight-Management Program and Herbalife's entire line of nutritional products.

Did You Know?

Studies have shown that increased consumption of fish oil reduces the incidence of sudden death and cardiac death in general. Other studies demonstrated a reduction of stroke, particularly in women. Another study documented a reduced risk of blockage of vein grafts in people who have had coronary artery bypass surgery. Higher consumption of fish reduces the risk of developing age-related macular degeneration. There is also evidence that higher levels of Omega-3 fatty acids are protective against the development of depression.

Fast Facts

- Highly refined marine-lipid blend.
- Provides vitamin E, a key oil-soluble vitamin that possesses antioxidant qualities.*
- Essential oils stabilize fish oil.
- No fishy taste.
- Small, easy to swallow soft-gel capsule.

3. PRODUCT BROCHURE

(Note: The asterisks appearing in the copy shown, relate to the rules DSHEA disclaimer boxes which are located on the same page of the product literature.)

Newly Reformulated Herbalifeline®

Maximize Your Heart's Health!

Now you and your customers can get even more of the heart-smart benefits of fish oil in our newly reformulated Herbalifeline®.* This exclusive blend of marine lipids contains high-quality Omega-3 fatty acids, especially eicosapentanoic acid (EPA) and docsahehexanoic acid (DHA). New Herbalifeline also contains vitamin E for maximum antioxidant benefit.*

Herbalife's exclusive combination of these highly refined fish oils and aromatic essential oils minimizes any unpleasant aftertaste. We've increased the potency, and we deliver it in smaller, soft-gel capsules.

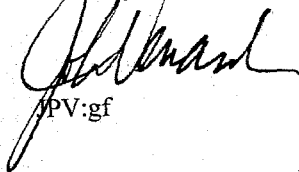
- More concentrated. Contains 50 percent more EPA and DHA than our original formula.
- New smaller capsule is easier to swallow.
- Utilizes a low-reflux formula so there's no fishy aftertaste.
- We use the finest premium fish oil available.
- The addition of three essential oils-thyme, peppermint and clove-helps keep fish oil fresh and pure.

Product labeling and literature 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 in this notice is complete and accurate, and that the Company has substantiation that the foregoing statements are truthful and not misleading.

If you have any questions, please do not hesitate to ask.

Sincerely,



JPV:gf



NEW & IMPROVED

Herbalifeline
with Omega-3 Fatty Acids
DHA and EPA
Dietary Supplement

90 SOFTGELS

Recommended Use: One to three capsules three times a day preferably with meals.

This exclusive blend of highly refined marine lipids contains high quality Omega-3 fatty acids, especially eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Herbalife's exclusive combination of these highly refined fish oils and essential oils from thyme, peppermint and clove will minimize any unpleasant aftertaste.

Individuals taking prescription anticoagulants should consult with their physician prior to using this product. Herbalife products are available only through Herbalife Independent Distributors.

30-day money-back guarantee.
Recycle this bottle.

Formulated exclusively for:
HERBALIFE INTERNATIONAL OF AMERICA, INC.
 Los Angeles, CA 90089-0210, U.S.A. • MADE IN U.S.A.
 © 2001 HERBALIFE INTERNATIONAL, INC., U.S.A.


Supplement Facts

Serving Size: 1 Softgel
 Servings Per Container: 90

	Amount Per Serving	% Daily Value*
Calories	5	
Total Fat	0.5 g	<1%
Vitamin E (as d-alpha tocopherol)	8 IU	27%
Marine Lipid Complex (Fish Oil)	500 mg	†

* Percent Daily Values are based on a 2,000 calorie diet.
 † Daily Value not established.

Other Ingredients:
 Gelatin, Glycerin, Soybean Oil, White Thyme Oil, Clove Oil, Peppermint Oil and Vanilla Flavor.



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Herbalifeline
with Omega-3 Fatty Acids
DHA and EPA
Dietary Supplement

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