DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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JAN 26 2001

Mr. Alan H. Jacobs
President/CEO
Cancer Wellness Institute
3850 Tampa Road
Palm Harbor, Florida 34684

Dear Mr. Jacobs:

This is in response to your letter to the Food and Drug Administration (FDA) dated November 16, 2000. In your letter, you stated that you disagreed with our position, stated in a letter to you dated November 6, 2000, that certain statements made for your products Earthmends™ Breast Health Program Dietary Supplement and Earthmends™ Prostate Health Program Dietary Supplement are not claims that may be made for dietary supplements under 21 U.S.C. 343(r)(6).

In our November 6, 2000 letter, we stated that the following claims were not claims under 21 U.S.C. 343(r)(6), but instead were disease claims under the Act and 21 CFR 101.93(g):

Earthmends™ Breast Health Program Dietary Supplement

"...nutritionally support individuals while undergoing treatment"
"...to assist you during this difficult time, while delivering specific ingredients intended to directly support healthy breast tissue"
"...designed to nutritionally combat the side effects of treatments such as fatigue and nausea"
"...product should be taken while undergoing treatment and during the following six months. This will nutritionally aid in the recovery process"
"...Fuel your body's fight..."

Earthmends™ Prostate Health Program Dietary Supplement

"...nutritionally support individuals who are undergoing treatment"
"...to assist you during this difficult time, while delivering specific ingredients intended to directly support prostate cells"
"...designed to nutritionally combat the side effects of treatments such as fatigue and nausea"
"...product should be taken while undergoing treatment and during the following six months. This will nutritionally aid in the recovery process"
"...Fuel your body's fight..."

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In your letter, you state that the claims that your products mitigate the side effects associated with cancer therapies are appropriate structure/function claims because the side effects are not themselves diseases. You further state that the other claims about the products being intended to "nutritionally support" patients undergoing cancer treatment are also appropriate structure/function claims because they are "intentionally tailored" to "emphasize (1) the nutritional (as opposed to any pharmacological) value of the products" and "(2) their role in supporting health and normal bodily structure."

We disagree. For purposes of 21 U.S.C. 343(r)(6), FDA defined the term "disease" to mean, in part, "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension) (see generally 21 CFR 101.93(g)(1)). In the final rule that established this definition of disease, FDA stated that the requirement of "damage to an organ, part, structure, or system of the body such that it does not function properly" included conditions where there is "direct evidence of structural damage" as well as conditions where there is "indirect evidence of damage, indicated by the failure of the organ, part, structure, or system of the body to function properly." We further stated that the reference to "a state of health leading to such dysfunctioning" also permits the agency to look at evidence other than actual damage to an organ, part, structure, or system of the body." (65 FR 1000 at 1010).

We do not agree that fatigue and nausea as side effects of conventional cancer therapies fall outside the scope of the definition of disease in 21 CFR 101.93(g)(1). In fact, FDA cited "reduces nausea associated with chemotherapy" as an example of a disease claim in the proposed rule on structure/function claims for dietary supplements (63 FR 23624 at 23628), and the agency reiterated that example in the final rule (65 FR at 1029). The fatigue and nausea that are a result of cancer therapies such as chemotherapy or radiation therapy are a consequence of the effect of the therapies on "an organ, part, structure, or system of the body such it does not function properly." Fatigue and nausea do not occur because the therapies deplete the body's supply of one or more nutrients or interfere with the metabolism of a nutrient or nutrients such that supplementation is needed to restore those nutrient losses or meet the body's needs for a particular nutrient (see 65 FR at 1029). Rather, the therapies cause damage that is evidenced by abnormal fatigue and the failure of the gastrointestinal system to function properly, resulting in nausea. Accordingly, the side effects (fatigue, nausea) mentioned in your claims fit squarely within the scope of the definition of disease in 21 CFR 101.93(g)(1) and are not structure/function claims under 21 U.S.C. 343(r)(6).

We also believe that the general claims about the two products' nutritional utility for cancer patients are disease claims under 21 CFR 101.93(g)(2)(vii) and (viii). In the final rule, the agency agreed that dietary supplements may be useful in providing nutritional support to persons with a disease or those undergoing a particular therapy, provided that no express or implied claims were made that the dietary supplement augments a therapy or drug action. In the case of your products, the mere use of the modifier "nutritionally" with the claims that your product will "aid" in recovery, "support" cancer treatment, and "combat" side effects

such as fatigue and nausea does not remove the implicit representation that your products are intended to directly effect the "damage to an organ, part, structure, or system of the body such that it does not function properly" in cancer patients; i.e., that they are intended to treat fatigue and nausea associated with certain cancer therapies and as an adjunct treatment for cancer itself. Hence, the claims are properly disease claims and not structure/function claims under 21 U.S.C. 343(r)(6). Although we agree, as we discussed in the January 6, 2000 final rule (65 FR 1028-29), that there may be nutritional support claims that could be used for dietary supplements intended to replace nutrients that are lost as a consequence of a drug therapy (e.g., a claim a potassium supplement is intended to replace potassium loss due to the use of thiazide diuretics) that would not cause a product to be subject to regulation as a drug, we do not believe that your claims are such claims and we stand by our original position stated in our November 6, 1999 letter.

Please contact us if we may be of further assistance.

Sincerely,

for Robert A. Moore

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, Florida District Office, Office of Compliance, HFR-SE240

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Nickerson)
r/d:HFS-811:RMoore:12/26/00
reviewed:LNickerson:1/24/00
f/t:HFS-811:rjm:1/25/00:docname:73432.adv:disc53

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November 16, 2000

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Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and
Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Room 1852A
200 C Street, S.W.
Washington, D.C. 20204

Re: Structure/Function Claims

Dear Mr. Foret:

This letter promptly replies to your November 6, 2000 letter to me (received last Thursday), in which you indicate that specific statements made in labeling two of our products, Earthmends™ Breast Health Program Dietary Supplement and Earthmends™ Prostate Health Program Dietary Supplement, suggest that these products are intended for use as drugs to treat, prevent, cure, or mitigate, respectively, breast and prostate cancers. I notified your agency about these statements by letter dated October 12, 2000, in conformity with requirements for marketing products making such statements, authorized under the Dietary Supplement Health and Education Act (DSHEA).

At the outset, let me assure you that it is not our intention to represent or sell our Earthmends™ dietary supplements as drugs. As background, at the Cancer Wellness Institute, we take a holistic approach to living with cancer, employing traditional treatments, but also integrating nutrition, exercise, and a positive outlook. The Earthmends™ products were developed, and are intended and offered, solely for nutritional purposes, to supplement the diet, as recommended by public health authorities. These dietary supplements, however, are just one component of an overall health program; they do not have, nor do we intend to represent them as having, a drug-like role in the treatment, prevention, cure, or mitigation of breast or prostate

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cancers. The products' innovators -- a medical doctor, nutritionist, and myself, a cancer survivor -- fully recognize and respect the distinctions between drugs and dietary supplements from a clinical and regulatory perspective.

Consistent with our understanding of the respective, but complementary, roles of cancer treatment and nutrition in bestowing wellness, and of the legal principles governing the use of so-called "structure/function claims" permitted for dietary supplements under the DSHEA, we took great care, in full consultation with our outside legal counsel, in crafting the informational statements used in labeling our products -- including the statements referenced in your letter -- so as to accurately describe their intended use and benefits, and to comply fully with 21 C.F.R. § 101.93(f)-(g), as these regulations were explained in volume 65 of the *Federal Register* at pages 1000-1050 when published on January 6 of this year. This being the case, while we appreciate your position and acknowledge that reasonable minds may differ, we respectfully do not concur that the statements referenced in your letter are disease claims impermissible in labeling our Earthmends™ dietary supplement products.

More specifically, your letter asserts, citing to 21 C.F.R. § 101.93(g)(2)(ix), that a label statement -- presumably "designed to nutritionally combat the side effects of treatments such as fatigue and nausea" -- is an impermissible disease claim because it suggests that the product is intended to treat or prevent adverse events associated with a therapy for a disease. We note, however, that the cited regulation contains an important caveat. The regulation, in pertinent part, states:

> A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:
>
> > Treats, prevents, or mitigates adverse events associated with a therapy for a disease, <u>if the adverse events constitute diseases</u> . . . [emphasis supplied].

In publishing the regulation in the January 6, 2000 *Federal Register*, FDA at page 1029 explained:

> The criterion is not intended to capture every adverse event claim, but only claims about adverse events that satisfy the definition of disease.

The term "disease" is defined in 21 C.F.R. § 101.93(g)(1) to mean:

> [D]amage to an organ, part, structure, or system of the body such that it does not function properly (*e.g.*, cardiovascular disease), or a state or health leading to such disfunctioning (*e.g.*, hypertension). . . .

Therefore, we believe that the statement, "designed to nutritionally combat the side effects of treatments such as fatigue and nausea," appearing on labels for both products, is not an

impermissible disease claim because, while fatigue and nausea are side effects associated with certain cancer therapies, these events themselves are not diseases.

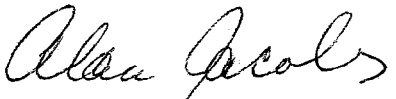
We similarly believe that the other label statements that you reference in your letter are not disease claims, and neither suggest that our dietary supplements are intended to augment a particular therapy or drug action for a disease (21 C.F.R. § 101.93(g)(2)(vii)), nor that they have a role in the body's response to a disease (21 C.F.R. § 101.93(g)(2)(viii)). To the contrary, consistent with science and regulation, we intentionally tailored the statements to emphasize (1) the nutritional (as opposed to any pharmacological) value of the products (*e.g.*, "nutritionally support individuals [while/who are] undergoing treatment"; "designed to nutritionally combat the side effects of treatments such as fatigue and nausea"; "products should be taken while undergoing treatment and during the following six months. This will nutritionally aid in the recovery process") and (2) their role in supporting healthy and normal bodily structure (*e.g.*, "to assist you during this difficult time, while delivering specific ingredients intended to directly support [healthy breast tissue/prostate cells]"). This intentional tailoring extended also to the other statement your letter references, which, as your agency was notified, in full context reads: "Fuel your body's fight, take control of your health. Supplement your diet with Earthmends™, the Nutritional Building Block to Good Health."

In light of the foregoing, we believe that no change in our labeling statements necessarily is warranted, and that FDA action to chill their expression would be legally and constitutionally questionable.

Nevertheless, we recognize that these matters are in a "gray" area. Moreover, we want to be responsive to your concerns and responsible in marketing our dietary supplements to consumers. This being the case, we presently are revising certain of the label statements that were the subject of your letter. We will notify your agency shortly about the resulting label statements, in conformity with 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93(a). These new statements will be used when the products' labels are next reprinted in approximately three months.

I appreciate your further consideration of this matter, which is of great importance to us. Please be assured that we take your expressed concerns quite seriously. This being the case, please feel free to contact me again, if necessary to facilitate a proper resolution.

Respectfully submitted,



Alan H. Jacobs
President/CEO