DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY 11 2001

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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 April 20, 2001 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter notified the agency of claims that you intend to make for the products Earthmends™ Breast Health Program Dietary Supplement and Earthmends™ Prostate Health Program Dietary Supplement. In previous letters to you dated November 6, 2000 and January 26, 2001 we informed you that certain claims that you intended to make for these two products were not claims that may be made for dietary supplements under 21 U.S.C. 343(r)(6), but instead were disease claims under the Act and 21 CFR 101.93(g).

We have carefully reviewed the revised claims in your April 20, 2001 and continue to believe that the following statements are not claims under 21 U.S.C. 343(r)(6), but instead are disease claims under the Act and 21 CFR 101.93(g):

Earthmends™ Breast Health Program Dietary Supplement

"Earthmends™ Breast Health Program has been developed to bolster you in several ways through the physically stressful time of treatment and recovery;"
"Other ingredients are included to inhibit the side effects of therapies, such as temporary fatigue and nausea;"

Earthmends™ Prostate Health Program Dietary Supplement

"Earthmends™ Prostate Health Program has been developed to bolster you in several ways through the physically stressful time of treatment and recovery;"
"Other ingredients are included to inhibit the side effects of therapies, such as temporary fatigue and nausea."

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In our previous letters, we stated that, 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 continue to maintain that fatigue and nausea, as side effects of conventional cancer therapies, fall within 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 that 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 being part of a program to "bolster you in **several ways** (emphasis added) through the physically stressful time of treatment and recovery" are disease claims because they imply that the products, in part, have an effect on patients undergoing cancer therapy beyond their simply meeting nutrient needs of cancer patients that are caused by the disease or disease treatment. Because these claims describe effects that the products will have on cancer patients that appear to include, but not be limited to, providing nutritional support, they are disease claims [see 21 CFR 101.93(g)(2)(vii) and (viii)]. As we discussed in the January 6, 2000 final rule (65 FR 1028-29), 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 therapy or a disease that would not cause a product to be subject to regulation as a drug. However, we do not believe that the claims identified above are such claims and we stand by our position stated in our November 6, 2000 and January 26, 2001 letters.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret

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)
f/t:HFS-811:rjm:5/3/01:docname:75648.adv:disc57

CancerWellness
INSTITUTE

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April 20, 2001

Division of Compliance and Enforcement (HFS-810)
Office of Nutritional Products, Labeling and Dietary Supplements
Center For Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Section 403(r)(6) Notification

Dear Sir or Madam:

Pursuant to section 403(r)(6) of the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6), and implementing regulation, 21 C.F.R. § 101.93, the Cancer Wellness Institute submits this notification that the following statements are being made in labeling for the dietary supplements, Earthmends™ Breast Health Program and Earthmends™ Prostate Health Program.

Earthmends™ Breast Health Program Dietary Supplement

- Earthmends™ Breast Health Program Dietary Supplement does not treat or cure cancer, but has been specifically designed to nutritionally support individuals during and following therapy.
- Earthmends™ Breast Health Program has been developed to bolster you in several ways through the physically stressful time of treatment and recovery.
- Our Earthmends™ products deliver specific dietary nutrients which may be depleted by therapies.
- Antioxidants help maintain cell integrity by inactivating free radicals that can cause cellular damage.
- Other ingredients are included to inhibit the side effects of therapies, such as temporary fatigue and nausea.

3850 Tampa Road, Palm Harbor, FL 34684 Toll Free: 1-877-789-6565 Phone: 727-789-6500 Fax: 727-773-9266
email: cwi@cancerwellness.com www.earthmends.com

Earthmends™ Prostate Health Program Dietary Supplement

- Earthmends™ Prostate Health Program Dietary Supplement does not treat or cure cancer, but has been specifically designed to nutritionally support individuals during and following therapy.

- Earthmends™ Prostate Health Program has been developed to bolster you in several ways through the physically stressful time of treatment and recovery.

- Our Earthmends™ products deliver specific dietary nutrients which may be depleted by therapies.

- Antioxidants help maintain cell integrity by inactivating free radicals that can cause cellular damage.

- Other ingredients are included to inhibit side effects of therapies, such as temporary fatigue and nausea.

The Cancer Wellness Institute is the distributor of these dietary supplements. The address of the Cancer Wellness Institute is: 3850 Tampa Road, Palm Harbor, Florida 34684.

I certify that the information contained in this notification is complete and accurate and that the Cancer Wellness Institute has substantiation that the foregoing statements are truthful and not misleading.

Sincerely,

CANCER WELLNESS INSTITUTE, INC.

Alan Jacobs
President / CEO

AJ:km