



NOV - 6 2000

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

Rec'd 11-2-2000
yb

Dear Mr. Jacobs:

This is in response to your letter of October 12, 2000 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 The Cancer Wellness Institute is making the following claims, among others, for the following products:

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..."

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 these products

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suggest that they are intended to treat, prevent, cure, or mitigate disease, namely, breast and prostate cancers¹. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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,

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

¹These claims are disease claims because they suggest that the product is intended to treat or prevent adverse events associated with a therapy for a disease (21 CFR 101.93(g)(2)(ix)), to have a role in the body's response to a disease (21 CFR 101.93(g)(2)(viii)), and to augment a therapy for disease (21 CFR 101.93(g)(2)(vii)).

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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 (Dorsey, Nickerson)

reviewed:RBehrman:10/30/00

reviewed:LNickerson:11/2/00

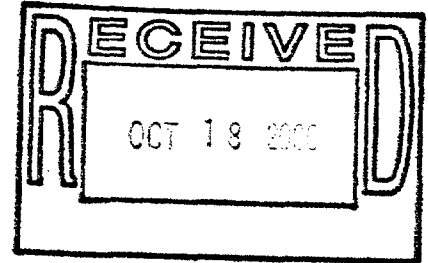
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CancerWellness

INSTITUTE

October 12, 2000

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, Earthmends™ Prostate Health Program, and Earthmends™ Total Health Program:

Earthmends™ Breast Health Program
Dietary Supplement

Earthmends™ Breast Health Program has been specifically designed to nutritionally support individuals while undergoing treatment.

Earthmends™ Breast Health Program has been developed to assist you during this difficult time, while delivering specific ingredients intended to directly support healthy breast tissue.

The natural substances found in our Breast Health Program have been shown to be safe to use with traditional therapies like radiation, chemotherapy and/or surgery.

One packet contains five capsules -- which are designed to nutritionally combat the side effects of treatments such as fatigue and nausea.

The phytonutrients in Earthmends™ products act in a variety of ways such as providing antioxidants to help maintain cell integrity by deactivating free radicals that can cause cellular damage.

As part of the Earthmends™ approach to Health and Wellness, this product should be taken while undergoing treatment and during the following six months. This will nutritionally aid in the recovery process.

Earthmends™ Prostate Health Program
Dietary Supplement

To maintain optimum health, the American Cancer Society recommends eating five or more daily servings of fruits and vegetables. If you are unable to meet these standards during and after treatment, we recommend you take the Total Health Program along with the Breast Health Program, as a dietary supplement.

Fuel your body's fight, take control of your health. Supplement your diet with Earthmends™, the Nutritional Building Blocks to Good Health.

Earthmends™ Dietary Supplements supply phytonutrients and natural ingredients which help replenish the body's natural store of nutrients, antioxidants, and immune builders.

Earthmends™ Prostate Health Program has been specifically designed to nutritionally support individuals who are undergoing treatment.

Earthmends™ Prostate Formula has been developed to assist you during this difficult time, while delivering specific ingredients intended to directly support prostate cells.

The natural substances found in our Prostate Health Program have been shown to be safe to use with traditional therapies like radiation, chemotherapy and/or surgery.

One packet contains five capsules -- which are designed to nutritionally combat the side effects of treatments such as fatigue and nausea.

The phytonutrients in Earthmends™ products act in a variety of ways such as providing antioxidants to help maintain cell integrity by deactivating free radicals that can cause cellular damage.

As part of the Earthmends™ approach to Health and Wellness, this product should be taken while undergoing treatment and during the following six months. This will nutritionally aid in the recovery process.

To maintain optimum health, the American Cancer Society recommends eating five or more daily servings of fruits and vegetables. If you are unable to meet these standards during and after treatment, we recommend you take the Total Health Program along with the Prostate Health Program, as a dietary supplement.

Fuel your body's fight, take control of your health.
Supplement your diet with Earthmends™, the Nutritional
Building Blocks to Good Health.

Earthmends™ Dietary Supplements supply phytonutrients and
natural ingredients which help replenish the body's natural
store of nutrients, antioxidants, and immune builders.

Earthmends™ Total Health Program
Dietary Supplement

Fuel your body's fight, take control of your health.
Supplement your diet with Earthmends™, the Nutritional
Building Blocks to Good Health.

Earthmends™ Dietary Supplements supply phytonutrients and
natural ingredients which help replenish the body's natural
store of nutrients, antioxidants, and immune builders.

Promotes Cellular Integrity.

Antioxidant

In addition, the Cancer Wellness Institute is making the following claims for dietary ingredients in each
of the above supplements:

Antioxidant

Chinese Skull Cap
Selenium Yeast
Vinox™ Gold Grapeseed
Green Tea
Red Clover
Tocotrienols
Astaxanthin
Vitamin E 5-87
Turmeric
Quercetin

Estrogen Antagonist

Chinese Skull Cap
Red Clover
Black Cohosh
Flax
Quercetin

Promotes Cellular Integrity

Maitaki Mushroom
Reishi Mycelia
Shitake Mushroom
Chinese Skull Cap
Licorice Root
Rabdosia Rubescens Hora
Dyers Woad
Pseudo Ginseng
Indole-3 Carbonals
Selenium Yeast

Decrease Treatment Side Effects

Vinox™ Gold Grapeseed
Green Tea
Red Clover
Tocotrienols
Dong Quai
Flax
Lycopene
Astaxanthin
A-Z Complex
Vitamin E 5-87
Bee Propolis
Turmeric
Quercetin
Maitaki Mushroom
Reishi Mycelia
Green Tea
Vitamin E 5-87
Glutamine
Ginseng
Ginger
Turmeric

Immune Modulator


Maitaki Mushroom
Reishi Mycelia
Shitake Mushroom
Agairus Extract
Chinese Skull Cap
Licorice Root
Colostrum
Flax
Astaxanthin
A-Z Complex
Vitamin E 5-87
Bee Propolis
Ginseng
Nettle Root
Zinc Amino Acid Chelate

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,



Alan H. Jacobs
President/CEO
The Cancer Wellness Institute