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May 24, 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: <u>Section 403(r)(6)</u> 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 regarding labeling statements for its dietary supplements, EarthmendsTM Breast Health Program and EarthmendsTM Prostate Health Program.

EarthmendsTM Breast Health Program Dietary Supplement

- Earthmends[™] Breast Health Program has been developed to bolster you nutritionally in several ways through the physically stressful time of treatment and recovery.
- Other ingredients are included to nutritionally support normal vitality and healthy gastrointestinal function.

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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 Letter to Division of Compliance and Enforcement (HFS-810) May 24, 2001 Page 2

Earthmends^{1M} Prostate Health Program Dietary Supplement

- Earthmends[™] Prostate Health Program has been developed to bolster you nutritionally in several ways through the physically stressful time of treatment and recovery.
- Other ingredients are included to nutritionally support normal vitality and healthy gastrointestinal function.

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,

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Alan H. Jacobs President/CEO The Cancer Wellness Institute