



FEB 18 2005

Nate Couture
Oregon's Wild Harvest
43464 S.E. Phelps Road
Sandy, Oregon 97055

Dear Mr. Couture:

This is in response to your letter of January 20, 2005 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)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual nor does it certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit a notification in accordance with the requirements in 21 CFR 101.93(a). A product that bears claims under 21 U.S.C. 343(r)(6), but that does not fully comply with the requirements of that section, may be subject to regulation under the drug provisions of the act. A

Nonetheless, in resubmitting your notification, you should be aware that the product Aller-Aid bears claims that do not appear to be claims subject to 21 U.S.C. 343(r)(6). This product uses the claims "Support During Allergen Exposure" and "[S]upporting the response of the body's natural defense system to seasonal allergen exposure."

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, including the use of the derived name "Aller-Aid," suggest that it is intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of

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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 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJK', with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
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-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Seattle District Office, Office of Compliance, HFR-PA340



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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, D.C. 20204

January 20, 2005

Notification of Statements
Of Nutritional Support

This notification is filed pursuant to section 403 (r) (6) of the federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C . ss 343 (r) (6). Please see attachment for a listing of dietary supplements and corresponding statements of nutritional support.

These statements are being accompanied by the required disclaimer pursuant to Section 403 (r)(6)(C) of the Act.

Statements of nutritional support are based on data which render these statements substantiated, truthful and non-misleading.

An original and two copies of this letter and its attachment are enclosed.

Sincerely,

Nate Couture
Q.C., Oregon's Wild Harvest

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Dietary Supplement	Brand Name	Product Name	Statement of Nutritional Support
Maitake Mushroom Mycelia	Oregon's Wild Harvest	Maitake	immune boosting properties
Astragalus Root, Reishi Mushroom Mycelia	Oregon's Wild Harvest	Astragalus Reishi	these tonic herbs are suitable for long-term use as an important aid in strengthening the body's natural defense system
Dandelion Root	Oregon's Wild Harvest	Dandelion Root	Bitters have been used traditionally to improve appetite and support normal digestion
Dong Quai Root	Oregon's Wild Harvest	Dong Quai	Considered the female "master herb" dong quai has been used throughout many eastern cultures as a long-term tonic.
Echinacea purpurea Tops, Echinacea purpurea Root, Echinacea angustifolia Root	Oregon's Wild Harvest	Echinacea	provides nutritional support to the immune system
Echinacea purpurea Tops, Echinacea purpurea Root, Echinacea angustifolia Root	Oregon's Wild Harvest	Echinacea	Echinacea was introduced to the early American settlers and was traditionally used to treat a variety of ailments
Echinacea purpurea flower and leaf, Echinacea purpurea Root, Goldenseal Root, Oregon Grape Root, Vitamin C	Oregon's Wild Harvest	Echinacea Goldenseal Vitamin C	provides nutritional support to the immune system, lungs, and sinuses.
Ginger Root	Oregon's Wild Harvest	Ginger	Ginger is a warming herb with a calming effect on the digestive tract.
Milk Thistle Seed, Milk Thistle Seed Standardized Extract	Oregon's Wild Harvest	Milk Thistle	an aid to healthy liver function.
Saw Palmetto Berry, Nettle Root, Pygeum Bark	Oregon's Wild Harvest	Saw Palmetto Pygeum	may provide nutritional support for the prostate gland

Dietary Supplement	Brand Name	Product Name	Statement of Nutritional Support
Valerian Root	Oregon's Wild Harvest	Valerian	an effective and gentle sleep aid
Cordyceps mushroom mycelia	Oregon's Wild Harvest	Cordyceps	cardiovascular, respiratory, and immune support, and also as a general energizing tonic
Vitamin C, Quercetin, N-Acetyl Cysteine, Nettle Tops	Oregon's Wild Harvest	Aller-Aid	Support During Allergen Exposure
Vitamin C, Quercetin, N-Acetyl Cysteine, Nettle Tops	Oregon's Wild Harvest	Aller-Aid	Shown scientific potential in supporting the response of the body's natural defense system to seasonal allergen exposure.
Burdock Root	Oregon's Wild Harvest	Burdock	traditional skin remedy
Eyebright Flower, Leaf, and Stem	Oregon's Wild Harvest	Eyebright	Traditionally Used for Eye Health
Eyebright Flower, Leaf, and Stem	Oregon's Wild Harvest	Eyebright	support of eye fatigue and vision
Gymnema Leaf Standardized Extract, Gymnema Leaf	Oregon's Wild Harvest	Gymnema	Traditionally Known as the Destroyer of Sugar.
Gymnema Leaf Standardized Extract, Gymnema Leaf	Oregon's Wild Harvest	Gymnema	interferes with the ability to taste sweetness
Hawthorn Flower and Leaf, Hawthorn Berry	Oregon's Wild Harvest	Hawthorn	a gentle and effective tonic for a healthy heart and circulatory system
Black Cohosh root, Alfalfa Tops, Licorice Root, Red Clover Tops	Oregon's Wild Harvest	Menopause Formula	exert a mild estrogen-like action
Black Cohosh root, Alfalfa Tops, Licorice Root, Red Clover Tops	Oregon's Wild Harvest	Menopause Formula	nutritional support to the female reproductive system
Zinc, Copper, Saw Palmetto Berry, Pygeum Bark Standardized Extract, Lycopene	Oregon's Wild Harvest	Prostate Health	Pygeum contains many compounds which may provide nutritional support for the prostate gland.
Zinc, Copper, Saw Palmetto Berry, Pygeum Bark Standardized Extract, Lycopene	Oregon's Wild Harvest	Prostate Health	Preliminary and epidemiological studies suggest that zinc may play a role in normal prostate function.
Vitamin C, Zinc, Copper, Echinacea purpurea flower and leaf	Oregon's Wild Harvest	Echinacea Zinc and Vitamin C	to nourish and support the immune system

Dietary Supplement	Brand Name	Product Name	Statement of Nutritional Support
Vitamin C, Zinc, Copper, Echinacea purpurea flower and leaf	Oregon's Wild Harvest	Echinacea Zinc and Vitamin C	Echinacea was introduced to the early American settlers and was traditionally used to treat a variety of ailments
Valerian Root, Hops Flower, St. John's Wort Flower Buds, Passion Flower Tops	Oregon's Wild Harvest	Valerian Hops	help naturally relax and support the mind and spirit
Chaste Tree Berry, Dong Quai Root, Borage Seed Oil Powder, Wild Yam Root	Oregon's Wild Harvest	Dong Quai Wild Yam	This holistic combination of herbs nourishes and strengthens the female reproductive system, helping to support hormonal balance.
Chaste Tree Berry	Oregon's Wild Harvest	Vitex	support female reproductive hormones
Chaste Tree Berry	Oregon's Wild Harvest	Vitex	helpful in supporting female hormonal balance
Wild Yam Root	Oregon's Wild Harvest	Wild Yam	a tonic for a variety of women's functions
Ashwagandha Root	Oregon's Wild Harvest	Ashwagandha	Supports Adaptation to Stress