

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

975 0162 LET 15555

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	Donq 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

see docket

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	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

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