



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 19 2007

20068 7 MAY 23 09:03

Ms. Candis L. Scott
Highland Laboratories
110 S. Garfield
PO Box 199
Mt. Angel, Oregon 97362

Dear Ms. Scott:

This is in response to your letter of March 30, 2007 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 Highland Laboratories is making the following claim, among others, for the product Berry Wellness:

“[B]uckthorn berry has been used...for treating skin diseases.”

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If your client intends to make claims of this nature, they 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.

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Please contact us if we may be of further assistance.

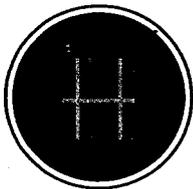
Sincerely yours,

A handwritten signature in black ink, appearing to read "Vasilios Frankos". The signature is written in a cursive style with a large initial "V".

Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, 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



HIGHLAND
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Fax (503) 845-6364

www.highlandvitamins.com
www.highlandcustom.com

March 30, 2007

RECEIVED
4/10/07

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
FDA
200 C Street, SW
Washington, DC 20204

RE: Notification for Statement on Dietary Supplement

Dear Sir/Madam:

In compliance with the Dietary Supplement Health and Education Act of 1994, **Highland Laboratories, 110 S Garfield, PO Box 199, Mt. Angel, Oregon 97362**, hereby makes its official notification under Section 101.93 that it has included a statement listed in Section 403(r)(6) of the Federal Food, Drug, Cosmetic Act on its label. Accordingly, enclosed please find two (2) copies of this Notification.

Company	Product Name	Dietary Ingredients	Statements
Highland Laboratories	Berry Wellness™	Gogi Berry Ext 250 mg. Sea Buckthorn Ext 150 mg. Pomegranate Ext 150 mg. Green & White Tea Ext 150 mg. Cranberry Ext 100 mg. Turmeric 100 mg. Blueberry Ext 80 mg. Elderberry Ext 70 mg. Cayenne 50 mg.	Immune system support. Berry Wellness™ combines nutrients scientifically documented as powerful antioxidants. <i>Please see attachment 1</i>

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I hereby certify that the information presented and contained in this notice is complete and accurate, and my files contain substantiation that the statements made are truthful and not misleading.

Sincerely,

Candis L. Scott
CEO Highland Laboratories

Attachment 1

Highland Laboratories

Berry Wellness™

The vibrant purples, scarlets and deep blues of berries are more than pretty packaging: plant pigments are powerful antioxidant flavonoids and carotenoids that can support and restore the immune system.

Blueberry

Known as America's favorite berry, blueberries have a long-standing reputation for healing in traditional medicine. Researchers at Tufts University recently gave blueberries the highest rating of all foods tested for their capacity to destroy free radicals. Blueberries are an excellent source of phytonutrient ellagic acid; vitamins A, C, and E; manganese; and folate. Perhaps surprisingly, blueberries are also a good source of omega-3 fat alpha-linolenic acid (ALA).^{1,2}

Elderberry

Native Americans and early American settlers considered the elderberry "the medicine chest of the common people." Elderberries are a source of potassium and vitamin A, and contain more vitamin C than any other herb except rosehips and black currants.

Cayenne

The red color of this fleshy berry announces its high beta-carotene (pro-vitamin A) content. Vitamin A is essential for healthy mucous membranes, including those that line the nose and throat, lungs, digestive tract and urinary tract. Cayenne is a source of 34 carotenoids, including zeaxanthin.^{3,4} Cayenne also provides a good supply of vitamin C.

Pomegranate Fruit

In Armenia, the pomegranate is a symbol of fertility and abundance—and it's no wonder. A rich source of potent flavonoid antioxidants,⁵ one pomegranate also provides 40% of an adult's requirement for vitamin C and plenty of folic acid.

Cranberry

A good source of folic acid, fiber, and potassium, these tart berries are a treasure trove of flavonoids. Cranberries are also a good source of vitamin C, which is necessary for

¹ Bere E. et al. Wild berries: a good source of omega-3. *Eur J Clin Nutr.* 2007 Mar;61(3):431-3.

² Margen, S. et al. *The Wellness Encyclopedia of Food and Nutrition.* Random House, 1992.

³ Ching LS, et al. Alpha-tocopherol content in 62 edible tropical plants. *J Agric Food Chem.* 2001 Jun;49(6):3101-5.

⁴ Deli J, et al. Carotenoid composition in the fruits of red paprika (*Capsicum annum* var. *lycopersiciforme rubrum*) during ripening; biosynthesis of carotenoids in red paprika. *J Agric Food Chem.* 2001 Mar;49(3):1517-23.

⁵ Seeram NP, et al. *J Nutr Biochem.* 2005 Jun;16(6):360-7.

tissue growth and repair. The total flavonol content of cranberries is higher than many of the most commonly consumed fruits and vegetables.⁶

Sea Buckthorn Berry (*Hippophae rhamnoides*)

While we might not be familiar with this berry in North America, the sea buckthorn berry has been used traditionally in China and Russia for treating skin diseases—likely due to the high content of alpha-linolenic acid (ALA) they contain.^{7,8} Sea buckthorn berries are also an excellent source of antioxidants vitamin C, tocopherols and tocotrienols.⁹

Goji Berry (*Lycium barbarum*)

According to legend, herbalist Ling Qing Yuen lived to the ripe old age of 225, giving credit for his longevity to a daily soup made from goji berries. Containing 19 amino acids, 21 trace minerals, antioxidants including beta-carotene, vitamin C and Vitamin E, essential fatty acids and many other health-promoting substances, these nutrient-dense berries have been used by traditional healers.¹⁰

Green Tea Extract (EGCG)

Green tea comes from the dried leaves of an evergreen tree, and because of minimal fermentation, contains more antioxidants than black tea. The most powerful antioxidant is a catechin called epigallocatechin-3 gallate, or EGCG, which should become as well-known as vitamins C and E for its antioxidant properties. Most research on the health benefits of EGCG is based on the typical Asian consumption of 3 cups daily, providing 240-320 mg polyphenols.¹¹

Turmeric

This plant is perhaps best known for the yellow powder that forms the base of curry. High in the antioxidant flavonoid curcumin, turmeric has been used by traditionally in Asia, India, Central and South America.

⁶ Hakkinen SH, et al. Content of the flavonols quercetin, myricetin, and kaempferol in 25 edible berries. *J Agric Food Chem.* 1999 Jun;47(6):2274-9.

⁷ Yang B, et al. *J Nutr Biochem.* 2000 Jun; 11(6):338-40.

⁸ Yang B, et al. Fatty acid composition of lipids in sea buckthorn (*Hippophae rhamnoides* L.) berries of different origins. *J Agric Food Chem.* 2001 Apr;49(4):1939-47.

⁹ Kallio H, et al. Triacylglycerols, glycerophospholipids, tocopherols, and tocotrienols in berries and seeds of two subspecies (ssp. *sinensis* and *mongolica*) of Sea Buckthorn (*Hippophae rhamnoides*). *J Agric Food Chem.* 2002 May 8;50(10):3004-9.

¹⁰ <http://www.gojicapital.com/about-goji-berries.html>

¹¹ http://www.nlm.nih.gov/medlineplus/druginfo/natural/patient-green_tea.html#Dosing