

formulas for your future



October 6, 2003

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10/21/03

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

P.O. Box 199

RE: Notification for Statement on Dietary Supplement

Dear Sir/Madam:

110 South Garfield

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.

Mt. Angel, OR 97362

Company	Product Name	Dietary Ingredients	Statements
Highland Laboratories	Love Your Legs™	Butcher's Broom (<i>Ruscus aculeatus</i>), Horse Chestnut Seed (<i>Aesculus hippocastanum</i>), Grape Seed Extract (<i>Vitis vinifera</i>), Ginkgo Biloba Leaf, Bilberry Fruit (<i>Vaccinium myrtillus</i>), Cayenne Fruit (<i>Capsicum annum</i>)	Circulatory system support. <i>Please see attachment 1</i>

503-845-9223

1-800-547-0273

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 misleading.

Sincerely,

FAX 503-845-6364

Candis L. Scott
CEO Highland Laboratories

email: highland@pdx.oneworld.com

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Attachment 1
Highland Laboratories

LOVE YOUR LEGS™
Circulatory system support

Made up of approximately 10,000 miles of arteries, veins, and capillaries. The circulatory system is like the New York subway: complex and hard to understand.

There are actually two parts to the system. The first is pulmonary circulation involving the heart and lungs. The second is systemic circulation, which sends oxygenated blood from the heart to the rest of the body.¹

Blood is more than just a red liquid; it's actually made up of plasma (transports fuel and iron), platelets (make the blood clot), red blood cells (transports oxygen to our tissues and picks up waste), white blood cells (help us fight infections), and lymphocytes (create antibodies).

We can't live without blood's many functions. Therefore it becomes imperative that we take care of the transporting system: our arteries, veins, and capillaries.

Arteries carry blood from the heart to the tissue. In the process of nourishing tissues, the blood begins collecting toxins and waste. "Dirty" blood is then transported back to the heart and lungs, via our veins, for cleaning and re-oxygenating.

Because of the direct pressure arteries are under, they are thick-walled. They are a combination of muscle fiber, elastic tissue, and a smooth, inner wall.

Vein walls are thinner than that of the artery. Many of the veins also contain valves. These valves help blood returning to the heart defy gravity. Think of them as stepping-stones.

The vessels in our legs take on more work than say a vessel in your arm. The blood not only has farther to go, but it has to go up instead of down. One way of helping is to flex your foot. The squeezing motion helps push the blood up. Walking is also good for the same reason. If your profession requires you to be on your feet all day, give yourself a treat when you get home and put your feet up. Again, this helps the circulation.

Then there are the capillaries. Capillaries are very tiny. They consist of a thin layer of tissue surrounded by a thin membrane. Their most important role is to help regulate body temperature.

A healthy circulatory system is integral to our overall health and well-being. Love Your Legs™ is a synergistic formula of herbs containing flavonoids, sterols, and tannins.

Flavonoids are believed to aid vascular permeability and strength by helping build collagen, the main component of our veins and arteries.²

- *Horse Chestnut* – contains the active ingredient escin as well as flavonoids, sterols, and tannins. Combined, they contribute to the normalization of vascular permeability.

¹ **KNOW YOUR BODY** Ulysses Press 2002 pp 86-94

² **EFFECTS OF FLAVONOIDS OF GINKGO BILOBA ON PROLIFERATION OF HUMAN SKIN FIBROBLAST** Skin Pharmacol. 1997;10(4):200-5

Attachment 1
Highland Laboratories

- *Ginkgo Biloba* – used by the ancient Chinese, ginkgo contains flavonoids, terpenes, and ginkgolides. It's thought the ginkgolides play a part in the inhibiting of PAF (platelet aggregating factor)³
- *Grape Seed Extract* – the proanthocyanidin content may help increase levels of VEGF, the compound that helps the body rebuild blood vessels.⁴
- *Bilberry* – also known as huckleberry, the flavonoids found in bilberry are important to collagen formation, a major component of capillary walls.
- *Cayenne Fruit* – works as a partner to other active ingredients making them more bioavailable.

2 Vegetarian Capsules contain the following:

Butcher's Broom (<i>Ruscus aculeatus</i>)	500 mg
Horse Chestnut Seed (<i>Aesculus hippocatanum</i>)	300 mg
Grape Seed Extract (<i>Vitis vinifera</i>)	100 mg
Ginkgo Biloba Leaf	40 mg
Bilberry Fruit (<i>Vaccinium myrtillus</i>)	25 mg
Cayenne Fruit (<i>Capsicum annum</i>)	25 mg

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

³ **GINKGO BILOBA** Hopes, Stanford University July 2003

⁴ **GRAPE SEED EXTRACT HELPS SPEED UP WOUND RECOVERY, STUDY SUGGESTS** Research News, Ohio State University Dec. 2002