



SEP 25 2003 7 8 3 2 '03 NOV -3 P 1:25

Maureen Kirkbride  
Marketing  
Highland Laboratories  
P.O. Box 199  
110 South Garfield  
Mt. Angel, Oregon 7362

Dear Ms. Kirkbride:

This is in response to your letter to the Food and Drug Administration (FDA), dated August 26, 2003. Your letter responded to our August 20, 2003 letter concerning information you submitted about a proposed informational flyer for your product Love Your Legs™.

In your current letter, it appears that you intend this letter to be the notification required by 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). As we stated in our previous letter, if it is intended to be the required notification, it does not meet the requirements set forth in 21 CFR 10193(a) and, therefore, you have not complied with the requirement to notify FDA.

21 CFR 101.93(a) sets forth the requirements for a notification being made for claims made in the labeling of a dietary supplement pursuant to 21 U.S.C. 343(r)(6). Among other things, 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** (see discussion about this matter in the preamble to the final rule promulgating the notification regulation in the September 23, 1997 Federal Register; 62 FR 49883; section III beginning on page 49883)(a copy of this document can be found on our web site at <http://www.cfsan.fda.gov/~dms/ds-ind.html>). Your submission does not meet this requirement in that while the notice is signed, the person signing the notice has not certified that the firm is in compliance with the requirements of the Act and the regulation as discussed above. 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) if you intend to make claims in the labeling of a dietary supplement pursuant to 21 U.S.C. 343(r)(6).

975-0163


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You can find copies of relevant documents on FDA's web site at <http://www.fda.gov>. You can access Title 21 of the Code of Federal Regulations (21 CFR) at <http://www.cfsan.fda.gov/~dms/reg-2.html> and can find copies of the laws that FDA enforces at <http://www.fda.gov/opacom/laws/lawtoc.htm>.

Please contact us if we may be of further assistance.

Sincerely yours,

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

Susan J. Walker, M.D.  
Acting 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-300

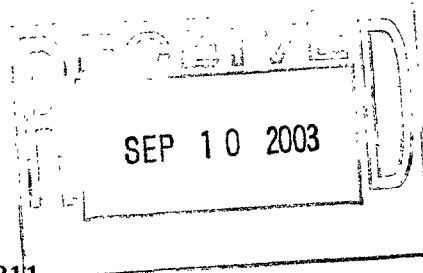
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340

formulas for your future



August 26, 2003



**FDA**  
Attn: Robert J. Moore, Ph.D. HFS-811  
Chief, Compliance and Enforcement Branch  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
And Dietary Supplements  
Center for Food Safety  
And Applied Nutrition  
200 C Street  
Washington, DC 20204

P.O. Box 199

110 South Garfield

Dear Dr. Moore,

I'm writing in response to your letter dated August 20, 2003 regarding my  
submittal of a proposed informational flyer for the product Love Your  
Legs™.

Mt. Angel, OR 97362

It's my understanding that when making a structure/function statement that I  
must submit the material to FDA for review. This was my intention since  
the flyer does not contain health claims.

I'm enclosing another copy for your review and I apologize for the  
confusion.

503-845-9223

Sincerely,

A handwritten signature in cursive script that reads "Maureen Kirkbride". The signature is written in black ink and is positioned above the printed name.

Maureen Kirkbride  
Marketing

1-800-547-0273

FAX 503-845-6364

email: [highlnd@pdx.oneworld.com](mailto:highlnd@pdx.oneworld.com)

85867

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.<sup>1</sup>

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.<sup>2</sup>

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

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<sup>1</sup> **KNOW YOUR BODY** Ulysses Press 2002 pp 86-94

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

- *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)<sup>3</sup>
- *Grape Seed Extract* – the proanthocyanidin content may help increase levels of VEGF, the compound that helps the body rebuild blood vessels.<sup>4</sup>
- *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.

<sup>3</sup> **GINKGO BILOBA** Hopes, Stanford University July 2003

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