

formulas for your future



August 24, 2004

20 2004

P.O. Box 199

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

110 South Garfield

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.

Mt. Angel, OR 97362

Company	Product Name	Dietary Ingredients	Statements
Highland Laboratories	Yourheart Nutrients™	Magnesium 270 mg. Potassium 90 mg. Beta-Sitosterol Phytosterol Complex 700 mg. L-Arginine 500 mg. Bromelain 120 mg. CoQ10 100 mg. Hawthorne Berry 100 mg.	Promotes healthy heart and circulatory system Please see attachment 1

503-845-9223

1-800-547-0273

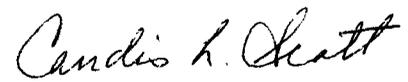
FAX 503-845-6364

975 0162 LET 14590

email: highlnd@pdx.oneworld.com

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,

A handwritten signature in black ink that reads "Candis L. Scott". The signature is written in a cursive style with a large, prominent initial "C".

Candis L. Scott
CEO Highland Laboratories

Attachment 1
Highland Laboratories

Yourheart Nutrients™
Heart Health Support

Hearts are complex: muscular, but with highly integrated plumbing and electrical systems. Given its importance – in love and in fact - then why do we spend more time on our teeth and our hair than on the health of our heart?

Yourheart Nutrients™ blend crucial minerals, Magnesium and Potassium, together with herbs and other valued ingredients. The minerals alone are key to proper regulation of heartbeat, our body's electrolyte balance and production of energy at the cellular level. Yet in our modern diet, most adults are woefully deficient in both.

Magnesium – Food processing strips most of this mineral from our daily diet, while whole foods are rich in it. Tofu, nuts, whole grains and green leafy vegetables are on the plus side of the equation while meat, fish, milk and commonly eaten fruits are on the lower side.

Bone formation depends on magnesium, as does the production of proteins and new cells. Magnesium helps in the blood-clotting process and is essential in the creation of adenosine triphosphate, or ATP, which begets the energy that runs our bodies. A variety of things: diuretics, alcohol, surgery, oral contraceptives and certain diseases (liver, kidney) tend to deplete magnesium further.

Potassium – Besides playing an essential role in the water and glycogen balances in the body, potassium is also key to proper muscle (e.g. heart) and nerve functions. At the cellular level, potassium is pumped out of the cell as sodium enters, which creates a change of electrical charge, allowing nerve transmission and muscle contraction.

Beta-sitosterol - is a plant-based compound similar to cholesterol, which is an animal-based equivalent. As this nutrient is absorbed into the bloodstream, it helps the body's natural tendency to balance blood chemistry and arterial health.¹

L-Arginine – is an amino acid involved in a healthy immune system. Thus, it is implicated as an aid in closing wounds. Arginine is also a precursor to nitric oxide, an important aspect in heart oxygenation and blood vessel dilation.

Bromelain – comes from pineapples and is readily absorbed by the body, despite a trip through the digestive tract. Internally, this beneficial enzyme works on – among other things – blood platlets.²

Hawthorne Berry – used medicinally from the 1st century A.D., hawthorne contains a number of bioflavonoids responsible for the flow of life through the plant. In humans, this quality may be a supplement to healthy blood flow and normal heart contractions.³ The bioflavonoid is also a strong antioxidant.

Sources –

1. Jones PJ, Raeini-Sarjaz M, Ntanos FY, et al. *J Lipid Res* 2000; 41:697-70
2. Heineke R, van der Wal L, Yokoyama M. *Experientia* 1972;28:844-5
3. Weikl A, Noh HS. *Herz Gefaße* 1993;11:516-24