

formulas for your future



August 24, 2004

SEP 21

P.O. Box 199

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

110 South Garfield

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.

Mt. Angel, OR 97362

Company	Product Name	Dietary Ingredients	Statements
Highland Laboratories	Water-Away™	Potassium 33 mg. Uva Ursi Leaf 120 mg. Juniper Berry 60 mg. Buchu Leaf 30 mg. Black Radish 30 mg. Parsley Leaf 30 mg. Asparagus Rt. 20 mg.	Urinary System Support  <b><i>Please see attachment 1</i></b>

503-845-9223

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975 0162

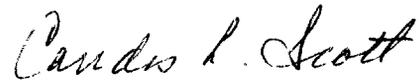
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email: highlnd@pdx.oneworld.com

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 cursive script that reads "Candis L. Scott".

Candis L. Scott  
CEO Highland Laboratories

**Attachment 1**  
**Highland Laboratories**

Water-Away™  
Urinary System Support

The human body, so we're told, is made up mostly of water. But most of us have experienced times when it seems like we're *all* water: swollen up, uncomfortable, tight skinned and about ready to burst.

There are occasions when excess water retention is just part of a natural cycle of things, like with menstruation or on very hot, humid weather.

Water-Away™ is a special blend of potassium and herbs with a combined use history dating back thousands of years. The net effect of this special formula is all about balance – keeping you comfortable and helping your body properly maintain water balance, electrolyte levels and electrical impulses needed for cardiac and neuromuscular health.

Remember, when trying to rid the body of excess water, it is important to avoid dehydration. Drink plenty of water as you Water-Away™.

**Potassium** – is very important for a healthy nervous system and regular heart rhythm. Aids in proper muscle contraction and works with sodium (electrolytes) to control body's water balance and blood chemistry. Potassium also plays a role in the transfer of nutrients through cell membranes. Potassium tends to dissipate when people are voiding excess amounts of body fluids in the form of urine. Bananas are a great food source of potassium.

**Uva Ursi Leaf** – has been used by indigenous people in northern latitudes for many centuries. The active ingredient in this herb is glycoside arbutin, from which powerful anti-bacterials are derived.<sup>1</sup> Its antiseptic qualities are valued in promoting a healthy urinary tract.

**Juniper Berry** – this familiar coniferous fruit finds its way into everything from flavoring agents to soap and perfume. It has also been used in traditional medicines for ages. One of its volatile oils (terpinen-4-ol) has been associated with an increase in urine volume.<sup>2</sup>

**Buchu Leaf** – was initially used by southern African peoples as a topical ointment, perhaps as an insect repellent. Early Europeans ingested Buchu Leaf preparations for a variety of things. The leaves contain volatile oils (including monoterpene disophenol) and flavonoids.<sup>3</sup>

**Black Radish Root, Parsley Leaf and Asparagus Root** – are all traditional medicinal herbs used for centuries. Each has specific value but they share some features as well: assisting in the elimination of excess water via urination. The first two are also rich in vitamin C while the first and last of this group bolster the body's natural tendency for fighting infection.

**Sources:**

1. Matsuda H, Nakamura S, Tanaka T, Kubo M. *J Pharm Soc Japan* 1992; 112:673-7
2. Tyler VE. *Herbs of Choice*, Pharmaceutical Products Press, 1994, 76-7
3. Wichtl M. *Herbal Drugs and Phytopharmaceuticals*. CRC Press, 1994, 102-3