

formulas for *our* future



February 20, 2004

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

P.O. Box 199

MAR 23 2004

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

503-845-9223

1-800-547-0273

FAX 503-845-6364

Company	Product Name	Dietary Ingredients	Statements
Highland Laboratories	Clean Review™	Bentonite, Psyllium Seed Husk, Apple Pectin, Diatomaceous Earth, Wheat Grass, Chamomile Flower ( <i>Matricaria chamomilla</i> ), Cascara Sagrada Bark, Buckthorn Bark ( <i>Rhamnus frangula</i> ), Ginger Root ( <i>Zingiber officinales</i> ), Marshmallow Root ( <i>Althaea officinalis</i> ), Butternut Root Bark ( <i>Juglans cinerea</i> ), Golden Seal Root ( <i>Hydrastis canadensis</i> ), Gentian Root ( <i>Gentiana lutea</i> ), Rhubarb Root ( <i>Rheum officinale</i> ) and Acidophilus Lactobacillus	Intestinal system support  <b><i>Please see attachment 1</i></b>

email: highlnd@pdx.oneworld.com

975 0162 LET 13843



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.

P.O. Box 199

Sincerely,

Candis L. Scott  
CEO Highland Laboratories

110 South Garfield

Mt. Angel, OR 97362

503-845-9223

1-800-547-0273

FAX 503-845-6364

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

*tachment 1*  
*Highland Laboratories*

CLEAN REVIEW™

Let's just say this upfront: Talking about your intestines and colon isn't pretty. However, it's an important part of human physiology. With that said, let's jump right in.

The moment a piece of food is placed in your mouth, your body starts producing enzymes to digest it. As the food travels down to the stomach, larger molecules are "downsized". They become smaller and easier for the stomach to digest.

When the food lands in the stomach, several different chemical and enzyme mixtures begin to take action, hydrochloric acid and pepsin is one example of these mixtures.

From the stomach the nutrients head for the intestines. This is where it really gets exciting.

The small intestine (approx. 22 ft. long) extracts nutrition from food and prepares the rest for elimination. If the "villi" (tiny finger-like nubs lining the intestinal wall) get coated with excess mucous – created by eating too much of the wrong foods – our bodies can't absorb the proper nutrition. Thus, some nutrition is scooted away into the colon and beyond, along with the body's natural waste products.

Your intestinal system harbors around 15 pounds of bacteria. Some of it is friendly and some is not. Our ancestors believed that spring-cleaning included the colon.

**Bentonite:** known for its ability to adsorb a variety of complex molecules (1,2,3).

**Psyllium Seed Husk:** supports normal bowel function, binds with cholesterol-rich bile in the small intestine, and facilitates the removal of bile from the body (4, 346-347).

**Apple Pectin:** increases fecal bile excretion (5, 6, 7).

**Diatomaceous Earth:** used to remove enteroviruses and other contaminants from water (8).

**Wheat Grass:** soothes mucous membranes (9, 331-332).

**Chamomile Flower:** soothing, reduces uncomfortable feelings associated with the gastrointestinal tract (10, p. 107)

**Cascara Sagrada Bark:** supports normal colon function (10, pp. 104-105).

**Buckthorn Bark:** supports normal colon function (10, pp. 95-96)

**Ginger Root:** promotes the secretion of saliva and gastric juices; (10, p. 136).

**Marshmallow Root:** when combined with water, marshmallow root forms a protective gel, which soothes and protects tissue (9, p. 227)

**Golden Seal:** stimulates the immune system (9, pp. 173-174)

**Gentian Root:** increases secretion of saliva and digestive juices (10, p. 135).

**Rhubarb Root:** supports normal colon function (10, pp. 195-196).

**Acidophilus:** part of natural flora, acidophilus inhibits pathogens by altering the pH through organic acid production (11).

Available in a 240 capsule bottle, Clean Review™ is a synergistic formula supporting intestinal health.

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

References:

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3. Sobsey MD and Cromeans T. Effects of bentonite clay solids on poliovirus concentration from water by microporous filter methods. *Appl Environ Microbiol* 1985 49(4):795-798.
4. Healing Power of Vitamins, Minerals and Herbs. *Readers Digest: Pleasantville, New York.* 1999.
5. Terpstra AH et al. Dietary Pectin with High Viscosity Lowers Plasma and Liver Cholesterol Concentration and Plasma Cholesteryl Ester Protein Activity in Hamsters. *J Nutr.* 1998 128(11):1944-1949.
6. Thaur BR et al. Chemistry and Uses of Pectin- a review. *Crit Rev Food Sci Nutr.* 1997 37(1):47-73.
7. Garcia-Diez F et al. Pectin Feeding Influences Fecal Bile Excretion, Hepatic Bile Acid and Cholesterol Synthesis and Serum Cholesterol in Rats. *J Nutr.* 1996 126(7):1766-1771.
8. Farrah SR et al. Used of Modified Diatomaceous Earth for the Removal and Recovery of Viruses in Water. *Appl Environ Microbiol.* 1991 57:2502-2506.
9. Weiner MA and Weiner JA. *Herbs That Heal.* Quantum: Mill Valley, California. 1994.
10. Blumenthal M, senior editor. *The Complete German Commission E Monographs.* American Botanical Council: Austin, Texas. 1998.
11. *Dairy Digest.* May-June 1979 50(3):13-17.

<p>These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.</p>
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