

Shining Mountain Herbs ®
Ridgway, CO 81432

February 16, 2005

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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., Washington, D.C. 20204

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RE: 21 U.S.C. 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir or Ma'am:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Organic Rocky Mountain Herbal Bitters, a dietary supplement. Shining Mountain Herbs® is the manufacturer of Organic Rocky Mountain Herbal Bitters.

Statements being made in the labeling of Organic Rocky Mountain Herbal Bitters are as follows:

- The majority of the herbs in this Bitters formula are grown on our family farm high in the Rocky Mountains. We use organic, sustainable and mindful growing practices. The remaining herbs come from the highest quality sources. Our herbs are never irradiated or fumigated.
- Certified Organic by the Colorado Department of Agriculture
- Supports Healthy Digestive Function*
- * This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.
- We create our organic products for your optimal health.
- Portions of our proceeds go to support the American Herbal Pharmacopoeia.
- Warning: Do not use this product while pregnant or lactating unless under the direct supervision of a health care professional.
- Keep out of reach of children.
- Serving size: 1 Teaspoon**
- Servings Per Container: 24
- Calories: 5
- Suggested Use: 1 tsp up to three times per day 15-30 minutes before meal. (May also take after meal.)
- Amount per serving: Proprietary Blend contains 1 g of total herb per 10 ml extract.
- ** Daily Value Not Established.
- Shake well before use. Do not use if safety seal is broken or missing.

9/10/13

5636 County Road 23, Ridgway CO 81432 PH: 970-316-0008 FAX: 970-626-3346

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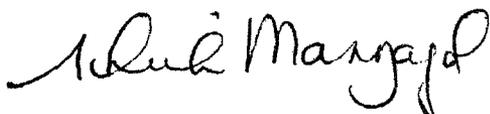
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RE: 21 U.S.C. 343(r)(6)
Organic Rocky Mountain Herbal Bitters
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- **Ingredients:** Aspen Bark (w/c), Angelica Root (or), Gentian Root (or), Oregon Grape Root (or), Yarrow Aerial (or), Wormwood Aerial (or), Dandelion Root (or), Milk Thistle Seed (or), Astragalus Root (or), Fennel Seed (or), Yerba Santa Leaf (or), Galangal Rhizome, Ginger Root (or), Orange Peel (or), Anise Seed (or).
- (or) Organic, (w/c) Wild Cultivated
- Herbal Dietary Supplement
- 4 fl. oz.
- Lot#

To the best of my knowledge and belief, and based upon information available at the time of execution of this notice, I certify that the above information is accurate and complete. Shining Mountain Herbs® possesses substantiation that the statements are truthful and not misleading.

Sincerely,



Sheila Manzagol
President
Shining Mountain Herbs®