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Office of Special Nutritionals,  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration  
200 C St. SW.  
Washington DC - 20204

May 03, 2005

Aboca USA Inc., located at 126 South Spokane Street/Suite C, Seattle – Washington 98134, with reference to notification letter of marketing in the United States of the product Bearberry Leaf Herbal Supplement sent on October 31, 2003, is resubmitting this claim notification letter to focus attention on the modification of the Brand name of the product.

The Brand name of the product has been modified from *Bearberry Leaf Herbal Supplement* to *Uva ursi Leaf Herbal Supplement*, by using the common botanical name *Uva ursi* instead of *Bearberry* because more appropriate from a technical point of view. This change didn't affect in any way the qualitative or quantitative composition of the product which remains the same.

Aboca will continue selling the product to medical practitioners and qualified retailers in the USA.

**NOTIFIES**

The marketing of the following Herbal Supplement:

- Brand Name:** Uva ursi Leaf Herbal Supplement
- Presentation:** 1.22 Oz (34.7 g) 90 Capsules in glass bottle
- Name and address of the manufacturer:** Aboca S.p.a., Via della Liberta' 37/ter – Pistrino di Citema Perugia - Italy
- Name and address of the distributor:** Aboca USA Inc., 126 South Spokane Street/Suite C, Seattle Washington – 98134 USA

**TEXT OF THE STATEMENT:** Uva ursi (*Arctostaphylos uva-ursi*), also named Bearberry, helps maintain a healthy urinary tract.\*

**Text of the disclaimer:** \*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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**HERBAL INGREDIENTS** (Amount per serving: 2 Capsules):

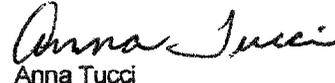
Uva ursi;(leaf) – W.P.C. \*\* 610 mg

**OTHER INGREDIENTS:** Gelatin (capsule).

**\*\*WPC:** "Whole Phytocomplex Concentrate" (W.P.C.) is a combination of freeze dried extract with the powder of the same portion of the plant.

**WARNING:** Contraindicated in kidney disorders. Do not take if you are pregnant or nursing. For other contraindications and cautions, please consult your health care practitioner. Keep out of reach of children.

I Anna Tucci, Executive Vice-President and General Manager of Aboca USA, certify that all the information presented and contained in this notice is complete and accurate, and that Aboca USA has substantiation that the statement is truthful and not misleading.



Anna Tucci

Executive Vice-President  
Aboca USA



**SUGGESTED USE:** Take 2 capsules twice a day or as directed by a qualified health care professional.

**Supplement Facts**

Serving size: 2 capsules  
Servings per container: 45

Colores, 2.6	Amount Per Serving
	mg % Daily Value
Uva Ursi - W.P.C.** ( <i>Arctostaphylos uva-ursi</i> ) (leaf)	610
Standardized to 9.84% arbutin, yielding 30 mg per capsule	
Other Ingredients: gelatin (capsule).	

\* % Daily Value not established  
\*\*Whole PhytoComplex Concentrate (W.P.C.) is a combination of freeze-dried extract with the practice of the same portion of the plant.

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Keep out of reach of children

**Aboca:  
Growing Herbs for Health**

Since 1978, Aboca has grown herbs using organic farming processes. Today Aboca's farmsteads occupy over 1700 acres, all certified organic in accordance with EU Directive 2092/91. Our mission is to provide the safest and most effective herbal supplements, by combining the ancient tradition of herbal remedies with the most sophisticated scientific research and production technology. Aboca is committed, from seed development to final packaging, to making the world's most natural herbal products for health needs, without the use of any chemical excipients or additives.

To learn more about Aboca, visit:  
[www.aboca.us](http://www.aboca.us)  
**MADE IN ITALY**

*The dark glass bottle is transparent to your protection, preserving this product from air, moisture and microbial contamination. Outer box prevents any further exposure to the light, fully ensuring its original stability and potency. All materials are completely recyclable. Keep in a dry cool place.*

**Herbal Supplement  
Uva Ursi**



**Whole PhytoComplex Concentrate**

Freeze-Dried Extract      Micronized Plant Powder  
305 mg per capsule

Net Wt. 1.22 oz (34.3 g) 90 Capsules

Uva Ursi (*Arctostaphylos uva-ursi*), also named Bearberry, helps maintain a healthy urinary tract.\*

This plant is carefully selected by Aboca adhering to the strictest protocols. Systematic quality controls implemented throughout the entire production process and analytical testing performed on raw material and finished product validate the safety and effectiveness of this herbal supplement.

Though arbutin is considered one of the main active ingredients of Uva Ursi, many other plant components contribute to the herb's efficacy. That is why Aboca has developed the exclusive W.P.C. (Whole PhytoComplex Concentrate) is a combination of the freeze-dried extract with micronized powder from the same portion of the plant, to assure maximum bioavailability, optimum concentration of active principle and the full-spectrum of constituents.

The result is a product with uniform content of arbutin without the use of excipients, colorings, flavorings, or preservatives, GMO free.

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

**100% NATURAL PRODUCT**



Manufactured by:  
Aboca S.p.A. Via della Libertà 37/39 - Pieve di Cadore  
Perù (Trentino - Italy)  
Distributed by:  
Aboca USA Inc. - 125 South Spokane Street, Suite C  
Seattle, Washington - 98134 USA

ASUSINA1ROPW-B

Best before  
Batch No.



ETUSUVAUROPW18

**Uva Ursi (Arctostaphylos uva-ursi), also named Bearberry, helps maintain a healthy urinary tract.\***

**SUGGESTED USE:** Take 2 capsules twice a day or as directed by a qualified health care professional.

**WARNING:** Contraindicated in kidney disorders. Do not take if you are pregnant or nursing. For other contraindications and cautions, please consult your health care practitioner.

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Batch n°

Best before



Distributed by: Aboca Usa Inc., 126 South Spokane St., Suite C,  
Seattle - Washington - 98134 USA - [www.abocausa.com](http://www.abocausa.com)

MADE IN ITALY

**Uva Ursi**  
Leaf



Whole PhytoComplex Concentrate  
305 mg per capsule

Net Wt 1.22 oz (34.7 g) 90 Capsules

Herbal Supplement

**Supplement Facts**

Serving size: 2 capsules  
Servings per container: 45

Calories: 2.6	Amount Per Serving	
	mg	% Daily Value
Uva Ursi - W.P.C.**	610	*
(Arctostaphylos uva-ursi) (leaf)		
Standardized to 9.64% arbutin, yielding 30 mg per capsule		
Other ingredients: gelatin (capsule).		

\* % Daily Value not established

\*\*Whole PhytoComplex Concentrate™ (W.P.C.) is a combination of freeze dried extract with the powder of the same portion of the plant.

Keep out of reach of children.