

# GRONEK & ARMSTRONG

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January 20, 2005

Office of Nutritional Products Labeling  
and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy  
College Park, MD 20740

JAN 21 2005

Re: Notification for Statements on Dietary Supplement Label

Dear Sir/Madam:

This firm represents Renaissance Herbs, Chatsworth, California, a manufacturer and distributor of dietary supplement products. Renaissance Herbs has requested that we notify your Agency on its behalf of the inclusion of statements of nutritional support on a dietary supplement product label.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the authorized provisions of 21 CFR §101.93(a), your Agency is hereby notified that Renaissance Herbs has made statements of "nutritional support", as described in 21 U.S.C. §343(r)(6)(A), for a dietary supplement as follows:

**Name**

**Label Statements**

WinterWell

Four season immune support. Immune and respiratory system support. This potent blend of Andrographis and other Ayurvedic herbs supports the health of the immune and respiratory systems during the winter season and throughout the year. Andrographis (*Andrographis paniculata*) leaf is traditionally used in Ayurveda and Traditional

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Chinese medicine to support healthy upper respiratory tract function. Double-blind, placebo-controlled clinical trials support the traditional use of Andrographis. In clinical trials with over 1300 subjects, Andrographis proved effective taken alone or combined with other herbal ingredients. Holy basil (*Ocimum sanctum*) is related to common basil and in the Ayurvedic tradition the leaves are used to support healthy upper respiratory tract function. Research has shown that Holy basil holds numerous potential health benefits, including support of healthy immune system function. Ashwagandha (*Withania somnifera*) is renowned as an herbal adaptogen. In the Indian Ayurvedic tradition the root is used as a Rasayana a dietary supplement or practice promoting rejuvenation, mental and physical health, as well as providing a defense against aging and challenging environmental factors. Research has shown that Ashwagandha root extracts support healthy immune system function. Trikatu or the "three pungent spices", is a traditional formula used to support healthy upper respiratory tract function. It consists of equal parts of Long Pepper fruit (*Piper longum*), Black Pepper fruit (*Piper Nigrum*), and Ginger root (*Zingiber officinale*). It can also enhance the bioavailability of other herbal products taken at the same time.

Two copies of this notification are enclosed with this original document.

The undersigned hereby certifies on behalf of Renaissance Herbs that the information contained in this correspondence is complete and accurate.

Sincerely yours,  
GRONEK & ARMSTRONG



Paul J. Wisniewski

PJW:  
pr  
Enclosures  
CC: Renaissance Herbs