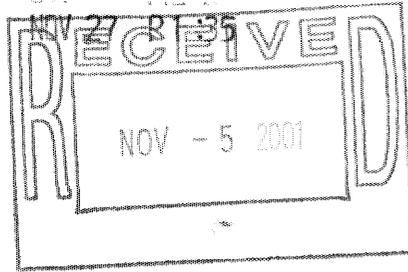




Innovative Nutrition Solutions

4385 '01



October 24, 2001

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

Dong Quai: [For] PMS support. Known in Asia as "Women's Ginseng," dong quai root contains compounds that help to normalize a woman's monthly cycle. It is used to tone and regulate the reproductive system and monthly cycle and provide support for the normal changes associated with menopause. Dong Quai relaxes smooth muscles of the uterus and, by increasing oxygenation of blood, helps to balance a woman's monthly cycle.

Perfect Iron, Folic Acid, Vitamin B-Complex, Calcium [and] Evening Primrose Oil: Optimal levels of key nutrients may help to ease the discomfort associated with PMS. Support your nutritional needs with these other Sundown products.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker, Esquire
Senior Vice President
Regulatory Affairs

Enclosure

975-0162

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