

**Corporate Headquarters** 

April 8, 2002

200 C. St. SW.

14500 N. Northsight Blvd.

Suite 316

Scottsdale, AZ 85260 USA

To Whom It May Concern,

Washington DC 20204

Food and Drug Administration

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition

This letter serves as notification to the Food & Drug Administration under regulations 6.H.2 of statements used in the labeling of a dietary supplement. Infinity2. Inc. has begun the marketing of a dietary supplement that bears a statement listed under section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

480-668-1801 Fax

480-668-1800

www.infinity2.com

Infinity2, Inc. is the distributor of a new product called "Prenatal Formula". Infinity2 is located at 14500 N. Northsight Blvd., Suite 316., Scottsdale, AZ 85260.

The product label for "Prenatal Formula" refers to the product as "Nutrition During Pregnancy" and contains the following statement: "During pregnancy and lactation the nutritional needs of women increase dramatically. Infinity2's Prenatal Formula provides whole-food vitamins and chelated minerals, plus powerful antioxidants in just the right balance to provide complete nutritional support for the body's increased needs during pregnancy. At the heart of Infinity2's all-natural Prenatal Formula is CAeDS, an exclusive nutrient delivery system that guarantees maximum effectiveness."

The disclaimer that states, "These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent ay disease." is included on the label. The disclaimer statement is listed with appropriate placement and typesize in harmony with the exemption to section 201(g)(1)(C) of the act that is provided by compliance with section 403(r)(6).

I certify that the information contained in this notice is complete and accurate, and that Infinity2 has substantiation that the statement is truthful and not misleading.

Respectfully,

Paul'M. Janson **Director of Operations** 

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