



# CellSentials Premarketing Evaluation: Safety and Quality of Life Survey

## Executive Summary

**For a four-week trial period, healthy adult consumers of the USANA Essentials switched to the upgraded CellSentials formulas. At the end of the trial, all subjects reported improvements in quality of life, and none experienced adverse events beyond what would be expected when beginning a new supplement. These results indicate that the new CellSentials formula offers significant perceived physical and mental health benefits, even among healthy, regular Essentials consumers.**

The Safety and Quality of Life Study evaluated the effects current Essentials consumers experienced when they switched to the upgraded CellSentials formulas for four weeks. Physicians affiliated with USANA and Sanoviv Medical Institute recruited the study subjects from their practices, and members of the United States' and Canadian Independent Distributor Councils also participated.

### Caveats

Subjects and administrators were aware that the product under investigation was an upgrade of USANA Essentials, but were deprived of any information concerning the ingredient list or rationale for the upgrade. In total, 127 volunteers were recruited and 96 subjects completed the evaluation.

### Survey method

To determine if subjects perceived any benefits or adverse consequences as a result of consuming the CellSentials, an SF-36 quality of life survey was administered at the beginning and end of the study period. The SF-36 is a standard set of 36 questions that evaluate a subject's self-perception of mental and physical health following a clinical intervention.

### Measures showing significant improvement

At the end of four weeks, statistically significant improvements were reported among all study participants in the majority of measures:

- **General health:** quantifies an individual's personal health (e.g., poor and likely to get worse versus excellent with little room for improvement)
- **Vitality:** measures of whether one feels tired and worn out or is full of pep and energy
- **Role-physical:** measures problems one may encounter with work or other daily activities as a result of physical health
- **Bodily pain:** measures the influence of bodily pain on physical function
- **Social functioning:** the extent to which physical and emotional problems interfere with normal social activities
- **Role-emotional:** the extent to which emotional problems interfere with work or other daily activities



- **Mental health:** quantifies feelings associated with mental health, such as nervousness, depression, calmness, and happiness

#### **Additional trends**

An upward trend was seen in **physical function**—the ability to complete routine daily tasks, such as bathing or dressing—but the change was not statistically significant. Overall, the SF-36 data provide considerable evidence that subjects perceived an improvement in both their mental and physical health as a consequence of consuming the CellSentials.

#### **Safety data**

To determine the safety of the new CellSentials formula, the study also collected data related to any adverse events. In all, there were 15 reports indicating that the CellSentials may have caused an unfavorable effect, and the effects were relatively minor and not surprising, as they are similar to the side effects often reported with the introduction of any new dietary supplement. The majority of these reports indicated that subjects experienced a decline in energy (8); although, headache (2), cold and flu (2), alterations in bowel movements (2), and weight gain (1) were also noted during the evaluation.

Conversely, however, there were 21 reports of positive health benefits, including increased energy (13), improved overall wellness (4), improved gastrointestinal function (i.e., less heartburn, improved digestion)(3), as well as improved sleep patterns (1).

The lack of any significant adverse events demonstrates that the new CellSentials are safe. And considering that participants were already healthy adults who were consuming the Essentials, the perceived improvements in quality of life are encouraging, providing substantial evidence that the CellSentials are effective and there are many benefits new consumers as well as current customers can expect to experience.