Peer Review of Clinical Research on Lily of the Desert Aloe Vera by Fenestra Research

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February 6, 2008

The practical goal of dietary supplement clinical testing is to determine whether the supplement achieves the intended or claimed results. Clinical research is used to promote new products that benefit consumers and to support the reasoned and supportable marketing of dietary supplements to consumers. Research is performed by a rigorous and meticulous means of testing the product to determine the effect of a supplement.

The purpose of this review is to evaluate clinical research performed by Fenestra Research Labs and determine whether the research on Lily of the Desert Aloe Vera Juice enhanced with Aloesorb™ supports marketing claims for increased absorption of vitamin C. The results of the Fenestra Research clinical trials on Lily of the Desert Aloe Vera Juice fully support the product claims of increasing vitamin C bioavailability.

Aloe vera has been used externally to treat various skin conditions such as cuts, burns and eczema. The sap from Aloe vera eases pain, promotes wound healing and reduces inflammation. Aloe has been marketed as a remedy for coughs, wounds, ulcers, gastritis, diabetes, cancer, headaches, arthritis, immune-system deficiencies, and many other conditions when taken internally.

Aloe contains over 200 biologically active, naturally occurring constituents, including vitamins, minerals, amino acids, antrhraquinines, enzymes and saccharides. Aloe vera's beneficial properties may be attributed to polysaccharides present in the inner gel of the leaf, especially acemannan (acetylated mannans), which has been demonstrated to be an immunomodulator. The polysaccharides in aloe have molecular weights up to over 2 million Daltons and it appears that the molecular weights greater than 200,000 Daltons support increased absorption of nutrients.

Lily of the Desert has quantified by High Performance Liquid Chromatography polysaccharides ranging from 200,000 to over 2 million Daltons and it is their assumption that these polysaccharides increase absoption in the intestinal tract. The purpose of the study by Fenestra was to determine if Lily of the Desert Aloe Juice enhanced with Aloesorb™ increases vitamin absorption. Aloe has been demonstrated to facilitate vitamin absorption in another study (Vinson et al, 2005). Also, aloe increased trypan blue penetration in fibroblasts in a dose dependant manner (Danhof, 1987). Therefore, the ability of aloe to increase absorption is a reasonable assumption.

Aloe vera leaves have three layers; the leaf or outer rind, the inner gel, and the Aloin or thin, slimy mucilage layer commonly known as the "yellow sap". Fillet aloe vera products are made by filleting off the outer rind of the aloe leaf and processing only the inner gel. Whole Leaf products are made by processing the entire leaf and filtering out the unwanted bitter constituents.

Lily of the Desert Aloe Vera Juice is an all natural certified organic dietary supplement and there are two types of juice, whole leaf and aloe fillet. Since each type of aloe juice contains different molecular weight polysaccharides, both types were tested for their ability to alter vitamin absorption. In addition, both types of juice were enhanced with Aloesorb™. This study is a follow up on a previous study performed by Fenestra that demonstrated a significant increase of Vitamin B_{12} when ingested with Lily of the Desert Whole Leaf enhanced with Aloesorb™ and Fillet Aloe enhanced with Aloesorb™ .

Fenestra Research Labs is an independent research facility that performed objective clinical trials on 15 subjects taking Lily of the Desert Aloe Vera Juice enhanced with Aloesorb over a 30-day period. The research reported by Fenestra Research was conducted by a credentialed investigator with experience in the type of research being conducted.

Neither the owner of Fenestra Research nor any of its employees have financial ties to Lily of the Desert, the manufacturer of Lily of the Desert Aloe Vera Juice, and therefore Fenestra Research provided a non-biased study on Lily of the Desert Aloe Vera Juice in terms of not having a financial interest in producing a desired outcome.

The ingredients of Lily of the Desert Aloe Vera Juice have no documented, historical, ill–effects on consumers and thus met Fenestra Research's criteria for clinical research.

The study employed 10 females and 5 male subjects, with a mean age of 48 in general good health that were drawn from a large and diverse population of people. The average Body Mass Index (BMI) was 23 +/- 4 kg/gm, which is in the average range. This subject selection is appropriate for the study and no difference between males and females was reported, indicating that the product does not produce gender specific effects.

The stringent inclusion and exclusion requirements were also appropriate for the study and rigorous enough to prevent study bias. Furthermore, interviewer bias (where an investigator conducts interviews that are influenced by his or her subjective judgments) was prevented by using objective guidelines for inclusion and exclusion of subjects. These guidelines prevented selection of people who have an underlying condition that might be worsened by the research and may cause those subjects harm. To further protect the subjects, all were required to give their informed consent; via a signature, to participate in the study

The study by Fenestra Research was a randomized, double blind, placebo controlled crossover study. Randomized, placebo–controlled, blinded trials are those that typically decide if a new drug will make it into the marketplace and are generally reported in scientific literature. This type of study is a Gold-Standard trial in pharmaceutical testing. All Gold–Standard trials include: randomization, placebo–controlled, blinding, physician oversight and bi–weekly status reports. Fenestra Research met all of these requirements for the Lily of the Desert Aloe Vera Juice study.

Crossover studies are those that test all products on the same subjects, with a washout period in between testing of each product. They are useful in that they compare placebo and product on the same person, thus preventing variability that can occur as a result of different subjects.

The 15 subjects were equally divided into those who received Lily of the Desert Aloe Vera Juice enhanced with Aloesorb™ prepared from either filleted aloe or whole leaf and those who received placebo. They were properly randomized into each group. Using this method, a group with similar characteristics is selected and randomly assigned to receive a placebo or to receive the supplement being tested. This serves to remove the possibility of psychological factors affecting the results because the subjects do not know whether they are getting the placebo or the supplement.

Dosing instructions were provided by the manufacturer and the duration of study was 30 days, which is long enough to reliably gauge whether a product related to these changes has a true effect on vitamin absorption. To protect the subjects, they were instructed to contact their regular healthcare professional if they had any unusual or uncomfortable symptoms during the course of this study. All subjects in the study were instructed to make no changes to their daily consumption of food or liquid relating to the amount, volume, or type consumed, which eliminated diet as a confounding variable. A confounding variable is a variable that may influence study outcomes but may not have been acknowledged or accounted for in original research.

Standard measurements were taken at time 0 and one week later to establish a baseline. After product consumption, measurements were taken by time points 0, 1, 2, 4 and 6 hours in this 24 hour period. These time points are more than adequate to follow the progress of how the supplement is working. The tests were run in triplicate and averaged for the report, which greatly reduces chances for error.

Compliance to the protocol was monitored and maintained through bi-weekly phone calls with Fenestra Labs personnel as well as in-person office visits that carefully following the subjects during the course of the trial to ensure their health and safety. This is an important component of a clinical trial. There were no dropouts during the study and no adverse effects, both are which are desirable in clinical trials.

Since none of the ingredients have a history of harmful effects, Lily of the Desert Aloe Vera Juice most likely does not produce any side effects.

There did not appear to be any systematic bias in the Lily of the Desert Aloe Vera Juice study by Fenestra Research. Systemic bias occurs when the study is flawed in its overall procedure thereby resulting in a study that does not actually measure the desired factors. This is prevented by expert study design and implementation, which was performed by Fenestra Research.

Additionally, there were no observed confounding variables in the study. In a study where it appears that there are positive results due to the product studied, confounding variables can contaminate the study findings because they bring up another potential cause for the positive results instead of the product being tested.

This study is a repeat of a study previously done on another Aloe product for the International Aloe Council by S. Devaraj, Associate Professor at UC Davis Medical Center. The results of the Fenestra study currently being reviewed are supported by this study and Vinson et al. (2003), who reported a significant increase in Vitamin C bioavailability after ingesting aloe. Multicenter studies are always more desirable than work performed at a single center, as it adds credibility when a different group confirms the results.

Both the Whole Leaf and Fillet Aloe significantly increased blood levels of vitamin C at all time points measured. These results were quite dramatic, with over a 20-fold increase in blood vitamin C for both the Lily of the Desert Whole Leaf enhanced with Aloesorb™ and Fillet Aloe Juice enhanced with Aloesorb™ at the one hour time point. At the 2,4 and 6 time points, the absorption was greater than 5 fold. These results markedly surpass other types of aloe that have been studied. An increase of the vitamin C in the blood indicates that the vitamin C exhibited an increased bioavailability when consumed with both types of aloe. This is the claim Lily of the Desert Aloe is supporting with these clinical trials.

In conclusion, the clinical trial performed by Fenestra Research met the criteria for the Gold Standard trial, which is the most rigorous

standard to meet. Furthermore, Lily of the Desert Aloe Vera Juice products produced extremely positive results in increasing bioavailability of Vitamin C.

References

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