

# Human Clinical Trial Evaluating the Safety and Efficacy of

Immune Enhancement, ORP (Oxidation and Reduction Potential) and Reduction of Toxicity Levels (Nitrates) Using Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™

> A Randomized, Placebo Controlled Study

> > FINAL REPORT SUBMITTED TO: Lily of The Desert Winter 2008

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**CONDFIDENTIAL INFORMATION** 

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### 1.0 STUDY PURPOSE

The purpose of this randomized placebo-controlled 30-day study was to evaluate an all-organic aloe vera dietary supplement product, to establish its safety and effectiveness.

### 2.0 STUDY OVERVIEW

Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb<sup>™</sup> is an all-organic exclusive propriety blend. This product is composed of Certified Organic Whole Leaf Aloe Juice, 60mg of Aloesorb<sup>™</sup> (per 2 ounce serving) and citric acid.

This was a 30-day, 75-subject study utilizing subjects drawn from a large population of people in general good health. The subjects were randomized into two groups and took either placebo or active treatment. Fifty-subjects were given the live product and 25-subjects were given the placebo product for the duration of this study.

The direct objective of this investigation is the performance of the test product compared to placebo within the thirty-nine cellular measurements of the *Optimal Wellness Test* along with arterial blood draws to evaluate White Blood Cell components. The *OPTIMAL WELLNESS TEST* portion of this research was done using proprietary devices and methodologies developed by FENESTRA RESEARCH LABS.

Fenestra Research Labs is the company that developed the revolutionary *Optimal Wellness Test* (Anti-Aging & Wellness Analyzer). The Optimal Wellness Analysis is an analytical, mathematically based test that actually measures wellness in every organ and system of the human body to within 2/100% accuracy. What we have established is a simple, reproducible, mathematical based system to determine if a natural product is resulting in your



body mover closer to or farther from *Wellness parameters*. Making it possible for healthcare professionals to *objectively* establish, determine and provide improved cellular health for patients. The *Optimal Wellness Analysis* cannot be compared to traditional lab testing devices because nothing-available today tests for wellness, they all test for disease. The typical patient in today's world is becoming more and more aware of the need to treat the cause rather than the symptom, and that is precisely what the *Optimal Wellness Test* provides, while eliminating all opinion and guess work!

The measurements we use for our analysis are not subjective nor are they questionable science. It is an analytical system that uses cutting edge science to evaluate health at the cellular level. Many of the measurements are based on multiple points of data. This system measures thirty-nine cellular parameters. Every measurement we use can be found in any college text book of chemistry, biochemistry, biology, or physics. The standard values of theses numbers have been well established for a decade at minimum.

### 3.0 PROTOCOL

#### 3.1 SCREENING and FOLLOW-UP

Following an initial screening at Visit 1 (week 0), subjects entered a 1-week baseline period (subjects were told to refrain from taking any unnecessary OTC's, prescription drugs, or natural products for the remainder of the study). Subjects who met all inclusion criteria and none of the exclusion criteria during the intake at Visit 2 (week 1) were then provided either the placebo or **Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™** The second evaluation on Visit 3 (week 3) was performed following standard procedures and the study's protocol was again reviewed with each subject on an individual basis. Final evaluations of test subjects were completed on visit 4 (week 5) of the study.

The placebo product and the test product were both taken orally on an empty stomach for this study. Each product was also ingested at a rate of



two ounces, three times daily for the duration of this study. There were no complaints about the products taste or stomach upset from either product.

Study subjects (18 yrs or older, M/F) had to be in generally good health.

# 3.2 INCLUSION CRITERIA

- A written informed consent consistent with required guidelines and meeting prior to participation in the trial.
- Male/female subjects 18 years of age or older.
- Subjects who were able to follow the protocol as designed by Lily of The Desert and Fenestra Research labs.
- Generally good health.

# 3.3 EXCLUSION CRITERIA

- History of head trauma.
- History of serious diseases or illness.
- Moderate to severe renal insufficiency.
- Recent history (<6 months prior to Visit 1) of myocardial infarction.</li>
- Regular use oxygen therapy.
- Active tuberculosis, a history of cancer within the last 5 years (treated basal cell carcinoma allowed), thoracotomy with pulmonary resection within 1 year prior to the trial, currently in a pulmonary rehabilitation program or who have completed a pulmonary rehabilitation program in the 6 weeks prior to the screening visit (Visit 1).
- Current prescriptions for diuretic medications, cardiac stimulants, or any other medication that may, in the opinion of the Fenestra Research staff, alter testing results.
- Use of opiate analgesics, prescribed or otherwise, obtained for recreation or for any treatment reason including migraine.



- History of drug addiction.
- Females who are pregnant, lactating, or nursing or who may become pregnant during the course of the study.
- Diagnosis as HIV-positive, diagnosis of AIDS, or with any neuromuscular condition including CP, MS, ALS, or Huntington's Chorea
- Uncontrolled hypertension (*e.g.* BP>150/100).
- Patients with any condition not previously named that, in the opinion of the investigators or intake staff, would jeopardize the safety of the patient or affect the validity of the data collected in this study.

## 4.0 OPTIMAL WELLNESS TEST DATA ANALYSIS

Certain physiologic parameters indicative of various states of oxidative stress, electrolyte imbalances, immune system function, and toxicity were measured during this study using OWT apparatus and calculation algorithms. OWT apparatus and calculation algorithms are proprietary and were developed by **Fenestra Research Labs**. All measurements were taken at baseline (Testing # 2), Testing #3 and at the study's end.

# 4.1 PARAMETERS MEASURED IN BOTH URINE AND SALIVA INCLUDED:

pH, rH<sub>2</sub> (a derived index of oxidative stress), ORP (redox potential), and r (resistivity),Conductivity, Nitrates, Nitrites, Ammonias, Milliewatts, Cations, Anions, Degrees Brix, Surface Tension, Specific Gravity, Urea's, Mercury Levels, Aluminum Levels, Lead Levels, Copper Levels, Anabolic Balance and Catabolic Balance.

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### 4.2 PLACEBO GROUP OWT DATA

There was no statistically significant change in any parameter measured for the placebo group.

### 4.3 COMPARATIVE TESTING

A simple non-paired t-test comparing the differences between baseline and final parameter values for placebo and live product groups showed small but statistically significant changes in salivary conductivity, and resistivity, and in urinary specific gravity, ammonia, nitrates, and conductivity.

Longer studies are planned to further investigate the significant positive changes seen in this study group.

### 5.0 BLOOD TEST DATA ANALYSIS

Arterial blood was drawn on visit #2(Baseline), #3, and #4 for all subjects in this study. Each blood test is an average of three drawn from the same subject, at the same time for each office visit. Standard blood draw practices were observed at followed for all office visits. Professional healthcare staff preformed all related blood contact protocol.

### 5.1 BLOOD COLLECTION:

Approximately 7ml of venous blood in a red top tub is collected from each subject at each blood draw.

### 5.2 BLOOD OBSERVATIONS:

Observation, measurement, and calculations of changes in White Blood Cells (WBC) were collected at each office visit from each subject.



### 6.0 CONCLUSIONS

Statistical analysis of these data shows a consistent picture between treatment group and the placebo group over the time of this study.

The Live Product group had a uniformly and dramatically more favorable response and achieved that response in a relatively short time.

Significant changes in the live product group were:

- ORP (oxidation and reduction potential)
  Reduced approximately 40% from baseline-final data collection
- Toxicity Levels (Nitrates)
  Reduced approximately 11% from baseline to final data collection
- Immune System Enhancement (White Blood Cells)
  Increased approximately 11.85% from baseline to final data collection additionally an increase of 16.18% from Control group.
  - The measurable change in WBC activation was specifically measured in macrophage and neutrophil cells. These WBC are responsible for ingesting invading microorganisms.

No significantly measurable changes were seen in the placebo subject's blood, urine, or saliva data.

No adverse events whatsoever were reported during the study.

Based on these clinical comparisons and the complete lack of known adverse side effects, interactions, or contra-indications from the herbal ingredients in the product, **Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™** was shown to be a safe and highly effective means of substantially reducing free radicals, toxic levels of Nitrates, while also increasing the cellular levels of White Blood Cells without impacting any system or function in the cellular body in a negative reaction.

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