



## Memorandum - Summary of AlkaPlex® Scientific Data

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In response to questions from medical and nutritional experts, I have assembled copies of various documents that may add to the understanding of the research surrounding **Alka-Plex** at pH Sciences® (the dba for pH Science Holdings, Inc). **Alka-Plex** is a proprietary, mineral based crystalline composition that is composed of strong alkalizing agents.

**Brief History:** pH Science Holdings (“pHS” or “Company”) has world-class technology for healthy alkalization. Healthy alkalization improves healthy aging, athletic endurance, and muscle recovery. The Company’s patents include Exact Blending and Compounding (“EBC”) equipment needed to make **Alka-Plex** and wide ranging utility patents controlling the uses and formulations of **Alka-Plex**.

The story of the discovery of **Alka-Plex** is engaging and the scientists involved with the discovery and development of products around **Alka-Plex** are available to travel and support marketing activities. This memorandum describes the scientific information available in Company files and transmits certain documents listed below.

**Safety:** **Alka-Plex** granules have a balancing effect on the complex and critical acid/alkaline relationships in the human body. **Alka-Plex** granules also can reduce 90% of the acidity in most foods and beverages without adversely affecting their flavor. Since the first applications were focused on reducing the acidity in foods and beverages, there was considerable safety data assembled on the composition as a food additive.

The safety data submitted to the U.S. Food and Drug Administration (FDA) convinced the FDA to issue a New Dietary Ingredient (NDI) letter – a designation of safety and uniformity for dietary supplements – in 2006. As an overview, the following memorandum offers safety information.

1. A September 23, 2005 memorandum from pHS staff summarizes the various safety data documents available at that time. (Since then, the World Anti-Doping Agency has tested the **Alka-Plex** composition and the US Anti-Doping Agency has opined that **Alka-Plex** has no steroids or stimulants even though athletic performance improvements appear significant.)

Use of **Alka-Plex** as a food additive gave rise to anecdotal evidence of health improvements. Improvements in bladder function and urinary tract health were the first indications that **Alka-Plex** had a profound health benefit even in moderate doses. Research on the health improvement aspects of **Alka-Plex** began with its effect on the bladder.

**Bladder Health Studies:** Considerable anecdotal evidence indicated significant bladder health improvements. People suffering from an untreatable condition called Interstitial Cystitis (“IC”) showed strong health improvements taking **Alka-Plex**. IC is a painful bladder disorder that affects about 700,000

people in the U.S. A standard methodology was adopted to run a pilot study on a specific group, then expand the studies to gather more data, and move to a double-blind, placebo-controlled clinical trial

Three documents are enclosed with bladder health testing with *Alka-Plex*.

2. A May 5, 2003 paper prepared by Susan Brown, Ph.D., a principal in the Nutrition Education and Consulting Service, entitled “A Novel Therapy for Interstitial Cystitis” which verifies the results of an eighteen month human trial of IC sufferers taking *Alka-Plex* in the form of a product called pH Control™. Dr. Brown’s paper was cited by the FDA in their NDI safety review.
3. A June 2003 draft report prepared by Robert Burns, Ph.D., scientific officer of pHS, entitled, “pH Control™ and It’s (sic) Effect on Urine Acid” that summarizes in-house studies of urine pH levels on various test subjects taking *Alka-Plex*.
4. An undated Power Point presentation entitled “2005-2008 Urinary Field Study of pH Control” with several slides indicating quantitative improvements in urinary urgency, frequency, and pain associated with taking *Alka-Plex*.

Based on these studies, a panel of nationally-recognized medical doctors recommended the National Institutes of Health (NIH) conduct a clinical trial of *Alka-Plex* to examine its application to treat IC. NIH administrators rejected the proposal and conducted a clinical trial of an anti-depressant as a possible treatment of IC. There remains no effective treatment for IC.

**Links to Chronic, Low-Grade, Metabolic Acidosis:** As early as 2003, Dr. Susan Brown and pHS scientists were drawing a link between the effects of *Alka-Plex* and a wide range of conditions that were thought to be triggered by acidic stress. Acidic stress is well documented among athletes but the link between acidic stress and health is not widely accepted in the U.S. medical community. Medical researchers refer to acidic stress as “chronic, low-grade, metabolic acidosis.” Company researchers undertook a review of over 400 peer-review articles and created a modest medical research library at pHS. Two seminal documents of this research are:

5. A February 2, 2005 memorandum from Dr. Robert Burns to me regarding “*Alka-Plex* and Acidosis” that includes many initial citations for further study.
6. An undated draft white paper from Joseph Pizzorno, ND; Lynda Frassetto, MD, and Joseph Katzinger, ND, entitled, “Diet-Induced Acidosis: Is It Real and Clinically Relevant?” This paper is slated for publication and is in the peer-review process at a major journal. This is the first of several papers likely to come out of the literature and clinical research.

Some well-regarded medical researchers began to embrace the concept that acidic stress may be linked to health issues. In addition to Dr. Pizzorno, Dr. Frassetto, and Dr. Katzinger, Jay Udani, MD, Mary Hardy, MD, Steve Sinatra, MD, Alex Schauss, Ph.D, Russ Jaffe, MD, and Loren Israelson began to follow our research and endorsed some of the health benefits of *Alka-Plex*.

It was reasoned that if there is a link between the effects of taking *Alka-Plex* and ameliorating the impacts of chronic, low-grade acidosis, there should be a wide range of health improvements that derive from adding *Alka-Plex* to the diet. In fact, that appears to be the case. Classic acid related conditions (such as Gout) show profound improvement with no negative side effects. Of particular interest to our scientists are two areas of documented improvements – mucosal membrane health and athletic performance. This research has also led to additional patent applications in the area of anti-inflammatory impacts associated with compositions like *Alka-Plex*.

**Mucosal Membrane Health:** Anecdotal evidence was indicating that mucosal membrane function and general health improved by adding *Alka-Plex* to the diet. Symptoms associated with conditions like irritable bowel syndrome, heartburn, and gum disease improved dramatically – especially if *Alka-Plex* came into direct contact with the mucosal tissue.

For example, a series of studies were conducted by dentists using toothpaste made from *Alka-Plex*. The studies started with persons experiencing extreme gum health issues and culminated in a double-blind, placebo controlled study that showed significant improvements in gum health for even modestly inflamed tissues. The three studies are summarized in the following memorandum.

7. A January 31, 2008 memorandum from Steve Loyd to file that summarizes the results of three studies (and one bacteriological profile) of subjects using *Alka-Plex* toothpaste.

**Athletic Performance:** Again, with the hypothesis that *Alka-Plex* may mitigate the effects of acidic stress, it seemed as though endurance athletes (who generate large amounts of metabolic acids) would see their performance improve. As an added bonus, athletes, who are generally perceived as healthy, usually permit physicians to monitor their physiological changes as they exercised to exhaustion with different levels of *Alka-Plex* supplementation. The Company's first step was a review of the literature followed by a pilot study and finishing with a double-blind placebo controlled clinical study.

8. A July 22, 2005 memorandum from Dr. Robert Burns to Steve Loyd entitled, "Exercise, Acidosis and Alka-Plex<sup>®</sup>" cited numerous studies and attempts to improve athletic performance with bicarbonates. Bicarbonates are difficult on the digestive system (unlike *Alka-Plex*).
9. A January 22, 2006 report by Emily Cooper, MD, from the Seattle Performance Medicine Clinic, entitled, "Elite Bicyclist Pilot Study Using Two Levels of Alka-Plex<sup>®</sup> Supplementation." Athletes in this study were under medical supervision and they allowed pHs to measure numerous physiological changes (heart rate, respiration, lactic acid levels, urinary pH, and others) as the athletes worked to exhaustion under various levels of supplementation.

The physiological responses and detailed information gathered by Dr. Cooper led to a double blind, placebo-controlled, study conducted by Dan Heil, Ph.D., the current President of the College of Sports Medicine. Dr. Heil's study is not available for distribution because it is being prepared for submission to a peer-review publication. It confirms Dr. Cooper's findings.

Dr. Cooper's study also provided sufficient physiological data to encourage further study and understanding of the unique health inducing alkalization characteristics of *Alka-Plex*.

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