A Report of The Clinical Research Study and Market Opportunity

October 16, 2006

A Double Blind Comparator Trial of The Effects of Beyond H2O™ Water Versus Tap, Distilled and Mineral Water on Rehydration After Exercise in Healthy Male Volunteers

TABLE OF CONTENTS

EXECUTIVE SUMMARY

Mild dehydration is defined as a loss of 1 to 2 percent of body weight as fluid. Studies show that nearly one-third of the nation is chronically mildly dehydrated.

Mild dehydration can impair mental performance by 20 percent.

Mild dehydration can diminish physical strength and aerobic capacity by 20 percent.

Current scientific and medical research indicates that low total water consumption and chronic mild dehydration may be risk factors in the development of urinary stone disease, fatal coronary heart disease, cancers of the urinary tract, colon and breast, childhood and adolescent obesity, mitral valve prolapse, and overall health in the elderly.

In an independent clinical study monitoring the rate of rehydration after dehydrating exercise, *Beyond H2O™ brand water demonstrated statistical significance and meaningfully outperformed tap water in rehydrating* after exercise, and sustained a significantly faster rate of rehydration 2 hours after exercise. (See Page 11)

In the same study, *Beyond H2O™ brand water had a greater and statistically significant effect on rehydration compared to mineral water* within 30 minutes and at 2 hours after exercise. (See Page 15)

In the U.S. Liquid Refreshment Beverage Market, Share of Volume by Category, Carbonated Soft Drinks both diet and non-diet show a projected decline from 2005 to 2010, bottled water by share volume is projected as the biggest individual growth category predicted to grow from 21.7% of market share in 2005 to 28.5% of market share in 2010. (See Chart Pg. 20)

Beverage Marketing Corporation bottled water and beverage industry analysts, project a continuing and very healthy and significant 14% compounded annual growth for years 2005-2010. (See Chart Pg. 21)

Beyond H2O™ can be classified in the “Added Value” segment of the bottled water category where Beverage Marketing Corporation bottled water and beverage industry analysts project growth in volume for that segment at a 25% compounded annual increase in years 2005 to 2010. (See Chart Pg. 22)

Much of this projected growth in bottled water demand may be attributed to a growing belief in the scientific community that water is the most preferred beverage for weight loss and better health.

INTRODUCTION

Water is the most abundant compound in the human body. All biochemical reactions occur in water, and water is an active participant in those reactions. There is no life (as we know it) without water. It is well known that severe dehydration acutely affects health. More recently mild dehydration has been identified as a risk factor for long-term health, and as a short-term influencer of both mental and physical performance.

The Functions of Water in the Body

Fluids fill virtually every space in cells and between them. Water molecules not only fill space, but they also help form the structures of macromolecules such as proteins and glycogen. As the primary fluid in the body, water serves as a solvent for minerals, vitamins, amino acids, glucose, and many other nutrients. Water also plays a key role in the digestion, absorption, transportation, and use of nutrients. Water is the medium for the safe elimination of toxins and waste products and whole-body thermoregulation is critically dependent on it. From energy production to joint lubrication to reproduction, there is no system in the body that does not depend on water.

Definition of Dehydration

Dehydration can be acute, as from a bout of intense exercise, or chronic, resulting from less than adequate rehydration of daily water losses over a period of time. Both types of dehydration are defined as a 1% or greater loss of body weight as a result of fluid loss (1), (2). For the purpose of this report, mild dehydration is defined as a 1% to 2% loss of body weight caused by fluid losses.

The symptoms of severe dehydration are commonly recognized, but the symptoms of mild dehydration are often misinterpreted as hunger, anxiety or fatigue, rather than dehydration.

SYMPTOMS OF DEHYDRATION

EARLY SIGNS	SEVERE SIGNS
Fatigue	Difficulty swallowing
Loss of appetite	Stumbling
Flushed skin	Clumsiness
Burning in stomach	Shriveled skin
Light-headedness	Sunken eyes and dim vision
Headache	Painful urination
Dry mouth	Numb skin
Dry cough	Muscle spasm
Heat intolerance	Delirium
Dark urine with a strong odor	

Influencers of Hydration Status

The primary controller of hydration status in human beings is thirst. Unfortunately, the threshold for the induction of thirst occurs at a point where a person is already dehydrated to a level of 0.8% to 2% loss of body weight (3) (4).

Environment can alter the thirst mechanism and hydration status. For instance, water immersion induces biochemical shifts that diminish the thirst response (4). Exercise also blunts thirst (5). Environmental factors such as increases in temperature and altitude and

decreases in relative humidity increase water loss through perspiration and respiration (6, 7, 8, 9, 10, 11).

Taste influences hydration and beverage choice in adults and children (12, 13). A survey conducted in 1994 at 2 community health centers in Rhode Island (12) showed that of the 124 respondents, 55% used only bottled water for drinking. Among the reasons cited for choosing bottled water, 43% of the respondents said taste was their reason. In children, the magnitude of rehydration is significantly affected by the flavor of the available beverage (13).

Requirements

Water accounts for one half to four fifths of body weight, depending on level of lean body mass. On average, men have a higher level of lean body mass than women. As a percentage of body mass, body water is higher in men than in women, and falls in both with age (14) Water is an essential nutrient because it is required in amounts that exceed the body ability to produce it. Even without perspiration (sensible losses) the normal daily turnover of water is approximately 4% of total body weight in adults and 15% of total body weight in infants.

The human requirement for water is metabolic and highly variable. Insensible losses may vary widely, yet there must be a minimal amount available to maintain a tolerable solute load by the kidneys. Water is manufactured in small amounts by the body through oxidation. Solid foods, especially fruits and vegetables, contribute fluids to the diet. Based on a 2,900-kcal diet (70-kg adult man), solid foods contribute approximately 1 L water per day, and the water of oxidation contributes another 250 mL (15) The rest must be supplied by fluid intake.

Based on the recent work of the committees defining the Dietary Reference Intakes being used in the United States and Canada, the "adequate intake" of fluids (AI, derived from the usual intake of total fluids in the general population) was set at 125 fl oz (15 cups) per day for men and 91 fl oz (11 cups) per day for women. Approximately 80% of that daily need is contributed by beverages, including water, and the rest by solid food.

Fluid Intakes of the US Population

Data from three national surveys: (1) the Third National Health and Nutrition Examination Survey, 1988-1994 (NHANES III); (2) the 1994-96 Continuing Survey of Food Intakes by Individuals (CSFII 94-96); and (3) the National Health and Nutrition Examination Survey, 1999-2000 (NHANES 99-2000) indicate that at least one-third of the population does not consume the recommended amounts of fluids daily. Based on these estimates, a proportion of the population may be chronically mildly dehydrated.

Influence of Hydration on Health and Disease

It was a practice of Hippocrates to recommend large intakes of water to increase urine output and decrease the recurrence of urinary tract stones (16). Today, approximately 12% to 15% of the general population will form a kidney stone at some time (17, 18). Many factors can modify the urinary risk factors for developing stones, including age, sex, heredity, occupation, social class and affluence, geographic location and climate, and diet. Of these, diet—especially fluid intake—is the only factor that can be easily changed and that has a marked effect on all urinary risk factors (19 -23).

Several studies have discovered a direct correlation between fluid intake and the incidence of certain cancers. Studies in Israel, Great Britain, and the United States have observed

that the more fluid that people drink, the lower their risks of bladder, prostate, kidney, testicle, renal pelvis, ureter, colon, and breast cancers. In several of the studies, a decrease in cancer risk was specifically associated with water intake. For instance, a study in Seattle, Washington showed that women who drank more than 5 glasses of water a day had a 45 percent significantly decreased risk of colon cancer vs those who consumed 2 or fewer glasses per day. Men had a non-statistically significant reduction of cancer by 32 percent when they drank more than 4 glasses a day vs 1 or fewer glasses a day. Although the data are preliminary, a pilot study in Great Britain found that the risk for developing breast cancer was reduced by 79 percent among water drinkers when adjusted for all other related factors (24-27)

Mild dehydration can also be a factor in the occurrence of mitral valve prolapse. In a study of 14 healthy women with normal heart function, mitral valve prolapse was induced by mild dehydration, and resolved with rehydration (28).

Obesity is occurring in epidemic proportions in the U.S., and is being exported worldwide. Calories are consumed not only from food, but also from beverages. A very recent panel discussion published in The American Journal of Clinical Nutrition in March of 2006 by leading experts has suggested a “guidance system” for beverage consumption in the U.S. The following is a synopsis of their recommendations (29):

- Energy intake from beverages represents 21% of the total energy intake of Americans over two years of age.

- Data show that from 1977-2001, the proportion of energy received from calorically sweetened soft drinks and fruit drinks (not including fruit juices) has increased 3-fold, with a concurrent reduction in milk intake.

- Studies show that the average portion sizes of beverages have increased, and at the same time Americans have also increased their number of daily servings of calorically sweetened beverages.

- Research on appetite shows that fluids are less satiating than solid foods.

- In the opinion of the Panel, a healthy diet does not rely on fluids to provide energy or nutrient needs. Therefore, potable water could be used to fulfill almost all the fluid needs of healthy individuals.

- The recommendations of the Panel incorporated advice directed at all fluids consumed by humans, with the exception of soups and liquid meal replacement products designed for use in weight loss diets.

- The guidance system classifies beverages on the basis of energy and nutrient density; contribution to total energy intake and body weight; contribution to the daily intake of essential nutrients; and evidence for beneficial and adverse health effects.

- The system uses eight ounces (250mL) as the standard portion size and is intended for use by all members of the population over six years of age

The Panel recommendations are as follows:

Description	RecommendedIntake (fluid ounces/day)	Notes
Level 1:Water	20-50	Most preferred by the Panel, should be consumed as the major beverage
Level 2:Tea and Coffee	0-40	Need to observe recommended caffeine limits
Level 3:Low-fat and Skim Milk and Soy Beverages	0-16	
Level 4: Non-calorically Sweetened Beverages	0-32	Need to observe recommended caffeine limits
Level 5: Caloric Beverages with Some Nutrients	0-8(100% fruit juices) 0-1 alcoholic drink (women) 0-2 alcoholic drinks (men)	Includes vegetable and fruit juices, whole milk, sports beverages and alcoholic beverages
Level 6: Calorically Sweetened Beverages	0-8	Least preferred by the Panel and should be consumed in limited quantities

Influence of Hydration on Performance

Cognitive/Mental Performance

When it comes to peak mental capacity, whether at the office or in competition, hydration state will affect performance. In a study of subjects' abilities to perform mental exercises after heat-stress induced dehydration, a fluid loss of only 2 percent of body weight caused reductions in arithmetic ability, short-term memory, and the ability to visually track an object by 20 percent compared to their well-hydrated state.(10)

Physical Performance and Exercise

Since muscles are nearly 70 percent water, even a small loss of fluid will affect their function. Muscles are controlled by nerves. The electrical stimulation of nerves and contraction of muscles occurs due to the exchange of electrolytes dissolved in water across the nerve and muscle cell membranes. When water levels are low electrolyte balance is disrupted, and muscle strength and control are weakened. A water deficit of just 2 to 4 percent of body weight can diminish strength by as much as 21 percent, and aerobic power by as much as 48 percent. (30-33)

The hydration state of muscle cells is commonly referred to as volumization. In a well-hydrated muscle cell, protein synthesis is stimulated and protein breakdown is decreased. On the other hand, muscle-cell dehydration promotes protein breakdown and inhibits protein synthesis. Cell volume has also been shown to influence genetic expression, enzyme and hormone activity, and metabolic regulation. Hydration promotes muscle-cell growth, whereas dehydration inhibits growth. (34)

One of the many goals associated with exercise is fat loss. Water is critically important to the successful outcome of this goal. Water can help take the edge off hunger, and as stated

above, it has no calories. As stored fatty acids are mobilized to burn off as energy, fat-soluble toxins are released that have been benignly stored in fat cells over time. The more fluid consumed the more dilute the toxins in the bloodstream, and the more rapidly they exit from the body. (35)

Fluid Guidelines for Americans

Based on the above discussion, the following fluid plan guidelines have been published (36).

- Drink a minimum of 1 quart (5 cups) of fluid for every 1,000 calories you eat every day.
- Drink at least 5 cups of water every day.
- Fluids should be cool.
- For moderate exercise that lasts an hour or less, water is sufficient for replacing lost fluids.
- For intense exercise that lasts less than 1 hour and exercise lasting more than an hour, carbohydrate-electrolyte sport drinks are best.
- Drink 2 cups of fluid 2 hours before exercise.
- Drink 4-6 ounces every 15 to 20 minutes during exercise.
- After exercise, drink 20 ounces (2½ cups) of fluid for every pound of body weight lost during exercise.

THE RESEARCH

The previous discussion makes it clear that it is scientifically and clinically relevant to offer the population a non-caloric water with superior taste and rehydration capability. While many water products are marketed making claims of superiority, no product can back the claims with research published in scientific, peer-reviewed journals. Therefore, the following study was conducted to investigate the influence of Beyond H2O™ branded water on rehydration compared to other water products. The study was conducted with valid and reliable scientific methodology with the goal of publication in a peer-reviewed scientific journal.

A DOUBLE BLIND COMPARATOR TRIAL OF THE EFFECTS OF BEYOND H2O™ BRANDED WATER VERSUS TAP, DISTILLED AND MINERAL WATER ON REHYDRATION AFTER EXERCISE IN HEALTHY MALE VOLUNTEERS

Study Investigators

The study was conducted at Miami Research Associates (MRA), an independent contract laboratory. MRA is a leading clinical services organization comprised of over 30 board-certified physicians coupled with more than 25 Associations of Clinical Research Professional Certified Coordinators. MRA has extensive experience in conducting pharmaceutical clinical trials, clinical trials for the National Institutes of Health, including trials with nutritionals, medical devices and specialty products. The following investigators designed and carried out the entire study:

Principal Investigator:
Diane R. Krieger, MD, Medical Director, Nutrition Division

Sub-Investigators:

Howard I. Schwartz, MD, Medical Research Director, Gastroenterology
Robert Feldman, MD, Director, Women Health
Athena Mayers, PA-C, Physician Assistant
Ellen Schwartzbard, MD, Staff Physician
Isabel Pino, ARNP, Nurse Practitioner
Douglas Kalman, MS, RD, CCRC, FACN, Dir. of Clinical Research, Nutrition
Samantha Feldman, MS, RD, CCRC, Senior Coordinator

Statistical Analysis:
John C. Pezzullo, PhD, for Miami Research Associates

Description of Study Design

Objectives of the Study

The objectives of this study were to determine the effect of Beyond H2O™ brand water compared to tap water, distilled water and commercially-available mineral water on hydration in healthy males. The objectives differed in the efficacy endpoints, each obtained at various times following ingestion of study product after a 1-hour exercise:

Efficacy Endpoints and Objectives:

1. Plasma and Serum Osmolality
2. Hematocrit
3. Body Weight
4. Serum Sodium
5. Urine Specific Gravity
6. Total Body Water (TBW)
7. Intracellular Water / Extracellular Water Ratio (ICW:ECW).

Structure of the Study

This is a prospective, randomized, comparator-controlled, double-blind, 4-arm, crossover study.

Description of the Study

The study enrolled healthy young non-smoking active male adults aged 18 to 45, with a history of at least 6 months of exercise experience, who could walk/run on a treadmill for ~60 minutes at a moderate pace without difficulty.

Subjects were pre-screened by phone; potential candidates were called in for a screening and baseline evaluation (Visit 1) after obtaining informed consent. Acceptable subjects were enrolled and brought back for four subsequent testing visits (visit 2, 3, 4 and 5). At each test visit subjects were provided a standardized breakfast, consisting of a toasted bagel, one tablespoon cream cheese and 500 ml of fluid, ingested 30 to 60 minutes prior to starting the exercise test procedure. Subjects then walked/ran on a treadmill at 2, 3, 4, 5, 6 and 7 miles per hour, 5 minutes per workload, with a 10 minute break at the 30-minute mark. Following the 10 minute break, subjects repeated the same exercise for a total of 60-minutes of exercise. During the exercise, the room was kept at a temperature of 33–40°C (91–104°F) and a relative humidity of 40–56%. This exercise regimen is known to induce a 2 to 3% reduction in body weight. If a subject had not lost at least 2% of his body weight by the end of the 60 minutes, he underwent up to three additional 12 minute sessions of exercise until the 2% weight loss had been achieved. Subjects were then given, one of the

four test products (Beyond H2O™ brand water, tap water, distilled water, and commercial mineral water, randomly assigned to the four testing visits). Blood and urine specimens for assessing efficacy variables were taken at pre-run, immediately post-run (before ingestion of study product), and at 30, 60, 90, and 120 minutes following the completion of ingestion of product. Weight was measured at pre-run, post-run, and at 30 and 120 minutes following ingestion of product. All subjects watched television (TV/DVD), slept, read or studied quietly during the post-exercise period.

This study was approved by the Aspire Independent Review Board of San Diego, CA. on July 5, 2006.

Products Tested

The following products were evaluated:
Product 1 – Beyond H2O™ brand water
Product 2 – tap water
Product 3 – distilled water
Product 4 – commercially-available mineral water

To maintain study blind, the beverages were identical in color and appearance, and were bottled and labeled to look the same. Beverage temperature was controlled.

Dosing and Product Administration

Subjects were given one serving of the randomly-assigned product immediately after finishing the of exercise session. Subjects had to consume all of the assigned product (16.9 oz/507ml). All subjects completed ingestion within five-minutes of starting the drink.

Statistical Method

Definition of Study Populations

The **safety population** was defined as all subjects who ingested any test product, and for whom any subsequent safety information was available.

The **efficacy population** was defined as all subjects who completed the rehydration procedure for all four products.

Examination of Data and Descriptive Statistics

All data elements were screened for reasonableness, and all missing, suspicious or impossible values were referred back to MRA for verification or correction. All numerical variables were tested for normality, and data found to be substantially non-normally distributed ($p<0.05$ by the Anderson-Darling test) were analyzed by appropriate non-parametric methods.

Descriptive statistics for each numerical variable were summarized as number of subjects, mean, standard deviation, median, minimum and maximum, and were calculated for each product tested. Changes in each endpoint from pre-exercise baseline were summarized in the same way, with the addition of a p-value indicating the significance of the mean change from baseline, and a 95% confidence interval around the mean change.

Statistical Analysis – Changes Over Time and Comparison of Treatments

The efficacy analyses were concerned with: (1) characterizing the changes in the efficacy

endpoints over the course of exercise (dehydration) and rehydration, and (2) identifying differences between Beyond H2O™ brand water and the three other types of water (tap, distilled, and mineral water). Because this was a crossover study, each subject received all four treatments (in random order), so paired analyses were performed, comparing Beyond H2O™ brand water against each of the other three water products. This removed the major portion of subject-to-subject variability, increasing the power of the study to detect differences between treatments.

For each efficacy variable, the value at each time point was compared to the same subject baseline value by a paired **Student t test** (or by the Wilcoxon Signed-Ranks test, for non-normally distributed variables). For each efficacy endpoint (including changes from baseline and percent return to baseline), the difference between Beyond H2O™ brand water and each of the other three products was tested by significance by the paired Student or Wilcoxon test.

The average rate of change of each efficacy variable following ingestion of product was obtained for each subject by fitting a least-squares straight line to that subject post-exercise values of that efficacy variable as the dependent variable, with time (in hours) as the independent variable. The slope of this line was the subject average rate of change in that variable.

The rate of change was analyzed statistically in two ways. First, a single-group Wilcoxon Signed-Ranks test was used to test whether or not that variable was significantly *different from zero within each product group.* Second, the slopes were tested for significant *differences between* Beyond H2O™ brand water *and each of the three other products.*

Software

Excel 2002 (Microsoft Corp, Redmond WA), was used for data entry, validation, restructuring, and calculating changes in variables over time. All data analysis (descriptive statistics, significance testing, and the generation of graphs) was performed using the “R” statistical/graphical programming system, ver.3.1.0 (R Foundation for Statistical Computing, Vienna, Austria, http://www.R-project.org).

RESULTS

Disposition of Subjects, and Analytical Populations

The **safety population** was defined as all subjects who ingested any test product, and for whom any subsequent safety information was available. For this study, all 14 enrolled subjects were included in the safety population.

The **efficacy population** was defined as all subjects who completed the rehydration procedure for all four products. Two subjects terminated the study before completing all four testing visits. The efficacy population consisted of 12 subjects.

Demographic and Baseline Characteristics of Subjects

The demographic and baseline characteristics of the 14 enrolled subjects in the Safety and Per-Protocol populations are shown in the following table. Numeric variables are summarized in the format:

Mean ± Standard Deviation (Number of Subjects)
Median (Minimum – Maximum)

Categorical variables are summarized as counts and percentages of total within product group.

Table 1. Baseline Characteristics of Subjects

Variable	Completed Study	Early Termination	Total	p-val
Age (years)	24.1 ± 5.1 (12) 22 (20 – 39)	21.0 ± 1.4 (2) 21 (20 – 22)	23.6 ± 4.8 (14) 22 (20 – 39)	0.171
Height (cm)	176.4 ± 8.2 (12) 174.8 (159.3 – 188.3)	176.5 ± 1.3 (2) 176.4 (175.5 – 177.4)	176.4 ± 7.6 (14) 175.3 (159.3 – 188.3)	0.994
Weight (kg)	80.7 ± 10.4 (12) 76 (65.9 – 99.5)	83.3 ± 25.7 (2) 83.3 (65.1 – 101.5)	81.1 ± 12.0 (14) 76 (65.1 – 101.5)	0.788
Heart Rate (beats/min)	69.0 ± 6.8 (12) 69 (60 – 84)	68.0 ± 2.8 (2) 68 (66 – 70)	68.9 ± 6.3 (14) 69 (60 – 84)	0.845
Systolic BP (mm Hg)	112.0 ± 8.6 (12) 112 (100 – 126)	117.0 ± 4.2 (2) 117 (114 – 120)	112.7 ± 8.2 (14) 113 (100 – 126)	0.448
Diastolic BP (mm Hg)	73.5 ± 7.8 (12) 75 (60 – 82)	78.0 ± 0.0 (2) 78 (78 – 78)	74.1 ± 7.4 (14) 78 (60 – 82)	0.780

Comments. There appears to be no substantive differences between subjects who completed the study and subjects who did not. The small number of non-completers precludes meaningful statistical testing. Thus there seems to be no difference in the subject pool if we were to have the 14 subjects enrolled complete the entire study.

Safety Conclusions

No serious adverse events were reported during this study, and there were only three adverse events reported, which were of mild severity, and were judged by the Principal Investigator to be unrelated to the study product. No safety concerns were raised in this study.

Efficacy Analysis Summary

The **value of each efficacy endpoint** at each time point at each of the four product testing sessions was summarized descriptively in a table, in the format:

Mean ± Standard Deviation (Number of Subjects) Median (Minimum – Maximum)

Changes in efficacy variables from baseline was summarized in the format:

Mean ± Standard Deviation (Number of Subjects) Median (Minimum – Maximum) p-value for Change from Baseline 95% Confidence Interval round Mean Change from Baseline

The last three columns of the table summarize the results of paired comparisons of the variable (or change from baseline) between Beyond H2O™ (Product C) and each of the three other water products. The results are presented in the format:

d= #.# #.#*sd p=0.###

The first line ("d=#.#") gives the mean paired difference between Beyond H2O™ and the other product; the second line ("#.#*sd") indicates the effect size, defined as the mean paired difference, relative the standard deviation of the paired differences (1.2*sd indicates a 1.2-sigma effect size); the third line contains the p-value from a paired Student or Wilcoxon test, indicating whether there is a significant difference between Beyond H2O™ and the other product. Cells with statistically significant p-values ($p \leq 0.05$) are highlighted in red text.

Due to the volume of data points generated in this study, only the very key endpoints and objectives with statistically significant p-values ($p \leq 0.05$) that support the marketing statements noted above the data will be included in this report. At no time point for any of the data not included here did Beyond H2O™ brand water under-perform the other test waters. In fact, there were other time points and parameters where Beyond H2O™ brand water outperformed the other test waters, but they are extraneous to the key marketing statements.

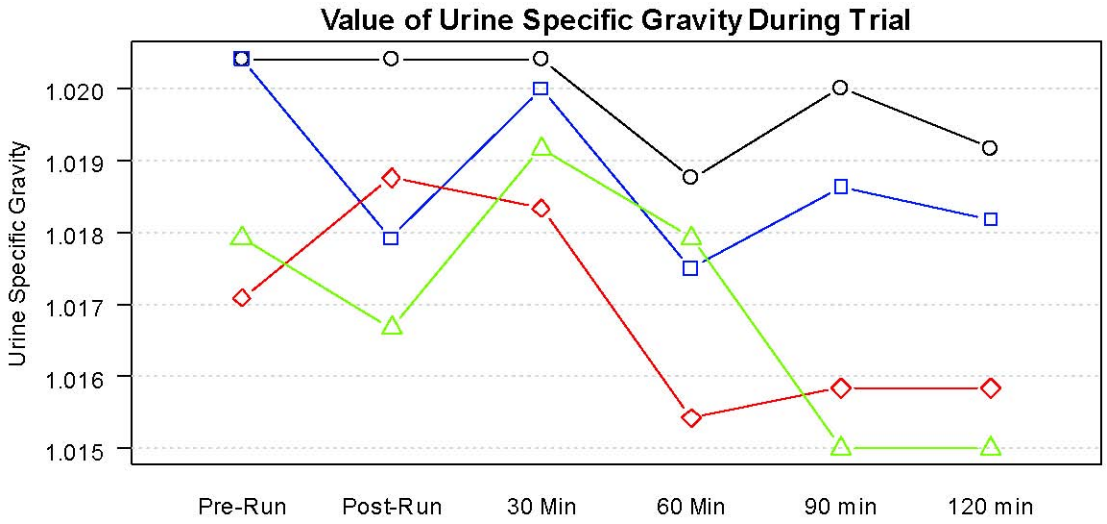
Marketing Statement A

- In an independent clinical study monitoring the rate of rehydration after dehydrating exercise, *Beyond H2O™ brand water demonstrated statistical significance and meaningfully outperformed tap water in rehydrating* after exercise, and sustained a significantly faster rate of rehydration 2 hours after exercise.

Urine Specific Gravity

Table 2. Urine Specific Gravity Over Time

	Type of Water				p-value vs. Beyond H2O™		
Time Point	**Beyond H2O™ (Product C)**	**Mineral (Product D)**	**Tap (Product A)**	**Distilled (Product B)**	**Min**	**Tap**	**Dist**
Pre-exercise (Baseline)	1.0171 ± 0.0050 (12) 1.02 (1.005 – 1.02)	1.0179 ± 0.0062 (12) 1.02 (1.005 – 1.025)	1.0204 ± 0.0050 (12) 1.02 (1.01 – 1.025)	1.0204 ± 0.0054 (12) 1.02 (1.01 – 1.03)	d= -8e-04 - 0.2322*sd p=1.000	d= -0.0033 - 0.4864*sd p=0.230	d= -0.0033- 0.7511*sdp=0.053
Post-exercise Pre-ingestion	1.0188 ± 0.0043 (12) 1.02 (1.01 – 1.025)	1.0167 ± 0.0086 (12) 1.02 (1 – 1.025)	1.0204 ± 0.0040 (12) 1.02 (1.015 – 1.025)	1.0179 ± 0.0062 (12) 1.02 (1.01 – 1.03)	d= 0.0021 0.3578*sd p=0.220	d= -0.0017 - 0.3755*sd p=0.343	d= 8e-040.1397*sdp=0.797
30 minutes post-ingestion	1.0183 ± 0.0044 (12) 1.02 (1.01 – 1.025)	1.0192 ± 0.0067 (12) 1.02 (1.005 – 1.03)	1.0204 ± 0.0040 (12) 1.02 (1.015 – 1.025)	1.0200 ± 0.0056 (12) 1.02 (1.01 – 1.03)	d= -8e-04 - 0.1495*sd p=1.000	d= -0.0021 - 0.3845*sd p=0.280	d= -0.0017- 0.2887*sdp=0.346
60 minutes post-ingestion	1.0154 ± 0.0040 (12) 1.015 (1.01 – 1.025)	1.0179 ± 0.0062 (12) 1.0175 (1.01 – 1.025)	1.0188 ± 0.0031 (12) 1.02 (1.015 – 1.025)	1.0175 ± 0.0054 (12) 1.015 (1.01 – 1.025)	d= -0.0025 - 0.5528*sd p=0.072	d= -0.0033 - 0.8563*sd p=0.015	d= -0.0021- 0.3578*sdp=0.229
90 minutes post-ingestion	1.0159 ± 0.0044 (11) 1.015 (1.01 – 1.025)	1.0150 ± 0.0067 (11) 1.015 (1.005 – 1.025)	1.0205 ± 0.0035 (11) 1.02 (1.015 – 1.025)	1.0186 ± 0.0055 (11) 1.02 (1.01 – 1.025)	d= 9e-04 0.1852*sd p=0.797	d= -0.0045 - 1.2975*sd p=0.013	d= -0.0027- 0.4495*sdp=0.105
120 minutes post-ingestion	1.0159 ± 0.0054 (11) 1.015 (1.01 – 1.025)	1.0150 ± 0.0078 (11) 1.01 (1.005 – 1.03)	1.0191 ± 0.0044 (11) 1.02 (1.01 – 1.025)	1.0182 ± 0.0056 (11) 1.02 (1.01 – 1.025)	d= 9e-04 0.2422*sd p=1.000	d= -0.0032 - 0.9439*sd p=0.018	d= -0.0023- 0.4029*sdp=0.288



Red Diamond = Beyond H2O™; Green Triangle = Mineral; Black Circle = Tap; Blue Square = Distilled

Table 3. Post-Ingestion Rate of Change for Urine Specific Gravity

Subject	Beyond H2O™(Product C)	Mineral (Product D)	Tap (Product A)	Distilled (Product B)
1	0.0000	0.0000	0.0020	0.0000
2	0.0000	0.0020	-0.0020	0.0000
3	0.0000	0.0050	-0.0030	-0.0030
4	-0.0010	-0.0020	0.0000	-0.0030
5	0.0020	0.0000	0.0030	-0.0020
6	-0.0060	-0.0050	-0.0020	0.0000
7	-0.0050	-0.0070	-0.0030	0.0000
8	-0.0020	-0.0040	-0.0020	0.0050
9	-0.0010	0.0020	0.0030	-0.0030
10	-0.0020	-0.0060	-0.0010	-0.0020
12	0.0000	0.0010	0.0000	0.0040
13	-0.0050	-0.0040	-0.0020	0.0000
Mean Slope	**-0.002**	**-0.002**	**-0.001**	**0.000**
Within-Group p-value	0.013	0.182	0.563	0.505

p-value vs. Beyond H2O™		0.502	0.030	0.124

Mean Slope is the average rate of change in urine specific gravity, per hour.
The Within-Group p-value tells whether there is a significant rate of change over the 2-hour post-ingestion period. The last row indicates whether any of the other three water products had a significantly different average rate of change compared to Beyond H2O™.

Interpretation of Urine Specific Gravity Data

Urine specific gravity is a surrogate marker for hydration. An increase in urine specific gravity indicates an increase in the concentration of the urine. More concentrated urine is made in response to dehydration.

When examining urine specific gravity over time, ***at the 60 minute time point there was a statistically significant difference between Beyond H2O™ brand water and tap water, this difference remained significant at the 90 and 120 minute time points.***

In examining the rate of change for this test parameter, ***a statistically significant difference was noted between Beyond H2O™ brand water and tap water.***

In order to evaluate the data points relative to physiologic ranges, the statistically significant urine specific gravity values at 60 minutes and 120 minutes for Beyond H2O™ brand water and tap water were compared to clinical normal range values.

The absolute difference between Beyond H2O™ brand water and tap water was divided by the magnitude of the outer values of the normal range to determine the percentage of the normal range by which the test values differed.

Example:

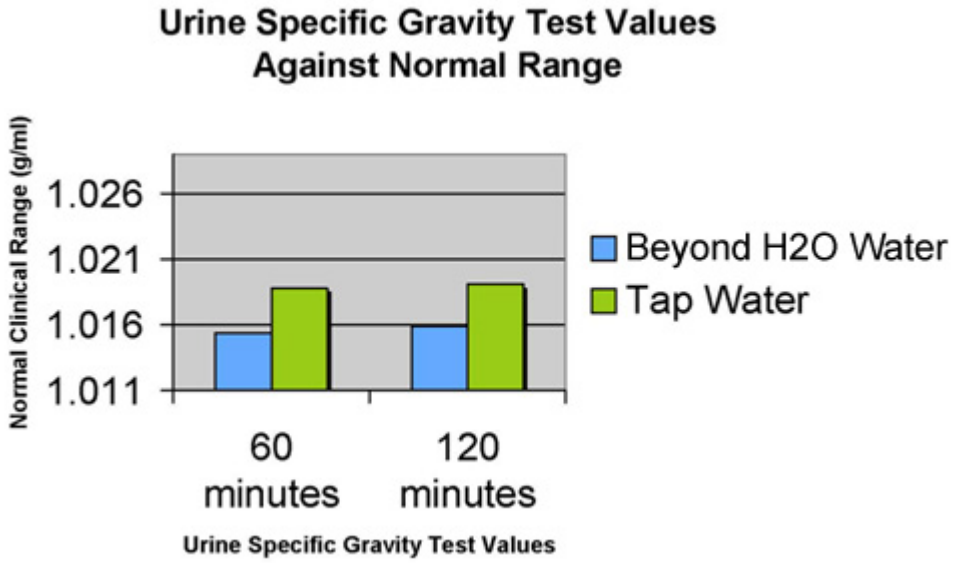
Normal range for urine specific gravity: 1.0110-01.029 g/ml (source: average of 4 different clinical laboratory values)
Magnitude of Range = 0.019

At 60 minutes:

Difference = (1.0188 – 1.0154) = .0035
(.0035/.019) X 100 = **18.4%**

At 120 minutes

Difference = (1.0191 – 1.0159) = .0032
(.0035/.019) X 100 = **16.8%**



Beyond H2O™ brand water resulted in a lower Urine Specific Gravity than tap water by 18.4% of the normal range at 60 minutes and 16.8% of the normal range at 120 minutes.

Marketing Statement B

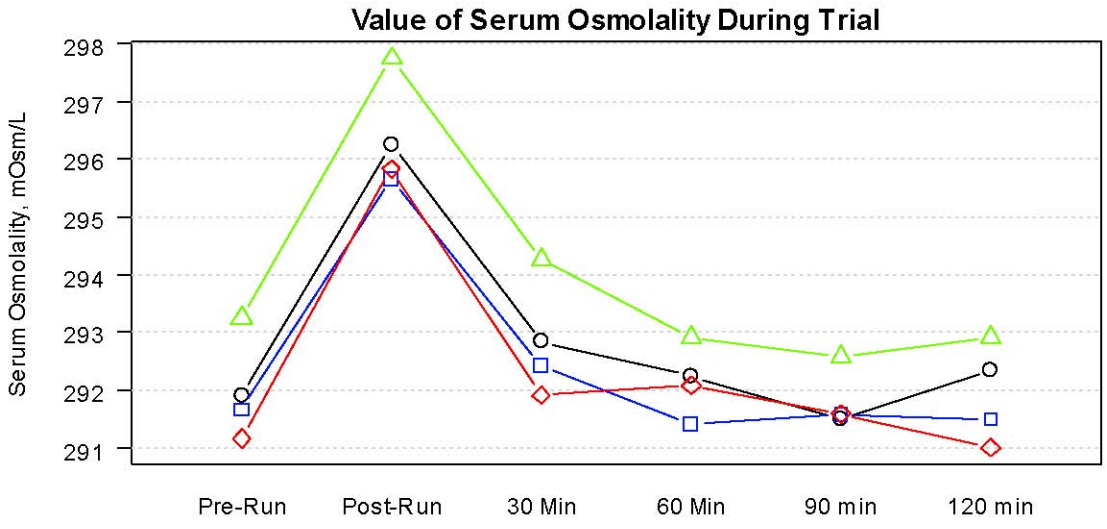
- In the same study, *Beyond H2O™ brand water had a greater and statistically significant effect on rehydration compared to mineral water* within 30 minutes and at 2 hours after exercise.

Serum Osmolality

Table 4. Serum Osmolality Over Time

	Type of Water				p-value vs. Beyond H2O™		
Time Point	**Beyond H2O™ (Product C)**	**Mineral (Product D)**	**Tap (Product A)**	**Distilled (Product B)**	**Min**	**Tap**	**Dist**
Pre-exercise (Baseline)	291.2 ± 2.6 (12) 291.5 (287 – 295)	293.3 ± 5.0 (12)292.5 (287 – 301)	291.9 ± 5.4 (12) 290 (285 – 304)	291.7 ± 5.2 (12)290.5 (285 – 305)	d= -2.1 -0.5*sd p=0.167	d= -0.8 -0.1*sd p=0.503	d= -0.5-0.1*sdp=0.878
Post-exercise Pre-ingestion	295.8 ± 2.3 (12) 296 (292 – 300)	297.8 ± 3.0 (12)297.5 (292 –	296.3 ± 3.7 (12) 296 (290 – 302)	295.7 ± 4.2 (12)295.5 (289 –	d= -1.9 -0.6*sd p=0.068	d= -0.4 -0.1*sd p=0.711	d= 0.20*sd p=0.900

		302)		303)			
30 minutes post-ingestion	291.9 ± 2.1 (12) 292 (288 – 296)	294.3 ± 3.3 (12)294 (289 – 300)	292.8 ± 4.0 (12) 293 (287 – 299)	292.4 ± 4.1 (12)292 (286 – 299)	d= -2.3 -0.8*sd p=0.022	d= -0.9 -0.2*sd p=0.471	d= -0.5-0.1*sdp=0.671
60 minutes post-ingestion	292.1 ± 2.2 (12) 291.5 (290 – 296)	292.9 ± 2.7 (12)292.5 (289 – 299)	292.3 ± 4.3 (12) 292 (287 – 300)	291.4 ± 4.1 (12)291 (285 – 301)	d= -0.8 -0.3*sd p=0.276	d= -0.2 0*sd p=0.894	d= 0.70.1*sdp=0.642
90 minutes post-ingestion	291.6 ± 2.6 (12) 291.5 (287 – 296)	292.6 ± 2.8 (12)292 (289 – 298)	291.5 ± 4.4 (12) 291 (285 – 299)	291.6 ± 3.3 (12)292 (285 – 298)	d= -1 - 0.2*sd p=0.434	d= 0.1 0*sd p=0.947	d= 0 0*sd p=1.000
120 minutes post-ingestion	291.0 ± 2.0 (12) 292 (287 – 293)	292.9 ± 2.9 (12)293 (287 – 298)	292.3 ± 4.3 (12) 292 (287 – 299)	291.5 ± 3.8 (12)290.5 (286 – 299)	d= -1.9 -0.8*sd p=0.024	d= -1.3 -0.4*sd p=0.239	d= -0.5-0.1*sdp=0.721



Red Diamond = Beyond H2O™; **Green Triangle = Mineral;** **Black Circle = Tap;** **Blue Square = Distilled**

Interpretation of Serum Osmolality Data

Serum osmolality is a marker for hydration. The higher the values the more concentrated the serum, indicating greater dehydration.

At the 30 and 120 minute time points there was a statistically significant difference between Beyond H2O™ brand water and the mineral water, showing significant improvement in hydration with Beyond H2O™ brand water compared to the mineral water at both time points.

In order to evaluate the data points relative to physiologic ranges, the statistically significant serum osmolality values at 30 minutes and 120 minutes for Beyond H2O™ brand water and mineral water were compared to clinical normal range values.

The absolute difference between Beyond H2O™ brand water and mineral water was divided by the magnitude of the outer values of the normal range to determine the percentage of the normal range by which the test values differed.

Example:

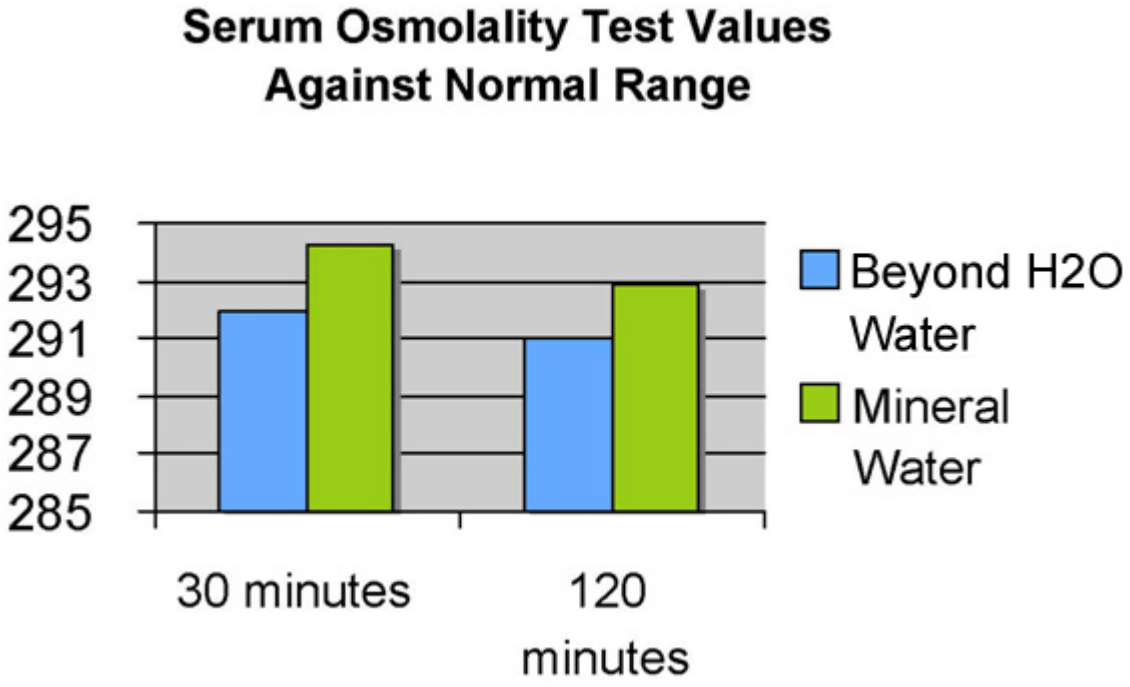
Normal range for serum osmolality: 285 -295 mOsm/L (source: med.cornell.edu)
Magnitude of Range = 10 mOsm/L

At 30 minutes:

Difference = (294.3 – 291.9) = 2.4
(2.4/10) X 100 = **24%**

At 120 minutes

Difference = (292.9– 291.0) = 1.9
(1.9/10) X 100 = **19%**



Beyond H2O™ water resulted in a lower serum osmolality than mineral water by 24% of the normal range (mOsm/L) at 30 minutes and 19% of the normal range at 120 minutes.

Efficacy Conclusions (including only data pertaining to key marketing statements)

- The exercise and environmental controls induced the desired effect – statistically significant reduction in body weight and a minimum of two-percent dehydration.

- Serum osmolality was statistically significantly different between Beyond H2O™ brand water and mineral water at the 30 and 120 minute time points.

- There was a statistically significant difference between Beyond H2O™ brand water and tap water for rate of change in the objective of urine specific gravity and at the 60, 90 and 120 minute time points.

- In summary, there were observed differences which were statistically significant as related to the primary outcomes of plasma and serum osmolality and hematocrit between Beyond H2O™ brand water and mineral water at several time points over the two-hour post-exercise time period. In addition, there was a statistically significant difference between Beyond H2O™ brand water and tap water for rate of change in the secondary objective of urine specific gravity.

- **Of the primary objectives (plasma/serum osmolality, hematocrit, and body weight), a *pattern of Beyond H2O™ brand water being superior to mineral water* emerged though not at each time point measured. Beyond H2O™ brand water *was superior to tap water* with respect to the rate of change for urine specific gravity, and at 60, 90 and 120 minutes.**

- To date we are not aware of any other bottled water brand that has done the research to back any claims that they may currently make about their product with statistically significant data. Beyond H2O™ brand water stands alone as a leader in clinical water research in an effort to bring you an ultra hydrating bottled water product.

Beverage Industry Marketing Research: Growth of the Bottled Water Sector

Historically, marketing research analysts have been bullish on the beverage industry in general. However, that perspective is becoming more specific and is changing. The most current statistics and projections show the bottled water category continuing to gain ground, while other beverages will begin to lose market share. More specifically, the category of "Added Value" water, where there is something more to sell the customer than just plain water (water with research testing behind it, for example), will see monumental growth.

In the U.S. Liquid Refreshment Beverage Market, Share of Volume by Category, Carbonated Soft Drinks both diet and non-diet show a projected decline from 2005 to 2010, bottled water by share volume is projected as the biggest individual growth category predicted to grow from 21.7% of market share in 2005 to 28.5% of market share in 2010.

U.S. LIQUID REFRESHMENT BEVERAGE MARKET
SHARE OF VOLUME BY CATEGORY
1995 – 2010(P)

Categories	**1995**	**2000**	**2005(E)**	**2010(P)**
Diet CSDs	13.2%	12.3%	13.5%	13.4%
Full-Calorie CSDs	35.1%	35.1%	29.8%	24.7%
CSDs	48.3%	47.5%	43.3%	38.1%
Bottled Water	**11.6%**	**15.5%**	**21.7%**	**28.5%**
Fluid Milk	22.8%	20.0%	17.8%	15.9%
Fruit Beverages*	14.4%	13.2%	11.8%	10.8%
Sports Beverages	1.6%	2.1%	3.3%	4.3%
RTD Tea	1.4%	1.6%	1.6%	1.6%
Energy Drinks	--	0.0%	0.4%	0.7%
RTD Coffee	0.0%	0.1%	0.1%	0.1%
Total LRB	**100.0%**	**100.0%**	**100.0%**	**100.0%**

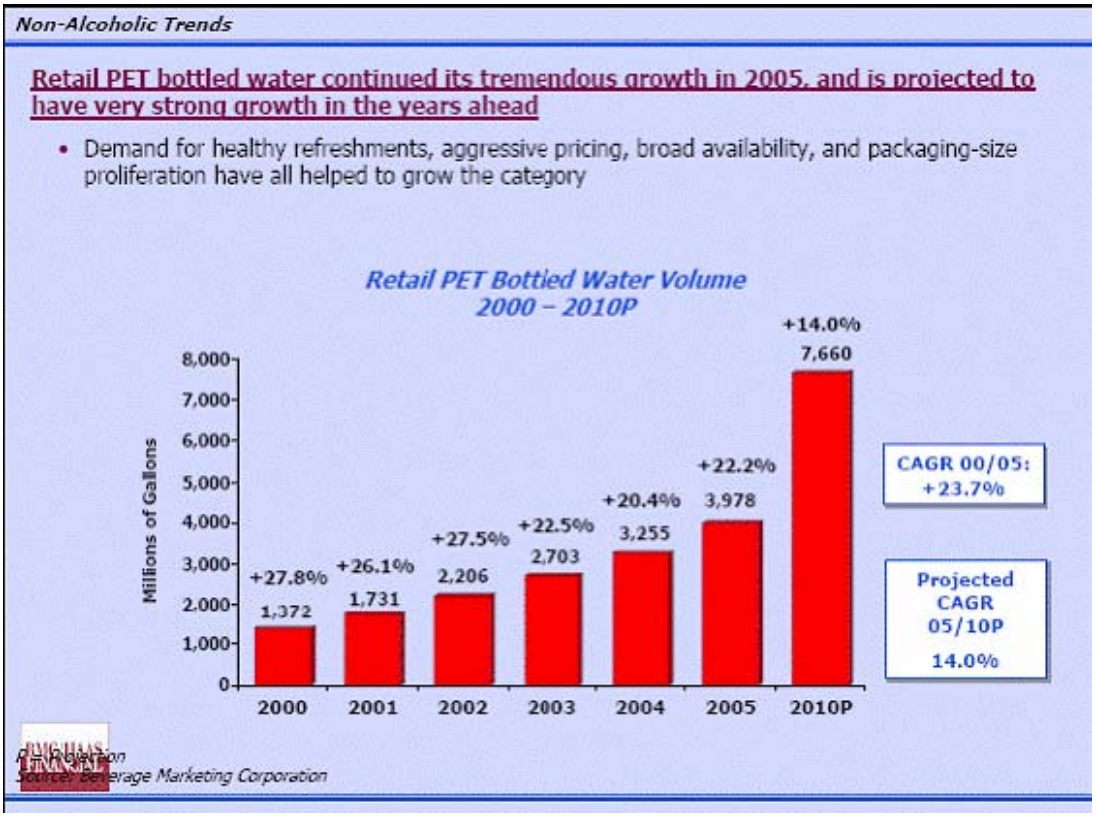
(E) Estimated; (P) Projected

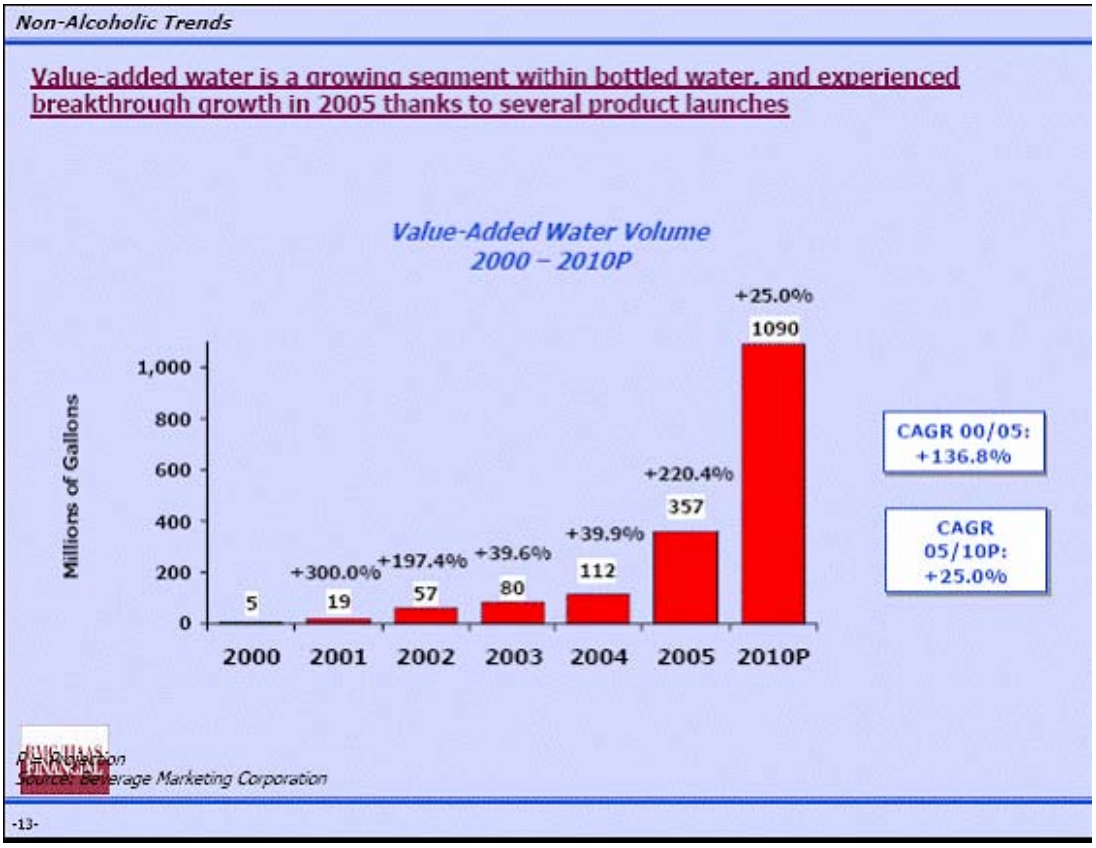
* Includes liquid fruit juice and fruit drinks; excludes powdered fruit drinks and vegetable juices.

Source: Beverage Marketing Corporation; Adams Business Media; Distilled Spirits Council of the U.S.; Florida Department of Citrus; International Dairy Foods Association; U.S. Tea Association

• Beverage Marketing Corporation bottled water and beverage industry analysts, project a continuing and very healthy and significant 14% compounded annual growth for years 2005-2010.

• Beyond H2O™ brand water can be classified in the “Added Value” segment of the bottled water category where Beverage Marketing Corporation bottled water and beverage industry analyst project growth in volume for that segment at a 25% compounded annual increase in years 2005 to 2010.





As scientists and health practitioners work to find solutions to the obesity epidemic, they are turning to water as an important aid for decreasing calories in the diet. In the published opinion of the Expert Panel on a Beverage Consumption Guidance System, ***"water could be used to fulfill almost all the fluid needs of healthy individuals." (29)***

Much of this projected growth in bottled water demand may be attributed to a growing belief in the scientific community that water is the most preferred beverage for weight loss and better health.

FINAL CONCLUSIONS

Nearly one-third of the population is chronically, mildly dehydrated. Chronic mild dehydration results in impaired physiologic responses and diminished mental and physical performance. Research indicates that fluid consumption in general and water consumption in particular can have an effect on the risk of urinary stone disease; cancers of the breast, colon, and urinary tract; fatal coronary artery disease; obesity; and mitral valve prolapse. Current guidelines from the scientific community recommend an increase in water consumption as a method of decreasing overall calorie intake to help combat the obesity epidemic.

The current research study demonstrates that Beyond H2O™ water brand can support the marketing claim that it is an "ultra hydrator". Under the conditions of exercise-induced mild dehydration, **Beyond H2O™ brand water *demonstrated statistical significance and meaningfully outperformed tap water in rehydrating*** after exercise, and sustained a significantly faster rate of rehydration 2 hours after exercise. **Beyond H2O™ brand water *had a greater and statistically significant effect on rehydration compared to mineral water*** within 30 minutes and at 2 hours after exercise.

We are witnessing an important convergence in the marketplace: where the population is known to be chronically, mildly dehydrated; current scientific recommendations are to "drink more water" and the recommendations will only continue to increase in volume, frequency and credibility; and The Beverage Marketing Corporation projects a remarkable rise in market share for bottled waters and the "Added Value" water category.

Based on this promising early stage research, Beyond H2O™ brand water is a scientifically-demonstrated superior rehydrating water product and is perfectly positioned to take advantage of the current and future market demands.

REFERENCES

1. Kristal-Boneh E, Blusman JG, Chaemovitz C, Cassuto Y. Improved thermoregulation caused by forced water intake in human desert dwellers. *Eur J Appl Physiol.*. 1988;57:220-224

2. Brooks G A, Fahey TD. *Exercise Physiology: Human Bioenergetics and its Applications*. New York, NY: John Wiley & Sons 1984

3. Sansevero AC. Dehydration in the elderly: strategies for prevention and management. *Nurse Pract.*. 1997;22:41-42,51-57,63-72.

4. Sagawa S, Miki K, Tajima F, Tanaka H, Choi JK, Keil LC, et al. Effect of dehydration on thirst and drinking during immersion in men. *J Appl Physiol.*. 1992;72:128-134

5. Bergeron MF, Armstrong LE, Maresh CM. Fluid and electrolyte losses during tennis in the heat. *Clin Sports Med.*. 1995;14:23-32

6. Maughan RJ. Fluid balance and exercise. *Int J Sports Med.*. 1992;13(suppl 1):S132-S135

7. Murray R. Fluid needs in hot and cold environments. *Int J Sport Nutr.*. 1995;5(suppl):S62-S73

8. Rintamaki H, Makinen T, Odsa J, Latvala J. Water balance and physical performance in cold. *Arct Med Res.*. 1995;54:32-36

9. Brouns F. Nutritional aspects of health and performance at lowland and altitude. *Int J Sports Med.*. 1992;13(suppl 1):S100-S106

10. Gopinathan PM, Pichan G, Sharma VM. Role of dehydration in heat stress-induced variations in mental performance. *Arch Environ Health.*. 1988;43:15-17

11. Weissman AM. Bottled water use in an immigrant community: a public health issue?. *Am J Public Health.*. 1997;87:1379-1380

12. Meyer F, Bar-Or O, Passe D, Salsberg A. Hypohydration in children during exercise in the heat: effect on thirst, drink preferences and rehydration. *Int J Sport Nutr.*. 1994;4:22-35

13. Food and Nutrition Board. . *Recommended Dietary Allowances*. (10th ed.) Washington, DC: National Academy Press 1989

14. Food and Nutrition Board. . *Recommended Dietary Allowances*. (9th ed.) Washington, DC: National Academy Press 1980

15. Borghi L, Meschi T, Amato F, Briganti A, Novarini A, Giannini A. Urinary volume, water and recurrences in idiopathic calcium nephrolithiasis: a 5-year randomized prospective study. *Urology.*. 1996;155:839-843

16. Curhan GC, Curhan SG. Dietary factors and kidney stone formation. *Comp Ther.*. 1994;20:485-489

17. Goldfarb S. The role of diet in the pathogenesis and therapy of nephrolithiasis. *Endocrinol Metab Clin North Am.*. 1990;19:805-820

18. Hughes J, Norman RW. Diet and calcium stones. *Can Med Assoc J.*. 1992;146:137-

19. Iguchi M, Umekawa T, Ishikawa Y, Katayama Y, Kodama M, Takada M, et al. Clinical effects of prophylactic dietary treatment on renal stones. *J Urology.*. 1990;144:229-232

20. Pin NT, Ling NY, Siang LH. Dehydration from outdoor work and urinary stones in a tropical environment. *Occ Med.*. 1992;42:30-32

21. Embon OM, Rose GA, Rosenbaum T. Chronic dehydration stone disease. *Br J Urology.*. 1990;66:357-362

22. Hiatt RA, Ettinger B, Caan B, Quesenberry Jr. CP, Duncan D, Citron JT. Randomized controlled trial of a low animal protein, high fiber diet in the prevention of recurrent calcium oxalate kidney stones. *Am J Epidemiol.*. 1996;144:25-33

23. Ackermann D. Prophylaxis in idiopathic calcium urolithiasis. *Urologic Res.*. 1990;18(suppl 1):S37-S40

24. Bitterman WA, Farhadian H, Abu S-C, Lerner D, Amoun H, Krapf D, et al. Environmental and nutritional factors significantly associated with cancer of the urinary tract among different ethnic groups. *Urologic Clin North Am.*. 1991;18:501-508

25. Shannon J, White E, Shattuck AL, Potter JD. Relationship of food groups and water intake to colon cancer risk. *Cancer Epidemiol Biomarkers Prev.*. 1996;5:495-502

26. Stookey JD, Belderson PE, Russell JM, Barker ME, J. Shannon et al., Correspondence re: Relationship of food groups and water intake to colon cancer risk. Cancer Epidemiol Biomarkers Prev. 1997;6:657-658

27. Wilkens LR, Kadir MM, Kolonel LN, Nomura AM, Hankin JH. Risk factors for lower urinary tract cancer: the role of total fluid consumption, nitrites and nitrosamines, and selected foods. *Cancer Epidemiol, Biomarkers Prev.*. 1996;5:161-166

28. Lax D, Eicher M, Goldberg SJ. Mild dehydration induces echocardiographic signs of mitral valve prolapse in healthy females with prior normal cardiac findings. *Am Heart J.*. 1992;124:1533-1540

29. Popkin BM, Armstrong, LE, Bray GM, Caballero B, Frei B., Willett WC. A new proposed guidance system for beverage consumption in the United States. Am J Clin Nutr 2006;83:529-42.

30. Burke LM. Fluid balance during team sports. *J Sports Sci.*. 1997;15:287-295

31. Salmon P. Nutrition, cognitive performance, and mental fatigue. *Nutrition.*. 1994;10:427-428

32. Cheung SS, McLellan TM. Influence of hydration status and fluid replacement on heat tolerance while wearing NBC protective clothing. *Eur J Appl Physiol Occupat Physiol.*. 1998;77:139-148

33. Maughan RJ, Shirreffs SM. Recovery from prolonged exercise: restoration of water and electrolyte balance. *J Sports Sci.*. 1997;15:297-303

34. Schliess F, Richter L, vom Dahl S, Haussinger D. Cell hydration and mTOR-dependent signalling. Acta Physiol (Oxf). 2006 May-Jun;187(1-2):223-9.

35. Imbeault P, Chevrier J, Dewailly E, Ayotte P, Despres JP, Tremblay A, Mauriege P. Increase in plasma pollutant levels in response to weight loss in humans is related to in vitro subcutaneous adipocyte basal lipolysis. Int J Obes Relat Metab Disord. 2001 Nov;25(11):1585-91.

36. Kleiner, SM. Water: An Essential But Overlooked Nutrient. J Am Dietet Assoc.1999;99(2):200-206.