Case #4904 (09/03/08)
The FRS Company
FRS Energy
Advertising Agency: Undisclosed
Challenger: National Advertising Division

- **Clinical testing on a product itself is the gold standard for supporting advertising**

- **When an endorser is commonly known to the public as an expert, and is endorsing a product as a celebrity, the advertising must make it clear that he or she is endorsing as a celebrity**

Basis of Inquiry: As a part of its ongoing monitoring program and in conjunction with NAD's initiative with the Council for Responsible Nutrition ("CRN") designed to expand NAD review of advertising claims for dietary supplements, NAD inquired about certain print advertisements disseminated by The FRS Company regarding its dietary supplement FRS Energy products. The advertising, print and Internet, included the following claims:

"Boosts Energy"

"Enhances Metabolism"

"Increases Focus"

"FRS was originally tested and refined by scientific researchers at Harvard University as a fatigue fighting and general health drink. It was then discovered by endurance athletes who found that it boosted and sustained their peak athletic performance while helping to keep them healthy."

"Now FRS is used by anyone who wants a sustained healthy energy boost."

"I need a healthy source of energy with all I have going on, I make it happen with FRS." (expert endorsement by Lance Armstrong).

"strengthens immune system" and ". . . while helping to keep them healthy."[1]

Advertiser's Position: The advertiser explained that the FRS formula was created in 1997 after years of scientific research concerning the pharmacologic effects and health benefits of plant derived antioxidants (flavonoids), vitamins, and other functional food ingredients, both as single ingredients and in combination. The company FRS was formed in 2003, and in the fall of 2004, FRS was introduced to consumers in concentrate form via the internet.[2] Soft chews and drink mix powders were added in 2005 and 2006. Also in 2006, Lance Armstrong agreed to become the exclusive spokesperson for The FRS Company and its products, based on his personal experience and belief in the FRS formula. To meet consumer preferences, the advertiser noted, it

[1] The advertiser represented that these two claims have been permanently discontinued.
[2] In 2003, upon formation, the company name was "New Sun Nutrition." In 2007, the name was changed to The FRS Company.

now offers a full line of FRS products, including ready-to-drink cans, chews, concentrates, and powders, all of which contain quercetin, green tea catechins, and 7 essential vitamins.

Describing its product, the advertiser stated that, FRS, "Free Radical Scavenger," is a patented antioxidant and energizing formula. The key dietary ingredients in FRS are quercetin, an antioxidant found in apple, onion and red grape skins, among other food products, catechins from standardized green tea leaf extract, antioxidant vitamins C and E, vitamin B1 (thiamin), vitamin B2 (riboflavin), vitamin B3 (niacin), vitamin B6, vitamin B12, and caffeine (equal to about ½ cup of coffee), which is a metabolic enhancer. The advertiser stated that FRS is based on the discovery that quercetin, an antioxidant and the key ingredient in the FRS formula, and a number of other antioxidant compounds and nutrients, exhibit synergistic health benefits.

FRS explained that free radicals, or reactive oxygen species ("ROS"), are unstable, unpaired electrons in the body that are produced as by-products of natural biologic and physiologic processes, including, among other processes, ongoing metabolism, electron transport in the mitochondria, cellular respiration (oxidative phosphorylation to produce adenosine triphosphate (ATP)), enzyme function, and physical and emotional stress. Further, stated FRS, strenuous exercise significantly increases oxygen consumption and production of ROS. ROS are also produced by exogenous sources, such as exposure to sun, environmental toxins and pollutants. Free radical damage occurs when these unstable molecules steal electrons from neighboring cells, resulting in cellular damage, oxidative stress and chronic inflammation. The advertiser stated that experts in the field of exercise physiology and sports medicine now believe that the increase in ROS production during strenuous exercise negatively impacts muscle function, causing fatigue. In addition, stated FRS, free radical damage is now implicated in a wide range of degenerative health conditions and chronic diseases.

Indeed, stated FRS, it is well established that ROS cause damage to cells and organelle membranes, including mitochondria, the "engine of the cell" where cellular energy or ATP is produced. Free radical damage reduces the functionality of cells, leading to oxidative stress and inflammation. Scientific experts recognize that, based on the wide body of evidence concerning the effects of free radicals in biological systems, when cellular mitochondria are damaged, such as in disease and inflammatory conditions, there is decreased energy. Free radical production appears to increase at a proportional rate to increased oxygen consumption during exercise. This is approximately 10-20 times baseline levels. Based on known human physiology and the role of free radicals and antioxidants in biological systems, athletes are said to have increased requirements for antioxidants.[3]

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[3] Powers, S. K. and S. L. Lennon. *Analysis of cellular responses to free radicals: focus on exercise and skeletal muscle.* Proceedings of the Nutrition Society. 58(4): 1025-33 (2005)(Muscular exercise results in an increased production of radicals and other forms of reactive oxygen species (ROS). Recent evidence suggests that radicals and other ROS are an underlying aetiology in exercise-induced disturbances in muscle redox status. These exercise-induced redox disturbances in skeletal muscle are postulated to contribute to both muscle fatigue and/or exercise-induced muscle injury. To defend against ROS, muscle cells contain complex cellular defense mechanisms to reduce the risk of oxidative injury. Two major classes (enzymic and nonenzymic) of endogenous protective mechanisms work together to reduce the harmful effects of oxidants in the cell. Primary antioxidant enzymes include superoxide dismutase (EC 1.15.1.1; SOD), GSH peroxidase (EC 1.11.1.9; GPX), and catalase (EC 1.11.1.6); these enzymes are responsible for removing superoxide radicals, H2O2 and organic hydroperoxides, and H2O2

Antioxidants, stated the advertiser, also known as "free radical scavengers," are essential to the body's ability to inactivate and neutralize free radicals, combat ongoing oxidative stress and inflammation, particularly during exercise, and protect cells and tissues from damage. Dietary antioxidants play an important role in supporting the body's protective antioxidant defense system to help maintain overall health and well-being. Quercetin, green tea catechins, and vitamins C & E are ingredients in the FRS formula that are known to have antioxidant activity. The advertiser asserted that the superior antioxidant activity of FRS has been measured and confirmed by a reliable laboratory testing method known as Oxygen Radical Scavenging Capacity ("ORAC").

The FRS Company formed and maintains a scientific advisory board consisting of leaders in the fields of biotechnology, antioxidant science, cellular biology, and nutrition and exercise physiology. Currently, stated FRS, the company's Scientific Advisory Board Member is Marcus Elliott, MD, a 1997 graduate of Harvard Medical School, specializing in training elite athletes for peak performance and injury prevention. Dr. Elliott is actively engaged in advising the company on scientific matters relating to FRS product effectiveness claims. FRS submitted a signed affidavit prepared by Dr. Elliott in support of its arguments.

Scientific Substantiation

"Boosts Energy"

The advertiser maintained that FRS has been shown in a clinical trial to "boost and sustain peak athletic performance" in endurance athletes and "to boost and sustain energy." In a randomized, double-blind, crossover study published in 2006 in the highly-regarded peer-reviewed scientific journal, International Journal of Sport Nutrition and Exercise Metabolism, FRS was shown to boost and sustain peak performance in elite cyclists. Describing the study, conducted by researchers at the Department of Sports Medicine at Pepperdine University, the advertiser stated that the effects of FRS antioxidant supplementation on cycling performance were measured in 11 elite cyclists. Study investigators tested the effects of FRS antioxidant formula with quercetin compared to FRS without quercetin, used twice daily during a six week period. Subjects were instructed to maintain and not modify their usual training, racing, and dietary program. The primary study endpoint was the time to complete a 30 km time-trial (TT). A secondary outcome measure was time to complete the last 5 km of the TT. The TT is sometimes referred to as the "race of truth," as the cyclist attempts to complete the distance in the shortest time possible, without focusing on tactics and pacing. Investigators used the Velotron Pro ergometer, a computer controlled electronic cycle ergometer, with a manufacturer-reported accuracy of +/-

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respectively. Important non-enzymic antioxidants include vitamins E and C, beta-carotene, GSH and ubiquinones. Vitamin E, beta-carotene and ubiquinone are located in lipid regions of the cell, whereas GSH and vitamin C are in aqueous compartments of the cell. Regular endurance training promotes an increase in both total SOD and GPX activity in actively-recruited skeletal muscles. High-intensity exercise training has been shown to be generally superior to low intensity exercise in the upregulation of muscle SOD and GPX activities. Also, training-induced upregulation of antioxidant enzymes is limited to highly-oxidative skeletal muscles. The effects of endurance training on non-enzymic antioxidants remain a relatively uninvestigated area.)

1.5% across the entire load range. Statistical analysis was conducted by an independent entity, Vital Research, Los Angeles, California. Subjects performed TT at baseline and at three and six week intervals. The advertiser asserted that FRS with quercetin users, as compared to the FRS without quercetin group, experienced a statistically significant 3.1% improvement in overall time in the 30 km simulated mountainous TT, demonstrating peak sustained power output. FRS with quercetin users also improved the final 5 km TT performance (2%), compared to baseline. As noted by the study investigators, a 1% improvement in exercise performance during competition in elite athletes is significant. For example, during the men's 2004 Olympic 50 km road TT, the difference between 1st and 9th place was 3%; the difference between 1st and 5th place was 1%. The advertiser argued that the study results demonstrate that FRS boosts and sustains energy and peak athletic performance.[4]

Citing an unpublished paper authored by Dr. Marcus Elliott, MD and Holden MacRae, PhD. *FRS and Athletes* (2005) FRS stated that its formula provides a significant ergogenic effect to athletes via two biological mechanisms. First, maintained the advertiser, as is now recognized among experts in the field of exercise physiology and athletic performance, quercetin boosts and sustains energy and enhances athletic performance by inhibiting the breakdown of an enzyme, catechol-O-methyltransferase (COMT), which naturally extends the body's adrenaline, allowing for a more pronounced catecholamine effect during exercise, extending adrenaline and directly increasing heart rate, triggering the release of glucose from energy stores, and increasing skeletal muscle readiness. Second, the advertiser stated, FRS is believed to enhance performance through its free radical scavenging role, as oxidative stress is known to contribute to muscle fatigue and a reduction in muscle force generating capacity.

In addition, argued the advertiser, FRS has been shown to inhibit phosphodiesterase-5 A (PDE 5A), in vitro. This mechanism is believed to be associated with both the energy producing and thermogenic effects of FRS (discussed below).[5]

The advertiser maintained that the sustained energy-producing effect of quercetin, the key dietary ingredient in the FRS formula, is attributable to its long half-life in the blood. The half-life of a substance is the time required for the body to eliminate one-half of the total amount of the substance consumed at a given time and, as demonstrated in scientific studies, quercetin is known to have a long half-life in human plasma, conservatively, approximately 16 hours. However, experts recognize that the half-life of quercetin may be even higher, about 18 – 20 hours.[6]

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[4] See, *Dietary Antioxidant Supplementation Combined with Quercetin Improves Cycling Time Trial Performance,* Intl J. Sport Nutr and Exerc Metab., MacRae, HS., Mefferd KM. *2006, 16, 405-419,* Dept. of Sports Medicine, Pepperdine University, Malibu, CA 90263.

[5] The advertiser submitted an unpublished study, FRS 1000, "An extract of red onion peel, strongly inhibits phosphodiesterase 5A (PDE)."

[6] Citing a submitted study, "*Bioavailabilities of Quercetin-3-Glucoside and Quercetin-4'-Glucoside Do Not Differ in Humans,* J. of Nutr. (Jan. 2000), presented at the XIX International Conference on Polyphenols, Lille, France, (Sept. 1998).

The advertiser further maintained that in another clinical trial, FRS with quercetin was shown to improve energy and reduce fatigue among non-athletes in a university industrial work setting. In a randomized, cross-over study, researchers at the University of Santa Barbara measured the effects of FRS supplementation over a six week period (48 days), in 33 university employees, aged 29 to 63 years, working in an industrial setting (e.g., grounds keepers, custodians and skilled trades). Participants completed a Work Productivity Assessment Index, modified to apply to an industrial setting, and were questioned in specific areas of fatigue, mental alertness and concentration. Subjects who used FRS with quercetin had statistically significant improvements in a number of areas, particularly those relating to energy and sustained energy as follows: in their ability to handle job tasks (work performance) (+ 11%, p=0.10); in reduced fatigue levels (45.5%, p=0.002); and in increased levels of concentration (24% improvement, p=0.002).[7]

In addition, FRS asserted that the effects of a six-week nutrition drink program were measured in 33 university employees who work in an occupational setting (e.g. grounds keepers, custodians and skilled trades). Staff work at various shifts during a 24-hour work period, and perform many jobs that require physical exertion, lifting, repetitive movements, and attention to detail. Specific areas of fatigue, mental alertness, and concentration were measured with a WPAI Questionnaire modified to apply to an industrial setting. Participants were chosen from the volunteers at the job site and randomly assigned to an energy drink containing quercetin (A), or non-quercetin (B), and midway through the program, changed cans in a crossover design. The program consisted of consuming two 8.4 fluid ounce cans of FRS energy drink daily for three (3) weeks per drink mixture. Participants filled out the WPAI survey pre, mid and post study regarding eating habits, work habits, and physical and mental demands of their work.

Results indicated improvements in two areas of the WPAI survey: In physical work demands. Group A had improvements in work performance (handle job task – 11%, p=0.10), work frustration (35.6%, p = 0.08), fatigue status (45.5%, p=0.002), and concentration (24%, p=0.02). Group B had improvements in phase II of the program using quercetin in areas of schedule demands, (4.6%, p=0.08), and concentration (10.3%, p=0.02). Both groups collectively had improvements in both work performance and quality of life indices, including a 30% improvement in overall fatigue status (p=0.004), and levels of concentration (17.1%, p<0.001).

FRS maintained that these results indicate that in the industrial work setting, FRS with quercetin, as compared to FRS without quercetin, improves work performance and quality of life aspects necessary to complete jobs on time and reduce chances of injury or illness during work efforts. Green tea catechins, another key ingredient in the FRS formula, are also known to inhibit COMT, which, as discussed above, is linked to extending the body's natural adrenaline to boost energy, as well as promoting thermogenesis. The advertiser noted that green tea extract has been shown to improve running endurance in an animal model, prolonging swimming times to exhaustion of mice in a current water pool.[8]

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[7] Citing an unpublished study submitted by the advertiser, *The Effects of an Antioxidant Nutrition Drink on Work Performance and Health Parameters in an Industrial Setting.* Eric Durak, MSc., Mica Bell, BS, Medical Health and Fitness, Santa Barbara, CA.

[8] T. Murase, S. Haramizu, et al. *Green Tea Extract improves running endurance in mice by stimulating lipid utilization during exercise.* Am J Physiol Regul Integr Comp Physiol. 290: R1550-R1556, 2006.

Enhances Metabolism

The advertiser maintained that FRS "enhances metabolism" because of green tea catechins, caffeine and quercetin. FRS contains "catechins" from standardized green tea extract, in labeled amounts per serving ranging from "50 mg" to "85 mg" depending upon the FRS product formula and, catechins from green tea extract, stated the advertiser, have been shown in scientific studies to promote thermogenesis, which is known to increase metabolic rate, thereby "enhancing metabolism." Thermogenesis is the process by which the body generates heat, or energy, by increasing the metabolic rate above normal. It should be recognized that thermogenesis may be activated by several different mechanisms, including dietary supplements, nutrition, exercise and exposure to cold.

There are two mechanisms by which green tea extracts are known to promote thermogenesis; the first is due to caffeine content. The second, and of greater significance, however, is the effect of green tea catechins on COMT. FRS stated that catechin polyphenols naturally present in green tea are known to inhibit COMT, the enzyme that degrades norepinephrine (NE). By inhibiting COMT, the effect of NE on thermogenesis is prolonged. Also, the advertiser added that quercetin is also known to inhibit COMT, as discussed above. Thermogenesis is modulated by hormones, enzymes and cofactors of the sympathetic nervous system, especially NE and NE has the ability to control biochemical pathways that lead to an increased rate of mitochrondrial oxidation and an increase in heat production. NE is released into nerve synapses and its activity is controlled by feedback systems involving a phosphodiesterase enzyme system (cyclic adenosine monophosphate (cAMP) as a cofactor), as well as enzymatic degradation by catechol-O-methyltransferase (COMT). The inhibition of COMT results in a prolonged effect of NE on the alpha and beta-adrenergic receptors, which increases cAMP concentration and thermogenesis.[9]

In addition, stated the advertiser, the effects of green tea catechins in increasing energy expenditure in humans is also recognized. In one randomized, double blind study, subjects consuming a green tea extract containing 90 mg of EGCG, combined with 50 mg of caffeine, experienced a 4% increase in 24-hour energy expenditure, reflecting a stimulatory effect on thermogenesis. This clinical trial also tested the use of 50 mg of caffeine (without green tea catechins), which failed to alter energy expenditure, with an amount of caffeine equivalent to that in the caffeine/EGCG extract combination. In short, and as summarized by the review authors, the advertiser maintained that both experimental and clinical data demonstrate that green tea extract, rich in catechins and caffeine, is an effective potentiator of sympathetically mediated thermogenesis. The advertiser also maintained that, even though the amounts of green tea catechins and caffeine used in various studies in the publically available scientific literature are not absolutely identical to those in the FRS Products, the studies are scientifically relevant to the FRS products, (containing meaningful, effective amounts of green tea catechins and quercetin),

[9] Shixian, et al. 2006, Green Tea Extract Thermogenesis-Induced Weight Loss by Epigallocatchein Gallate Inhibition of Catechol-O-Methyltransferase.

in demonstrating the known thermogenesis-stimulating effects of these compounds, which, by definition, "enhance metabolism."[10]

Reports have shown that green tea extract intake is associated with increased weight loss due to diet-induced thermogenesis, which is generally attributed to the catechin epigallocatechin gallate. That catechin-polyphenols are known to be capable of inhibiting catechol-O-methyltransferase (the enzyme that degrades norepinephrine) is a possible explanation for why the green tea extract is effective in stimulating thermogenesis by epigallocatechin gallate to augment and prolong sympathetic stimulation of thermogenesis. Knowledge about thermogenesis-induced weight loss produced by green tea's epigallocatechin gallate and its ability to inhibit catechol-O-methyltransferase is important for health benefits and for prolonging the action of norepinephrine in the synaptic cleft. [11]

Caffeine and green tea, among other dietary compounds, have been proposed as strategies for weight loss and weight maintenance, since they may increase energy expenditure and may counteract the decrease in metabolic rate that is present during weight loss. Green tea, which contains both tea catechins and caffeine, may act through inhibition of catechol O-methyl-transferase, and inhibition of phosphodiesterase. Here, the advertiser argued, mechanisms are believed to operate synergistically.

As previously discussed, quercetin is known to inhibit COMT, which is scientifically accepted as a mechanism for promoting thermogenesis, thereby increasing metabolic rate or enhancing metabolism. Both quercetin and the FRS formula have been shown to inhibit cAMP phosphodiesterase and quercetin has also been shown to increase lipolysis in the adipocytes, with a synergistic effect when combined with epinephrine.[12]

Addressing NAD's concerns about the amount of catechins in the product versus the amount of those included in the studies, the advertiser maintained that FRS contains "catechins" from green tea extract in labeled amounts per serving ranging from "50 mg" to "85 mg" depending upon the FRS product formula. In addition, FRS contains between "35 mg" to "48 mg" of "caffeine" per serving, based on the specific FRS formulation. The amount of "quercetin" in the FRS concentrate is "250 mg" per serving, while each ready-to-drink can contains "325 mg" of "quercetin."

The advertiser stated that, while The FRS Company recognizes that studies conducted on EGCG, the most widely studied of the green tea catechins, and caffeine have generally used amounts somewhat higher than those contained in FRS, it believes that many of these studies are nonetheless scientifically relevant to FRS Products containing these ingredients. The advertiser

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[10] Q. Shixian, B. VanCrey, et al. *Green Tea Extract Thermogenesis-Induced Weight Loss by Epigallocatechin Gallate Inhibition of Catechol-O-Methyltransferase.* J. Med Food. 9 (4) 2006; 451-458.

[11] K. Diepvens, K. Westerterp and M. Westerterp-Plantenga. *Obesity and thermogenesis related to the consumption of caffeine, ephedrine, capsaicin, and green tea.* Am J Physiol Regul Integr Comp Physiol. 292:R77-R85 (2007).

[12] U.R. Kippusamy & N.P. Das, *Effects of Flavonoids on Cyclic AMP Phosphodiesterase and Lipid Mobilization in Rat Adipocytes,* Biochem Pharm. 77:7; 1307-1315 (1992).

also noted that no "threshold" level of activity has been established in the scientific literature concerning these ingredients, that is, precise levels that would be considered not effective.

In addition, stated FRS, "caffeine" alone has been shown to increase or enhance metabolic rate.[13] Caffeine and EGCG are thermogenic agents known to increase metabolic rate, but by different mechanisms. Caffeine is thought to act by inhibiting the phosphodiesterase-induced degradation of intracellular cAMP. Green tea contains polyphenolic catechins, of which epigallocatechin (EGCG) is the most pharmacologically active. The catechins in green tea stimulate thermogenesis through inhibition of COMT. Caffeine and green tea catechins, when combined, are believed to have an additive effect on thermogenesis as they work through different mechanisms (Diepvens et al, 2007).

In addition to green tea catechins and caffeine, FRS also contains a significant amount of quercetin (250 mg or 325 mg), which has been shown to be effective in boosting and sustaining performance and energy. As discussed previously, in the cyclists study, the "active" test product was FRS with quercetin, while the "control" product was FRS without quercetin. The FRS Company's position is that the results in the cyclists study demonstrate that quercetin is an "active" ingredient in the FRS Products, present in meaningful amounts. Further, as discussed by study investigators, referencing other data, time trial performance is believed to be associated with quercetin's inhibition of COMT. Moreover, again as previously discussed, quercetin has also been shown to inhibit cAMPphosphodiesterase, the mechanism by which caffeine acts as a thermogenic agent. Based on the known biological activity of quercetin, it would thus be expected that quercetin would add to the activity of both caffeine and EGCG in promoting thermogenesis, or enhancing metabolism, producing an "additive effect."

The advertiser explained that "metabolism" is the term for the coordinated process of chemical change that occurs in the body through thousands of chemical reactions. Metabolism creates a release of chemical energy through the breakdown of organic compounds. This chemical energy can be transformed into body heat, used for chemical energy in the body or stored for future use. About 60% of the energy released during metabolism is released as heat. This process of the generation of heat through the breakdown of fats, carbohydrates and proteins is called "thermogenesis." The metabolic rate is the total energy expenditure over time. The metabolic rate is lowest when sleeping. It increases following eating and with exercise. For this reason, the basal metabolic rate (BMR) is measured when a subject has not eaten for at least 12 hours and is at mental and physical rest in a room at a comfortable temperature. As an example, a 70 Kg man at rest might have a metabolism of 77 Kcal/hour. That rate will increase to 200 Kcal/hour while walking and 570 Kcal/hour while jogging.

The metabolic rate is influenced by the size, age and sex of a person. In addition, hormones affect the metabolic rate, with thyroid hormones being the most important determinant of the BMR. The adrenal glands (adrenal medulla) also release hormones that affect the metabolic rate.

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[13] Researchers demonstrated this effect in amounts equivalent to about 2 or 3 cups of coffee. Acheson, KJ, et al. *Caffeine and coffee: their influence on metabolic rate and substrate utilization in normal weight and obese individuals.* Am J Clin Nutr. 1980
May;(33): 989-997.

The adrenal glands secrete hormones known as catecholamines that help the body prepare for "fight or flight." These hormones include adrenaline (also known as epinephrine) and noradrenaline (norepinephrine), which increase the metabolic rate.

Adrenaline is principally secreted by the adrenal gland and acts as a hormone. Nor-adrenaline is secreted by the adrenal gland in lesser amounts than adrenaline and is also secreted by nerves in the sympathetic nervous system. Nor-adrenaline has the ability to control biochemical pathways that can lead to an increased rate of mitochondrial oxidation and an increase in heat production.

The activity of nor-adrenaline is controlled by feedback systems that can either increase or decrease its presence in the nerve endings (nerve synapse). Inhibition of phosphodiesterase (with cyclic adenosine monophosphate (cAMP) as a cofactor) or catechol-O-methyltransferase (COMT) will result in prolonging the presence of nor-adrenaline in the synapse and increasing thermogenesis (Shixian et al, 2006).

In sum, the advertiser stated, FRS contains ingredients that affect the metabolic rate, namely, "caffeine," "green tea catechins" and "quercetin." The scientific information in the record provides a reasonable basis of support for the claim that FRS products "enhance metabolism."

Increases Focus

In support of its claims that FRS increase focus, the advertiser maintained that FRS has been shown in clinical studies to "increase focus." As discussed above in the Durak study on workers in an industrial setting, FRS with quercetin users had improvements in work performance (handle job task – 11%, p=0.10), and particularly in concentration, (24%, p=0.02), which supports the claim that FRS "increases focus."[14] In another clinical trial, investigators assessed the efficacy of FRS with respect to brain and cognitive functions, demonstrating positive results in cognitive performance, including "increased focus." In a 6 week, randomized, double-blind clinical trial, investigators at the University of California, Irvine measured the effects of FRS with quercetin as compared to orange juice. Per the study protocol, the study was designed to measure the effects of FRS in a healthy sample of 20 young and 20 elderly subjects. However, investigators enrolled and randomized 25 subjects, and completed the study on 21 subjects. Of the 21 subjects that completed the study, 17 were in the younger age group (mean age = 25 +/- 4.3) and 3 were in the elderly group (mean age = 75 +/- 6.2).[15] Efficacy measures included comprehensive neurocognitive evaluations conducted on the Computerized Multiphasic Interactive Neurocognitive Diagnostics System (CIMINDS®) (a test developed in collaboration with the National Institutes of Health), Neurocognitive assessment, using procedures such as those employed in the study are regarded as meritorious in investigating the usefulness of products intended to affect cognitive function, including memory, executive functions, (planning; foresight), attention, language and motor coordination. Study investigators also recorded subject electrical brain activity via electroencephalogram (EEG). The results

[14] *The Effects of an Antioxidant Nutrition Drink on Work Performance and Health Parameters in an Industrial Setting.* Eric Durak, MSc., Mica Bell, BS, Medical Health and Fitness, Santa Barbara, CA.

[15] The results of the study reflects data on the younger subjects, as the elderly group was too small to analyze statistically.

demonstrated that subjects receiving FRS had significantly greater improvement (F=6.26; p+0.026) in executive cognitive functions, including "increased focus."[16] Lastly, the advertiser added that it is well known that the B vitamins are essential for positive mood, cognitive function and support energy production in the body and FRS contains 100% or more of the Recommended Daily Intake of Vitamins B1, B2, B3, B6, and B12.

The FRS Company maintains that in these two product specific clinical studies, FRS with quercetin was found to produce statistically significant results with respect to increases in focus and concentration, based on an adequate number of subjects tested over an adequate time period, and therefore, provide a reasonable basis of substantiation for the "increases focus" advertising claim.[17]

Lastly, the advertiser pointed out that caffeine increases key aspects of cognitive functions related to alertness. Caffeine enhances self-rated moods such as vigor, efficiency and how energetic and clearheaded people report that they feel. These effects have been documented by a number of laboratories to occur with amounts as low as 32 mg of caffeine. As indicated, a serving of FRS contains between 35 to 48 mg of caffeine.[18]

In addition, behavioral studies with caffeine indicate that it helps to improve the efficiency of information processing. Measurement of brains waves with EEG support the general belief that caffeine acts as a mental stimulant. Studies using event-related brain potentials (ERP) measures indicate that caffeine has an effect on attention.[19] Mechanism studies indicate that caffeine acts by blocking adenosine receptors and this action can occur at concentrations achieved after intake of a single cup of coffee.

"FRS Refinement by Scientific Researchers at Harvard University"

The advertiser provided a statement prepared by Dr. Mitsunori Ono, PhD., one of the researchers involved in the early testing of the FRS formula, in support of this statement.

"[n]ow FRS is used by anyone who wants a sustained healthy energy boost."

The advertiser maintained that it is indisputable that the FRS Products may be described as "healthy," based not only on the ingredients in the products, but also on what they do not contain. The FRS Products contain no ingredients known to present a public health problem such as "saturated fat," "cholesterol," or "sodium."

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[16] See, Efficacy of FRS 1000-D in Cognitive and Brain Activity Measures, report of study investigator, Dr. Yi Jin, University of California at Irvine, May 30, 2006.
[17] The advertiser added that, while these studies have not yet been published, as NAD is aware, the FTC does not require studies to be published in order that they are considered as competent and reliable scientific evidence. See, FTC, Dietary Supplements: An Advertising Guide for Industry (1998), at p. 12.
[18] See, Lieberman HR. *The effects of ginseng, ephedrine, and caffeine on cognitive performance, mood and energy.* Nutr Rev. 2001 Apr; 59(4):91-102.
[19] See, Lorist MM, Tops M. *Caffeine, fatigue, and cognition*. Brain Cogn. 2003 Oct;53(1):82-94,

As indicated, FRS is an antioxidant formula with superior free radical scavenging capacity. FRS has been tested and analyzed for its Oxygen Radical Absorbance Capacity (ORAC) value by Brunswick Laboratories, Norton, Massachusetts, the leader in antioxidant testing and developer of the method now used by the United States Department of Agriculture (USDA). The ORAC assay was developed to provide a versatile, reliable, and standardized way of measuring antioxidants in foods and other substances. Brunswick Laboratories is the leading commercial provider of ORAC testing, and its test results are widely recognized in the U.S. and internationally as an authoritative source of antioxidant values. A can of FRS Wild Berry measured 10,659 ORAC units. By comparison, the total antioxidant capacity (ORAC) of 6 servings of fruits (a banana, an average apple, an orange, one serving each of watermelon, cantaloupe and green grapes) is approximately 10,566 ORAC units, based on data for fruits derived from the USDA nutrient database. A copy of the Brunswick ORAC report was submitted in support.

Lance Armstrong Endorsement

The advertiser represented that Lance Armstrong is a celebrity endorser of the FRS Products. A letter confirming such endorsement, signed by Lance Armstrong, was submitted in support.

Addressing NAD's concern that although Lance Armstrong is a celebrity, he might also be viewed by consumers as an expert, the advertiser stated that the FRS Company's position is that Lance Armstrong is a celebrity endorser, not an expert endorser of the FRS Products. Lance Armstrong's endorsement is not as a professional cyclist and, further, there is no evidence that it is viewed as such. The FRS Company maintained that its view of this matter is consistent with FTC's regulation of advertising claims made by product endorsers.

Armstrong's statement, "I need a healthy source of energy with all I have going on, I make it happen with FRS" describes Lance's experience with FRS Products *in his current life*, not in his prior capacity as a professional cyclist. He is describing his experience in his everyday life, in a way that might appeal to everyday consumers—including athletes and non-athletes. The statement does not describe the use of FRS in athletic training, performance or competition, nor does it make any specific claim about athletic performance or competition while using FRS products. In addition, noted the advertiser, it should be recognized that a celebrity does not become an expert under FTC law because the endorsed product touches on the endorser's prior career; Rather, argued the advertiser, the fact that Armstrong obtained celebrity status as a superior athlete in his prior career brings added credibility to Lance's statements. The FRS Company stated that celebrities are often used to endorse a company's product because of the celebrity's marketing and commercial appeal; celebrities capture attention—they are "pagestoppers" and "channel-stoppers." As a result, the use of celebrities as product endorsers is common industry practice. In the skin care and beauty industry, for example, actresses and celebrities who have made a career out of being beautiful are widely used to promote cosmetics and beauty products (e.g., Cher, Victoria Principal), without being deemed "experts" in skin care. Such celebrity endorsers generally talk about the importance of good skin care, adhering to a daily regimen, and will recommend skin care products—without being considered "experts." In

fact, stated the advertiser, it is aware of no case in which any such celebrity endorser of a skin care product has been deemed to be an "expert" based on these types of testimonial statements. In a similar way, the statement attributed to Lance does not render him an "expert"; rather, he is a celebrity endorser.

Clearly, the advertiser maintained, the statement at issue in this inquiry, "I need a healthy source of energy with all I have going on, I make it happen with FRS" is not an express "fitness" or "health" claim. Regarding any potential implied "fitness" or "health" claim conveyed to consumers by Lance's statement, i.e., that the FRS Products may be useful in enhancing performance and promoting energy among athletes, including professional cyclists, the statement is adequately substantiated, supported by a product-specific clinical trial (i.e., randomized, double-blind, crossover study), published in the peer-reviewed scientific journal, International Journal of Sport Nutrition and Exercise Metabolism.

As described above, the advertiser maintained that FRS has been shown to boost and sustain peak performance in elite cyclists.[20]

In sum, The FRS Company maintained that Lance Armstrong is not an "expert" under FTC law but is a celebrity endorser offering his testimonial experience reflecting his true and honest belief about the FRS Products. However, argued the advertiser, assuming Armstrong is considered an "expert" based on an implied claim, he is qualified by his training and experience, including as a former world champion cyclist, to make such a statement.

Decision: FRS Energy, short for "Free Radical Scavenger," is a patented antioxidant and energizing formula. The key dietary ingredients in FRS are quercetin, an antioxidant found in apple, onion and red grape skins, among other foods, catechins from standardized green tea leaf extract (EGCG), antioxidant vitamins C and E, vitamin B1 (thiamin), vitamin B2 (riboflavin), vitamin B3 (niacin), vitamin B6, vitamin B12, and caffeine. The advertising for FRS Energy, primarily Internet advertising, makes performance claims for the product such as *"Boosts Energy," "Enhances Metabolism,"* and *"Increases Focus,"* and also includes an endorsement from Lance Armstrong, that states *"I need a healthy source of energy with all I have going on, I make it happen with FRS."*

In support of its performance claims, the advertiser provided three studies conducted on the product, FRS Energy, as well as ingredient studies on several of the key ingredients. NAD has often recognized that clinical testing on the product itself is the gold standard for supporting advertising claims.[21]

"Boosts Energy"

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[20] See, *Dietary Antioxidant Supplementation Combined with Quercetin Improves Cycling Time Trial Performance,* Intl J. Sport Nutr and Exerc Metab., MacRae, HS., Mefferd KM.*2006, 16, 405-419.*

[21] Patent Health, LLC (Fluid Joint - Dietary Supplement for Joint Function), *NAD Case Reports,* Report #4335 (May 2005); Indigene Pharmaceuticals Inc. (Relaxane), NAD Case Reports, Report *#4756* (November 2007).

In support of its claim that FRS Energy "Boosts Energy," the advertiser relied on two clinical studies, both conducted on FRS Energy.

The first study involved elite cyclists. This randomized, double-blind, crossover study published in 2006 in the International Journal of Sport Nutrition and Exercise Metabolism was conducted by researchers at the Department of Sports Medicine at Pepperdine University, and measured the effects of FRS Energy antioxidant supplementation on cycling performance in 11 elite cyclists. Study investigators tested the effects of FRS antioxidant formula with quercetin (300 mg of quercetin per drink) compared to FRS without quercetin, used twice daily during a six week period. Subjects were instructed to maintain and not modify their usual training, racing, and dietary program. The primary study endpoint was the time to complete a 30 km time-trial (TT). A secondary outcome measure was time to complete the last 5 km of the TT, considered by competitors as the "race of truth," as the cyclist attempts to complete the distance in the shortest time possible, without focusing on tactics and pacing.

The study found that FRS with quercetin users, as compared to participants consuming FRS without quercetin, experienced a statistically significant 3.1% improvement in overall time in the 30 km simulated mountainous TT, demonstrating peak sustained power output. FRS with quercetin users also improved the final 5 km TT performance (2%), compared to baseline. The advertiser maintained that these percentage improvements, although seemingly small, must be viewed in context, as a 1% improvement in exercise performance during competition in elite athletes is significant. The advertiser argued that this study's results demonstrate that FRS Energy boosts and sustains energy and peak athletic performance.

The researchers stated:

> "We investigated whether 6 wk of antioxidant supplementation (AS) would enhance 30 km time trial (TT) cycling performance. Eleven elite male cyclists completed a randomized, double-blind, cross-over study to test the effects of twice daily AS containing essential vitamins plus quercetin (FRS), and AS minus quercetin (FRS-Q) versus a baseline TT (B). MANOVA analysis showed that time to complete the 30 km TT was improved by 3.1% on FRS compared to B (P = 0.01), and by 2% over the last 5 km (P = 0.05). Absolute and relative %HRmax) heart rates and percent VO2max were not different between trials, but average and relative power (% peak power) was higher on FRS (P = or = 0.01). Rates of carbohydrate and fat oxidation were not different between trials. Thus, FRS supplementation significantly improved high-intensity cycling TT performance through enhancement of power output. Further study is needed to determine the potential mechanism(s) of the antioxidant efficacy."

A second study on FRS Energy, the Durak study, also found that FRS with quercetin was shown to improve energy and reduce fatigue among non-athletes in a university industrial work setting. In a randomized, cross-over study, at the University of Santa Barbara the effects of FRS supplementation were measured over a six week period (48 days), in 33 university employees, aged 29 to 63 years, working in an industrial setting (e.g., grounds keepers, custodians and skilled trades). Participants were randomly assigned an energy drink containing quercetin or non-

quercetin and midway through the program, changed cans in a crossover design. Participants completed a Work Productivity Assessment Index ("WPAI"), modified to apply to an industrial setting, and were questioned in specific areas of fatigue, mental alertness and concentration.

Results of this study indicated improvements in two areas of the WPAI survey: Group A had improvements in work performance (handle job task – 11%, p=0.10), work frustration (35.6%, p = 0.08), fatigue status (45.5%, p=0.002), and concentration (24%, p=0.02). Group B had improvements in phase II of the program using quercetin in areas of schedule demands, (4.6%, p=0.08), and concentration (10.3%, p=0.02). Both groups collectively had improvements in both work performance and quality of life indices, including a 30% improvement in overall fatigue status (p=0.004), and levels of concentration (17.1%, p<0.001).

The researchers concluded that the use of FRS Energy in the industrial work setting showed improvements in both work performance markers (i.e., scheduling demands, climbing stairs, dealing with stress) by an average of 15.3%, and physical function (fatigue, concentration, and sleep patterns) by an average of 21.4%.

Reviewing these studies, NAD found that while both suffering from some drawbacks, e.g., the first study had a relatively small number of participants (11) and a limited population (elite cyclists) and the second study gathered the results from surveys filled out by the participants themselves (a subjective evaluation), they still consistently showed that FRS Energy with quercetin generally "boosts energy."

Accordingly, NAD found that the advertiser provided a reasonable basis for the general claim that FRS Energy "boosts energy."

"Enhances Metabolism"

In support of the claim that FRS enhances metabolism, the advertiser submitted studies conducted on the individual ingredients in FRS; caffeine, green tea extract and quercetin. The advertiser maintained that FRS "enhances metabolism" because of the green tea catechins, caffeine and quercetin. The advertiser maintained that catechins from green tea extract have been shown in scientific studies to promote thermogenesis, which is known to increase metabolic rate, thereby "enhancing metabolism."

NAD has previously recognized in several cases that both green tea and caffeine can effectively "increase metabolism."[22] Accordingly, based on the research that NAD has carefully reviewed and considered in other cases involving products containing green tea extract and/or caffeine, including the research submitted in the present case, NAD determined that both green tea extract and caffeine, in certain "optimal" amounts, can "enhance metabolism."

[22] WellNX Life Sciences, Inc., (Slimquick Extreme), NAD Case Reports, Report *#4876 (July 2008)*, Irwin Naturals, (Green Tea Fat Burner), NAD Case Reports, Report *#4725 (September 2007)*, Vital Pharmaceuticals, Inc., (Redline Princess), NAD Case Reports, Report #4868 *(July 2008)*

The issue in the present case was whether the concentrations of caffeine and green tea extract in FRS Energy was sufficient and comparable to the amounts administered in the leading studies conducted on the thermogenic effects of green tea extract and caffeine.

The advertiser disclosed that FRS Energy contains "catechins" from green tea extract in labeled amounts per serving ranging from "50 mg" to "85 mg" depending upon the FRS product formula. In addition, FRS Energy contains between "35 mg" to "48 mg" of "caffeine" per serving, based on the specific FRS formulation. The amount of "quercetin" in the FRS concentrate is "250 mg" per serving, while each ready-to-drink can contains "325 mg" of "quercetin."

NAD was concerned that these amounts fell significantly short of the amounts considered by researchers to be effective at enhancing metabolism. First, it should be noted that the advertiser acknowledged that the "studies conducted on EGCG, the most widely studied of the green tea catechins, and caffeine have generally used amounts somewhat higher than those contained in FRS." The Acheson study cited by the advertiser in support of its assertion that caffeine alone can increase metabolism, founds effectiveness with an amount of caffeine equivalent to that found in 2 to 3 cups of coffee.[23] Similarly, the amount of EGCG, the active ingredient in green tea that has been shown to effectively enhance metabolism is approximately 250 mg (or even slightly more). The study cited by the advertiser regarding EGCG supplementation, the Dulloo study from 1999, concluded that "oral administration of green tea extract stimulated thermogenesis," but it must be noted that participants of that study were given 270 mg of EGCG per day, far more than the amount included in FRS Energy.[24] The advertiser also maintained that quercetin inhibits cAMPphosphodiesterase, the same mechanism by which caffeine is thought to act as a thermogenic agent, and based on the known biological activity of quercetin, it would thus be expected that quercetin would add to the activity of both caffeine and EGCG in promoting thermogenesis, or enhancing metabolism, producing an "additive effect."

Based on the ingredient studies provided on caffeine and green tea extract, as well as the advertiser's arguments regarding quercetin, NAD found insufficient evidence to substantiate a claim that FRS Energy "enhances metabolism." As stated above, the concentrations of the known thermogenic enhancing ingredients in FRS Energy, i.e., caffeine and green tea, fell significantly short of the amounts found to effectively enhance metabolism in the cited studies. FRS Energy contains the equivalent of approximately ½ of a cup of coffee, and the studies, particularly the Acheson study cited by the advertiser, found 2 to 3 cups of coffee to be an effective enhancer of metabolism. FRS Energy contains 50 to 85 mg of EGCG, and the studies, particularly the Dulloo study cited by the advertiser, found that approximately 270 mg of EGCG can effectively increase thermogenesis/metabolism. While it is true, as the advertiser argued, that

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[23] Researchers demonstrated this effect in amounts equivalent to about 2 or 3 cups of coffee. Acheson, KJ, et al. *Caffeine and coffee: their influence on metabolic rate and substrate utilization in normal weight and obese individuals.* Am J Clin Nutr. 1980
May;(33): 989-997.

[24] See, Dulloo AG., Duret C., et al. *Efficacy of a green tea extract rich in catechin polyphenols and caffeine in increasing 24-h energy expenditure and fat oxidation in humans.* Int J Obes Relat Metab Disord. 2000 Feb; 24 (2): 252-8.

no "threshold" amount of these ingredients has been established, none of these studies suggested that the lesser amounts of caffeine and/or green tea extract found in FRS Energy would effectively "enhance metabolism." As to quercetin, the advertiser provided no evidence that quercetin has been proven to enhance metabolism.[25] The advertiser provided a logical scientific analysis regarding why quercetin *could* be an effective metabolism enhancer, but beyond that, there are no studies supporting this hypothesis. Lastly, while some studies have suggested a synergistic effect between caffeine and green tea extract, there was no evidence that these amounts as combined in FRS Energy would provide the claimed enhanced metabolism.

Accordingly, based on the studies submitted on the metabolism enhancing ingredients in FRS Energy, and the generally accepted science regarding these ingredients, NAD determined that the advertiser has not provided sufficient evidence to support its claim that FRS Energy "enhances metabolism," and NAD recommended that the claim be discontinued.

"Increases Focus"

In support of its claim that FRS Energy "increases focus," the advertiser relied on two clinical studies conducted on FRS Energy. The first clinical study, described in detail above and also submitted in support of the advertiser's "boosts energy" claim, was the study conducted on industrial workers. In that study, the Durak study, researchers found that FRS with quercetin users had improvements in work performance (handle job task – 11%, p=0.10), and particularly in concentration, (24%, p=0.02), which the advertiser argued supports the claim that FRS "increases focus."[26]

In another clinical trial, investigators assessed the efficacy of FRS with respect to brain and cognitive functions, demonstrating positive results in cognitive performance, including "increased focus." In a 6 week, randomized, double-blind clinical trial, investigators at the University of California, Irvine measured the effects of FRS with quercetin as compared to orange juice. Per the study protocol, the study was designed to measure the effects of FRS in a healthy sample of 20 young and 20 elderly subjects. However, investigators enrolled and randomized 25 subjects, and completed the study on 21 subjects. Of the 21 subjects that completed the study, 17 were in the younger age group (mean age = 25 +/- 4.3) and 3 were in the elderly group (mean age = 75 +/- 6.2).[27] Efficacy measures included comprehensive neurocognitive evaluations conducted on the Computerized Multiphasic Interactive Neurocognitive Diagnostics System (CIMINDS®) (a test developed in collaboration with the National Institutes of Health), Neurocognitive assessment, using procedures such as those employed in the study are regarded as meritorious in investigating the usefulness of products intended to affect cognitive function, including memory, executive functions, (planning; foresight), attention, language and motor coordination. Study investigators also recorded subject

[25] The advertiser cited animal studies regarding quercetin and metabolism, but such animal studies cannot support a performance claim for this product on humans.

[26] *The Effects of an Antioxidant Nutrition Drink on Work Performance and Health Parameters in an Industrial Setting.* Eric Durak, MSc., Mica Bell, BS, Medical Health and Fitness, Santa Barbara, CA.

[27] The results of the study reflects data on the younger subjects, as the elderly group was too small to analyze statistically.

electrical brain activity via electroencephalogram (EEG). The results demonstrated that subjects receiving FRS had significantly greater improvement (F=6.26; p+0.026) in executive cognitive functions, including "increased focus," as compared to the orange juice group.[28]

As further support, the advertiser added that it is well known that the B vitamins are essential for positive mood, cognitive function and support energy production in the body and FRS contains 100% or more of the Recommended Daily Intake of Vitamins B1, B2, B3, B6, and B12. The advertiser also argued that caffeine, also in FRS Energy, increases key aspects of cognitive functions related to alertness and enhances self-rated moods such as vigor, efficiency and how energetic and clearheaded people report that they feel. These effects, argued the advertiser, have been documented by a number of laboratories to occur with amounts as low as 32 mg of caffeine (FRS Energy contains between 35 to 48 mg of caffeine per serving).[29] The advertiser cited behavioral studies conducted on caffeine that indicated that it helps to improve the efficiency of information processing. Measurement of brains waves with EEG support the general belief that caffeine acts as a mental stimulant and studies using event-related brain potentials (ERP) measures indicate that caffeine has an effect on attention.[30]

The advertiser maintained that these two studies, conducted on FRS Energy, in addition to the evidence regarding B Vitamins and caffeine, support the claim that FRS Energy can "increase focus." The studies, argued the advertiser, were conducted according to principles generally accepted by the scientific community to yield accurate and reliable results and in both studies, FRS with quercetin was found to produce statistically significant results with respect to increases in focus and concentration, based on an adequate number of subjects tested over an adequate time period.

While NAD recognized that both B Vitamins and caffeine have been shown to have a positive effect on focus, concentration and cognitive function in general, it was persuaded by the studies conducted on FRS Energy itself, studies designed to specifically evaluate the concentration and focus of the participants. NAD found that these studies provide a reasonable basis for a general claim that FRS Energy "increases focus."

"Now FRS is used by anyone who wants a sustained healthy energy boost." and *"I need a healthy source of energy with all I have going on, I make it happen with FRS."*

As to these claims, describing FRS Energy as "healthy," and a "healthy source of energy," the advertiser maintained that it is indisputable that the FRS Products may be described as "healthy," based not only on the ingredients in the products, but also on what they do not contain.[31] The advertiser stated that FRS products contain strong antioxidants with superior free radical

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[28] Efficacy of FRS 1000-D in Cognitive and Brain Activity Measures, report of study investigator, Dr. Yi Jin, University of California at Irvine, May 30, 2006, submitted in support.
[29] See, Lieberman HR. *The effects of ginseng, ephedrine, and caffeine on cognitive performance, mood and energy.* Nutr Rev. 2001 Apr; 59(4):91-102.
[30] See, Lorist MM, Tops M. *Caffeine, fatigue, and cognition*. Brain Cogn. 2003 Oct;53(1):82-94,
[31] It should be noted that the advertiser has discontinued making the "healthy" performance claims, i.e., *". . . while helping to keep them healthy."*

scavenging capacity and high Oxygen Radical Absorbance Capacity ("ORAC") value.[32] Further, stated the advertiser, FRS Products contain no ingredients known to present a public health problem such as "saturated fat," "cholesterol," or "sodium."

NAD recognized the fact that FRS Energy contains strong antioxidants and relatively low levels of caffeine and green tea extract, but none of the potentially harmful ingredients found in some other "energy" drinks. Accordingly, NAD found that the advertiser can accurately describe FRS Energy as a "healthy" product.

Endorsement

The advertising for FRS Energy features endorsements from Lance Armstrong. His endorsement reads:

> *"I need a healthy source of energy with all I have going on, I make it happen with FRS."*

The advertiser represented that Lance Armstrong is endorsing the product as a celebrity in his daily life, and not in his capacity as a professional athlete. Alternatively, the advertiser argued that even if Lance Armstrong is considered an "expert" (based on an implied claim), he is qualified by his training and experience, including as a former world champion cyclist, to make such a statement.

NAD found that a reasonable takeaway from the FRS Energy advertising is that Lance Armstrong is endorsing the product *as an expert* – a professional cyclist. In other words, NAD found an implied claim that his endorsement is that he drinks the product because it enhances his performance capability as an elite athlete. In arriving at this conclusion, NAD considered the surrounding language, including a paragraph that appears right next to the endorsement that states:

> "It was then discovered by endurance athletes who found that it boosted and sustained their peak athletic performance while helping to keep them healthy."

In addition, one of the key studies submitted in support of its "boosts energy" claim was, in fact, conducted on 11 elite cyclists. Importantly, Mr. Armstrong is identified in the advertising as "7 Time Tour De France Winner." Accordingly, the endorsement from a professional athlete – Lance Armstrong, former professional cyclist – coupled with the fact that the support for certain performance claims for FRS Energy is a study conducted on professional cyclists, and the fact that he is identified as "7 Time Tour De France Winner," in NAD's view, leads to the reasonable takeaway that Lance Armstrong is endorsing this product, not simply as a celebrity (as the advertiser claims), but as a professional athlete, an expert in cycling and training.

[32] The advertiser submitted an independently conducted laboratory analysis of FRS Energy measuring its ORAC value.

The FTC Rule on Expert Endorsements (Section 255.3) states that,

"Whenever an advertisement represents, directly or by implication, that the endorser is an expert with respect to the endorsement message, then the endorser's qualifications must in fact give him the expertise that he is represented as possessing with respect to the endorsement."

While Mr. Armstrong is a former professional cyclist, and capable of providing an endorsement as a professional athlete, there is no evidence that he did so here.

The FTC rule further states that, *"While the expert may, in endorsing a product, take into account factors not within his expertise (e.g., matters of taste or price), his endorsement must be supported by an actual exercise of his expertise in evaluating product features or characteristics with respect to which he is expert and which are both relevant to an ordinary consumer's use of or experience with the product and also are available to the ordinary consumer."*

At a minimum, Mr. Armstrong would have had to have reviewed the studies, and as a professional athlete, it is not even clear whether or not he could provide an expert opinion on a scientific study, such as the ones conducted on FRS Energy provided here. There was no evidence that he did anything that would be consistent with an expert endorsement, and, in fact, the advertiser argued that Mr. Armstrong was acting as a celebrity endorser in his current life and not an expert (professional cyclist) endorser.

Therefore, NAD recommended that to avoid the potential for any consumer confusion, the advertiser make it clear in its advertising that Lance Armstrong is endorsing FRS Energy as a *celebrity in his current regular life* and not in his capacity as a professional (or former) professional cyclist.

Conclusion: NAD found that, based on three different studies conducted on the advertised product itself, the advertiser provided a reasonable basis for its performance claims that the FRS Energy generally "Boosts Energy," and "Increases Focus." NAD, however, found insufficient evidence to support the claim that FRS energy "enhances metabolism."

Regarding the "healthy" claims, NAD found that based on the ingredients that are included in FRS Energy, as well as those that are not, the advertiser can accurately describe FRS Energy as "healthy" and a "healthy source of energy."

Lastly, NAD recommended that the advertiser clarify in its advertising that Lance Armstrong is endorsing FRS energy as a celebrity in his current life, and not as a professional cyclist and 7-time Tour De France winner.

Advertiser's Statement: The FRS Company, a responsible marketer and distributor of "FRS® Healthy Energy" dietary supplements, appreciated the opportunity to participate in NAD's voluntary advertising review program and is committed to truth-in-advertising. The FRS Company is pleased that NAD, having reviewed product-specific clinical studies and having considered the composition of FRS®, agreed that the FRS products may be accurately described

as "healthy" and "a healthy source of energy," and that the company's core performance claims, "boosts energy" and "increases focus," are substantiated. While The FRS Company disagrees with NAD's view that the current scientific evidence is insufficient to substantiate the claim "enhances metabolism," the company nonetheless accepts NAD's decision and agrees to consider appropriate revisions in future advertising.

The FRS Company was pleased to provide NAD with Lance Armstrong's signed statement confirming his endorsement of FRS Healthy Energy products. NAD, having considered Mr. Armstrong's endorsement of FRS, recommended that The FRS Company "clarify in its advertising that Lance Armstrong is endorsing FRS energy as a celebrity in his current life, and not as a professional cyclist and 7-time Tour de France winner." NAD's recommendation is consistent with the manner in which Mr. Armstrong's statements and image appear in FRS product advertising. The FRS Company's advertising featuring Mr. Armstrong as a product endorser will makes it clear that he is endorsing the product in his current life as a celebrity.

Notwithstanding, The FRS Company respectfully disagrees with NAD's view, stated in its decision, that if Mr. Armstrong is considered an "expert" (rather than a "celebrity") endorser of FRS products, he would be required to review the scientific studies concerning FRS in order to provide an opinion that FRS "boosts energy." The FRS Company maintains that, even if Lance Armstrong is considered an "expert" endorser rather than a "celebrity" endorser, he is qualified by athletic training and experience to evaluate the FRS products and may opine that the products "boost energy." While The FRS Company disagrees with NAD in this regard, the company's future advertising will continue to make clear, as recommended by NAD, that Mr. Armstrong is endorsing FRS Healthy Energy products in his current life as a celebrity. **(#4904 MBL, closed 09/03/2008)**