

VITAL PHARMACEUTICALS, INC.

Redline Princess

Advertising Agency: *Undisclosed*

Challenger: *National Advertising Division*

- **Health-related performance claims that are product specific should be supported by competent and reliable scientific evidence demonstrating that the product or product's ingredients (as combined and formulated in the advertised product) will produce the claimed benefits.**
- **NAD has consistently held that the nature and extent of claims made by an advertiser should mirror the precision and specificity of the data relied on as substantiation.**

Basis of Inquiry: As part of NAD's routine monitoring program, NAD requested substantiation for certain health-related performance claims made by Vital Pharmaceuticals, Inc. ("Vital Pharm") in print advertisements and on product packaging for Redline Princess, a dietary supplement energy drink.

The following are representative of the claims that served as the basis of the instant challenge:

Express Claims

- "A New Breakthrough Designed Especially for Women to Enhance:
 - Mood
 - Energy
 - Fat Loss"
- "Mood, Energy & Fat Loss Matrix!"
- "The World's Most Effective Energy Drinks ..."

Advertiser's Position:

At the outset the advertiser explained that its submission provides scientific data in support of the first two challenged claims above and that the third claim is not a claim but rather constitutes non-actionable puffery. The advertiser then divided the first two claims into four individual claims and presented scientific literature regarding the product's ingredient properties as substantiation. The four claims listed by the advertiser were as follows: (1) Mood, Energy and Fat Loss Matrix, (2) Designed to Enhance Mood (3) Designed to Enhance Energy, and (4) Designed to Enhance Fat Loss.

The advertiser maintained that its REDLINE PRINCESS ("RP") product is a ready-to-drink ("RTD") beverage that contains a variety of ingredients linked to the various physiological processes touted in RP's advertising. The advertiser first explained that, although RP contains unique combination of ingredients, its primary and most effective ingredient is caffeine. The advertiser contended that there is an abundance of scientific evidence demonstrating that caffeine provides each of the benefits touted in RP's advertising claims ("Enhanced Mood, Energy and

Fat Loss”) and thus concluded that the challenged claims are supported by third-party scientific data on caffeine alone. In addition, the advertiser stated that there is also data which suggests that the other active ingredients in RP (such as phenylethylamine (“PEA”), 5-Hydroxytryptophan (“5-HTP”), Vinpocetine and Yohimbine) may promote changes in mood, energy and/or fat metabolism. Thus, the advertiser further divided its claim substantiation into two additional groups to support the claims at issue: studies on caffeine and studies on the additional active ingredients.

I. Caffeine Enhances Energy, Fat Loss and Mood

According to the advertiser, caffeine (which is also known as 1,3,7-trimethylxanthine) is used as an ergogenic aid (i.e., improves exercise capacity and energy), an adjunct to exercise for promoting fatty acid lipolysis¹ and mood enhancement. The advertiser’s response discussed each of these characteristics individually and summarized the scientific evidence submitted in support of each of these claims.

A. Caffeine & Energy

The advertiser referred to six different studies regarding caffeine’s effects on physical performance. The results emphasized by the advertiser demonstrated that caffeine improves endurance during cycling, increases maximal anaerobic power, increases muscle strength, increases time to exhaustion, increases swim sprint speed, has a direct effect on muscle fibers and does not impede muscle recovery.

The advertiser explained that the seminal study on caffeine was performed by Dr. David Costill to determine the effects of caffeine ingestion on the metabolism and performance during prolonged exercise. In this study, nine competitive cyclists (2 females and 7 males) exercised until exhaustion on a bicycle ergometer at 80% of maximal oxygen uptake (VO₂max). One test was performed an hour after ingesting decaffeinated coffee and a second test required that each subject consume coffee containing 330 mg of caffeine 60 minutes before the exercise. The results, according to the advertiser, demonstrated that the subjects given 330 mg of caffeine prior to their workout had a significantly greater (p<0.05) exercise time, greater fatty acid oxidation² and experienced a lower perceived exertion (i.e., the exercise felt easier) rating than the decaffeinated group.

The advertiser noted that in a second very similar study in which eight subjects cycled to exhaustion³, the caffeine-treated group also had a significantly longer exercise time⁴ and reported a significant reduction in the amount of glycogen used for fuel in the first 15 minutes of exercise. The advertiser emphasized the studies’ conclusion that caffeine before exercise decreased muscle

¹ The splitting or breaking down of fatty acids.

² With regard to the oxidation of free fatty acids, the caffeine group was significantly higher (118 g or 1.31 g/min) than the decaffeinated group (57 g or .75 g/min).

³ Subjects cycled to exhaustion at approximately 80% maximal oxygen uptake (VO₂max) one hour after ingestion of 9 mg/kg body weight dextrose (the placebo) or caffeine.

⁴ Caffeine consuming subjects lasted 90.2 minutes versus 75.8 minutes in the placebo trial.

glycogenolysis (glycogen breakdown) by approximately 55% over the first 15 minutes of exercise allowing this spared glycogen to be available later and thus contributed to the subjects' enhanced time to exhaustion.

The third study the advertiser referred to consisted of nine male caffeine users who performed exercise rides to exhaustion (at 80% VO₂max) after ingesting either a placebo, 5 mg x kg⁻¹ of caffeine or 2.5 mg x kg⁻¹ of caffeine, one hour before the exercise. The exercise rides were conducted twice a day (once in the morning and once 5 hours later in the afternoon) under four different conditions: (1) high caffeine in the morning, low caffeine in the evening; (2) placebo in the morning, placebo in the evening; (3) high caffeine in the morning, placebo in the evening; and (4) placebo in the morning, high caffeine in the evening. According to the advertiser, the results demonstrate that caffeine is an effective performance enhancing aid in the morning or afternoon and that a single dose in the morning still provides an ergogenic (performance-enhancing) benefit in the afternoon (several hours later).⁵

The fourth study discussed by the advertiser focused on caffeine's ability to improve muscular power and strength. The advertiser explained that this study, which conducted computerized testing of 20 elite male athletes to determine the effect of 7 mg per kilogram body weight of caffeine on strength and power of the knee extensors (ET) and flexors (FT) (i.e. quadriceps and hamstring muscles), found that caffeine can favorably affect some strength parameters in highly resistance-trained males.⁶

The fifth study which the advertiser submitted consisted of seven trained and seven untrained subjects who swam freestyle 2 x 100 m distances (at maximal speed and separated by 20 minutes of passive recovery) once after ingesting 250 mg of caffeine and once after ingesting a placebo. The results showed that only the trained subjects swam faster during the caffeine trial, which the advertiser maintained, is further evidence that caffeine can enhance activities that require very quick energy production.

Finally, with regard to caffeine's ability to assist physical performance via its pain-reducing effects the advertiser submitted a sixth study. The advertiser explained that this study consisted of low-caffeine consuming college-aged males who were made to consume one of two doses of caffeine (either 5 or 10 mg/kg(-1) body weight) or a placebo and then one hour later complete 30 minutes of moderate intensity cycling exercise (60% VO₂peak). The study concluded that caffeine ingestion has a dose-response effect on reducing leg muscle pain during exercise.

B. Caffeine & Fat Loss

⁵ The advertiser also noted that many scientists posit that enhanced endurance performance may result in part from a sparing of muscle glycogen, increased lipolysis and fat oxidation, a decrease in pain sensation, as well as a profound effect on the central nervous system.

⁶ Specifically, the study found significant caffeine-related increases in ET and FT at both fast and slow speeds of movement and no significant effects were found in the placebo trial at any variable.

VITAL PHARMACEUTICALS, INC.

Redline Princess

Page : 4

According to the advertiser, there is a plethora of data showing the lipolytic⁷ and thermogenic⁸ effects of caffeine. In particular, the advertiser referred to studies demonstrating that caffeine increases metabolic rate in both lean and obese subjects as well as the metabolic rate in both young and old subjects, and increases fat burning/ oxidation.

With respect to caffeine's ability to increase the resting metabolic rate of both lean and obese subjects the advertiser referred to a study in which a single-dose of 100 mg caffeine increased the resting metabolic rate of both lean and post-obese human volunteers by 3-4% over 2 hours and 30 minutes. The advertiser noted that repeated caffeine administration (100 mg) at 2-hour intervals over a 12-hour day period increased the energy expenditure of both subject groups by 8-11% during that period, which translated into an additional 150 kcal oxidized by the lean subjects and 79 kcal in the obese subjects. According to the advertiser, the authors of this study concluded that "caffeine at commonly consumed doses can have a significant influence on energy balance and may promote thermogenesis in the treatment of obesity."

The advertiser stated that caffeine was also shown to increase energy expenditure in both young and old subjects but that it affected the subjects differently. According to the advertiser, older individuals (65-80 yr) absorb caffeine as well as the young (19-26) and while they differed in thermogenic response, caffeine ingestion (5 mg caffeine per kilogram of fat-free mass, ~ 350 mg in young and ~295 mg for old) resulted in similar increases in energy expenditure (Young = 11%, Old = 9.5%).

The advertiser also referred to a study in which 12 young healthy male volunteers consumed 150 ml decaffeinated coffee with or without 200 mg caffeine. The results, according to the advertiser, demonstrated that metabolic rate increased by 7% during the three hours of examination, further suggesting that a dose-response relationship to caffeine consumption exists. The advertiser then went on to discuss a similar study which used much higher dosages of caffeine (eight healthy young men were given 10mg per kg of caffeine). The advertiser noted that the average thermic effect was 13.3% and that the caffeine also doubled the turnover of lipids (of which 24% were oxidized and 76% were recycled). Therefore, the advertiser concluded, caffeine clearly has very potent effects of metabolism and the turnover of the body's fat stores.

C. Caffeine & Mood

At the outset the advertiser stated that caffeine has a significant effect on the central nervous system (CNS), adding that because of the multi-factorial effects of caffeine one could reasonably conclude that this single ingredient does indeed enhance mood and provide energy under various

⁷ Lipolysis was defined by the advertiser as the splitting or breaking down of fatty acids.

⁸ Thermogenesis is the process of heat production in organisms. There is exercise-associated thermogenesis and non-exercise associated thermogenesis; Thermogenesis can also be achieved by artificial means by increasing the body's metabolism, thereby increasing its core temperature. It is becoming common for people to use thermogenic substances to help control fluctuation in weight.

VITAL PHARMACEUTICALS, INC.

Redline Princess

Page : 5

conditions. The advertiser then described seven different studies in support of its position that the caffeine contained in its ready-to-drink Redline Princess product enhances mood. Four of the seven studies submitted by the advertiser examined the effects of caffeine on subjects suffering from sleep deprivation⁹, two of the studies focused on caffeine deprivation and consumption¹⁰ and one study examined the relationship between habitual coffee and tea consumption and cognitive (brain) performance.

With respect to caffeine and its effects on sleep deprivation, the advertiser first summarized the McLellan Study of 2004, in which the scientists concluded that “caffeine is an effective strategy to maintain physical performance during an overnight period of sleep loss at levels comparable to the rested state.” In the McLellan Study, 16 subjects went through a control day, sleep day and then 28 hours of sleep deprivation. The subjects were then given a 400 mg dose of caffeine at 9:30 pm followed by two additional 100 mg doses at 3:00 am and 5:00 am. The advertiser explained that at 10:00 pm the subjects began a 2-hour long forced march followed by a sandbag piling task; then on the second day of sleep deprivation the subjects performed a treadmill run to exhaustion at 85% of maximal aerobic power at 7:00 am. The advertiser emphasized the results, which demonstrated that caffeine decreased the ratings of perceived exertion (meaning the subjects’ perceived effort of exercise was lessened), the time to exercise task was 6.5% less with caffeine (or 12.9 minutes compared to 13.8 minutes with placebo) and that the time to exhaustion increased 25% during the run with caffeine (17 minutes compared to 13.5 minutes in the run with placebo).

The advertiser next referred to the Patat Study, which examined the pharmacodynamic profile of a single oral dose of 600 mg caffeine on 12 young, healthy males. The study was a randomized, double-blind, crossover and placebo-controlled process that studied 12 sleep deprived subjects (36 hours) using EEG¹¹ and various measures of psychomotor and cognitive functions.¹² According to the advertiser, the study found that caffeine significantly ($p < 0/05$) antagonized the detrimental effects of sleep deprivation; The effect peaked 4 hours after dosing and was maintained until the end of sleep deprivation (i.e.24 hours after dosing). The advertiser emphasized the study’s conclusion that a single dose of slow or sustained release caffeine possesses alerting effects which are able to reverse the deleterious effect of 36 hours sleep deprivation for at least 24 hours. The advertiser went on to state that given these results, it would be reasonable to suggest that lower doses may have a similar benefit. In support of this statement the advertiser noted that the Beaumont Study, conducted in 2001, showed that 300 mg of slow release caffeine given twice daily during 64 hours of sleep deprivation antagonizes the impairment produced on vigilance and cognitive functions.

The advertiser also submitted a fourth study, Reyner and Horne 2000, which conducted 2 independent studies following a night of either restricted (5 hours) or no sleep. The advertiser

⁹ See, McLellan et al., 2004; Patat et al., 2000; Beaumont et al., 2001; and the Reyner and Horne Study of 2000.

¹⁰ See, Smith et al., 1985; and Robelin and Rogers 1998.

¹¹ EEG is a method used to measure brain activity.

¹² The scientists performed a series of cognitive and psychomotor tests such as critical flicker fusion (CFF), choice reaction task (CRT), tracking, continuous performance task (CPT), Stroop test, body sway and subjective evaluation (Stanford Sleepiness Scale).

VITAL PHARMACEUTICALS, INC.

Redline Princess

Page : 6

explained that the subjects drove for two hours in an immobile car on an interactive roadway made to be dull and monotonous, and after two hours were given 200 mg caffeine or placebo; driving incidents (lane drifting), sleepiness, and brain activity were logged. The advertiser claimed that in the first study where subjects had 5 hours restricted sleep caffeine significantly reduced incidents and subjective sleepiness throughout the two-hour drive, and in the second study (where subjects had no sleep) caffeine reduced incidents significantly for the first 30 minutes and subjective sleepiness for the first hour.

In addition to the four studies on caffeine and sleep deprivation, the advertiser also submitted two studies on caffeine deprivation and consumption: Smith et al., 1985; and Robelin and Rogers 1998. The advertiser pointed out that the Smith Study consisted of 144 subjects (72 male and 72 female with a mean age of 21) who were randomly assigned to one of the groups formed by combining breakfast (cereal versus no breakfast) and caffeine (caffeinated versus decaffeinated coffee) conditions.¹³ The results, according to the advertiser, showed that those who consumed breakfast cereal had a more positive mood at the start of the test sessions, performed better on a spatial memory task and felt calmer at the end of the test session than those with no breakfast. In addition, the advertiser noted that ingestion of caffeine also improved encoding of new information and counteracted the fatigue that developed over the test session.

The advertiser also referred to the Robelin and Rogers Study, which observed 64 moderate caffeine consumers (an average intake of 453 mg/day) who were deprived of caffeine overnight and then received one of four treatments: three treatments of placebo, three treatments of caffeine, one caffeine and two placebo treatments and two caffeine and one placebo treatments.¹⁴ The advertiser explained that either caffeine or placebo were administered double-blind in novel fruit juice drinks at 10:15am, 11:30am and 1:00pm on the test day; before baseline and 45 minutes after each of the dosage times the participants completed a mood questionnaire and psychomotor performance tests lasting 25 minutes. The results, the advertiser stated, demonstrated that all of the treatments in which caffeine was administered resulted in a significantly increased energetic mood and improved psychomotor performance relative to placebo.

Finally, the advertiser referred to a cross-sectional survey of a representative sample of 9003 British adults, conducted in 1993, to examine the relationship between habitual coffee and tea consumption and cognitive (brain) performance. The study, according to the advertiser, indicated that the more coffee the subjects consumed, the better they performed in tests of simple reaction time, choice reaction time, incidental verbal memory and visuo-spatial reasoning. (Jarvis, 1993). Thus, the advertiser concluded, it would seem reasonable to suggest that caffeine, consumed as a pill or within another liquid form, would indeed produce similar results.

II. Redline Princess' Additional Mood-Enhancing Ingredients

¹³ The volunteers completed a baseline session between 8:00am-8:45am, then the breakfast/caffeine administration took place between 8:45am-9:15am. The volunteers then performed a battery of mental tests starting at 9:45am and had a coffee break at 10:45am, followed by a final session starting at 11:45am.

¹⁴ The caffeine treatments were 1.2 mg/kg.

A. Vinpocetine

According to the advertiser, there is a plethora of evidence that vinpocetine consumption has significant effects on both cognitive and motor function in humans.¹⁵ The advertiser contended that vinpocetine, found in the lesser periwinkle *Vinca minor*, is an excellent vasodilator and cerebral metabolic enhancer with proven benefits for vascular-based cognitive dysfunction.¹⁶ The advertiser also discussed three studies on the effects of vinpocetine treatments: Subhan and Hindmarch, 1985; Bhatti and Hindmarch, 1987; and Valikovics 2007.

The advertiser first discussed the Subhan and Hindmarch 1985 Study in which 12 female subjects received pre-treatments with vinpocetine 10, 20, 40 mg and placebo for two days,¹⁷ on the third day subjects completed a battery of psychological tests including Critical Flicker Fusion (CFF), Choice Reaction Time (CRT), Subjective Ratings of Drug Effects (LARS) and a Sternberg Memory Scanning Test. The results reported no statistically significant changes from placebo on CFF, CRT or subjective ratings of drug effects. The advertiser noted, however, that memory (as assessed using the Steinberg technique) was found to be significantly improved following treatment with Vinpocetine 40 mg.

The advertiser then referred to the Bhatti and Hindmarch 1987 investigation, which examined the effects of pre-treatment with 40 mg Vinpocetine, on flunitrazepam-induced impairment of memory in 8 normal volunteers.¹⁸ The advertiser explained that, like the previous study, tests of Critical Flicker Fusion Threshold, a Sternberg Memory Scanning Task as well as subjective rating of drug action were used to evaluate the effect of the Vinpocetine pre-treatment. Once again, the advertiser noted, Vinpocetine treatment was associated with improvements in short-term memory processes.

The final investigation the advertiser mentioned was conducted by Valikovics in 2007. In this study scientists examined the characteristics of blood flow parameters in patients with ischemic stroke and mild cognitive impairment both in resting conditions or following chemical stimulus; they also investigated the severity of mental deterioration in the two patient groups. According to the advertiser, the authors examined the influence of a 12-week long oral Vinpocetine therapy on the blood flow parameters and cognitive functions in two patient groups, and after the 12 week treatment the increase of blood flow velocity in resting conditions compared to the baseline values was significant in the vascular group. The advertiser emphasized that investigators concluded that “vinpocetine improved the cerebrovascular reserve capacity in both patient groups and favorably influenced the cognitive status and general condition in patients with chronic hyperfusion.” In addition, the advertiser noted that the authors recommended the use of vinpocetine for the treatment of patients with mild cognitive impairment.

¹⁵ Hennessy et al., 2002.

¹⁶ Kidd, 1999.

¹⁷ Treatments were applied according to a randomized, double-blind crossover design.

¹⁸ Flunitrazepam is a highly-potent hypnotic drug with powerful sedative, anxiolytic, amnestic, and skeletal muscle relaxant properties commonly prescribed for the treatment of insomnia.

B. 5-HTP

According to the advertiser, 5-Hydroxytryptophan (5-HTP) is the intermediate metabolite of the essential amino acid L-tryptophan (LT) in the biosynthesis of serotonin.¹⁹ The advertiser noted that 5-HTP is well absorbed from an oral dose (with about 70 percent ending up in the bloodstream), easily crosses the blood-brain barrier and effectively increases central nervous system (CNS) synthesis of serotonin.

The advertiser emphasized that, in the CNS, serotonin levels have been implicated in the regulation of sleep, depression, anxiety, aggression, appetite, temperature, sexual behavior and pain sensation. The advertiser went on to explain that therapeutic administration of 5-HTP has been shown to be effective in treating a wide variety of conditions, including depression (as well as fibromyalgia, binge eating associated with obesity, chronic headaches and insomnia).²⁰ Thus, the advertiser concluded, the available evidence suggests that 5-HTP is better than placebo at alleviating depression.²¹

C. PEA

The advertiser explained that beta-phenylethylamine (PEA) is an endogenous neuroamine that resembles amphetamine in chemical structure and has been identified in human and other mammalian brains. The advertiser maintained that PEA increases attention and activity in animals and has been shown to relieve depression in 60% of depressed patients. In its submission, the advertiser referred to a study which proposed that PEA deficit may be the cause of a common form of depressive illness. Specifically, the advertiser noted that upon re-examination (20-50 weeks later) 12 out of 14 patients with major depressive episodes that responded to PEA treatment²² had maintained the antidepressant response, the effective dosage did not change with time and there were no apparent side effects.

According to the advertiser, the study demonstrated that PEA produced sustained relief of depression in a significant number of patients, including some who were unresponsive to standard treatments, and improves mood as rapidly as amphetamine without producing tolerance.

D. St. John's Wort

According to the advertiser, the role of St. John's Wort (extracts of *Hypericum perforatum*) on depression has been investigated extensively. In support of its position, the advertiser referred to a meta-analysis that found that hypericum was more effective than placebo in the treatment of

¹⁹ The advertiser stated that intestinal absorption of 5-HTP does not require the presence of a transport molecule, and is not affected by the presence of other amino acids. Thus, it may be taken with meals without reducing its effectiveness. Unlike L-tryptophan, 5-HTP cannot be shunted into niacin or protein production.

²⁰ Birdsall, 1998.

²¹ Shaw, Turner, and Del Mar, 2002.

²² Patients orally consumed 10-60 mg/day with 10/mg/day selegiline to prevent rapid PEA destruction.

mild to moderately severe depressive disorders.²³ The advertiser also noted that a 1976 study conducted by Iakimenko and Popova found that hypericum perforatum was more effective than placebo and similar in effectiveness to low-dose tricyclic anti-depressants in the short-term treatment of mild to moderately severe depression.²⁴ The advertiser explained that St. John's Wort has been favorably compared to numerous anti-depressant drugs, the studies having revealed equivalent results and a much more favorable incidence of side effects. In addition, the advertiser stated that studies have also demonstrated that the extract has been effective in treating seasonal affective disorder. (Miller, 1998). Finally, the advertiser emphasized that a 2008 study published by the European Archives of Psychiatry and Clinical Neuroscience concluded that St. John's Wort extract WS 5570 has a meaningful beneficial effect during acute treatment of patients suffering from mild depression and leads to a substantial increase in the probability of remission.²⁵

III. Redline Princess' Additional Fat Loss Enhancing Ingredients

A. 5-HTP

In addition to its mood enhancement properties, the advertiser asserted that there is also evidence that 5-HTP can promote body weight loss. As the advertiser stated previously, the therapeutic administration of 5-HTP has been shown to be effective in treating a wide variety of conditions, including binge eating associated with obesity. In support of this claim the advertiser referred to a 1989 study in which scientists investigated the effects of 8mg/kg/day oral 5-HTP administration on the feeding behavior, mood state and weight loss of 19 obese female subjects with a body mass index of 30-40.²⁶ The advertiser noted that although no changes in mood state were reported, the study demonstrated that administration of 5-HTP promotes typical anorexia-related symptoms, decreased food intake and weight loss.

The advertiser also discussed a second study in which 20 obese patients were randomly assigned to receive either 900/mg/day 5-HTP or a placebo for two consecutive 6-week periods (of which no diet was prescribed for the first period and a 5040-kJ/day diet was prescribed for the second period). The advertiser emphasized the study's results, which reported significant weight loss in the 5-HTP-treated patients during both periods as well as a reduction in carbohydrate intake and consistent presence of early satiety.

²³ In particular the advertiser noted that a meta-analysis, which consisted of 23 randomized trials and included a total of 1757 outpatients with mild to moderately severe depressive disorders, found extracts of hypericum to be more effective than placebo for the treatment of mild to moderately severe depressive disorders. (Linde et al., 1996)

²⁴ The advertiser explained that typically, clinical studies on the use of St. John's Wort for depression have utilized liquid tinctures and standardized sold extracts (0.3% hypericin -- 300 mg three times a day); Severe depression may also respond to this botanical, although it appears a larger dose is needed (600 mg solid extract three times a day).

²⁵ Kasper et al., 2008.

²⁶ Feeding behavior was investigated by means of a questionnaire designed to establish the onset of anorexia and related symptoms; Food intake was evaluated using a three-day diet diary and BDI, SI, STAI-T and STAI-S were used to assess mood state.

According to the advertiser, these findings together with the good tolerance observed suggest that 5-HTP may be safely used to treat obesity.

B. Yohimbine

The advertiser's submission also discussed a study on the effects of yohimbine supplementation on body composition and exercise performance. The advertiser stated that the study consisted of 20 professional soccer players randomly assigned to either the placebo or yohimbine groups, noting that subjects in the yohimbine group orally ingested 20 mg/day in two equal doses for 21 days. In its conclusion the advertiser noted that although no significant changes in body mass, muscle mass or performance indicators were observed, yohimbine supplementation appears to be suitable as a fat loss strategy in elite athletes.²⁷

IV. "Designed Especially for Women"

With respect to the express claim that the RP energy drink was designed especially for women the advertiser stated that the bright pink RP container was designed to aesthetically appeal to females.

In addition, the advertiser explained that each of the active ingredients (Caffeine, PEA, Yohimbine, St. John's Wort, and 5-HTP) in RP have been shown to support a woman's energy, mood and fat loss (as explained above). Finally, the advertiser's web page and product descriptions state that one of the primary concerns women have when choosing an energy drink is that they do not want to feel "jacked up". Thus, the advertiser created RP, which has lower dosages of its active ingredients, in order to match the average female's lower body mass.

V. The World's Most Effective Energy Drinks

The advertiser argued that the statement, "The world's most effective energy drinks ..." is not a claim but rather non actionable puffery, which does not subject an advertiser to false advertising under the Lanham Act. In its response, the advertiser noted that the Third Circuit has described "puffing" as "advertising that is not deceptive for no one would rely on its exaggerated claims."²⁸ The advertiser also referred to a Ninth Circuit decision which defined "puffing" as "exaggerated advertising, blustering and boasting upon which no reasonable buyer would rely and is not actionable under 43(a)."²⁹ The advertiser further noted that a leading authority on unfair competition has defined "puffery" as an "exaggerated advertising, blustering, and boasting upon which no reasonable buyer would rely, " or "a general claim of superiority over a comparative product that is so vague it would be understood as a mere expression of opinion."³⁰

²⁷ The yohimbine group reported a significant decrease in percentage of body fat as well as a lower fat mass.

²⁸ U.S. Healthcare, Inc. v. Blue Cross of Greater Philadelphia, 898 F.2d 914 (3d Cir.1990).

²⁹ Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134,1145 (9th Cir.1997).

³⁰ 4 J. Thomas McCarthy, McCarthy on Trademark and Unfair Competition §27.38 (4th ed. 1996).

VITAL PHARMACEUTICALS, INC.

Redline Princess

Page: 11

The advertiser maintained that courts have consistently found that claims so general in nature, and so exaggerated in content that no reasonable person would rely upon them, to be puffery and non actionable under the Lanham Act. In particular, the advertiser stated that the court in *American Italian Pasta* concluded that the phrase “America’s Favorite Pasta” was not a specific measurable claim and cannot be reasonably interpreted as an objective fact. Likewise, the advertiser argued, “The World’s Most Effective Energy Drinks” cannot be reasonably interpreted as an objective fact. Instead the advertiser contended that it would be impossible to determine what every person in the world felt was the most effective energy drink and further noted that the “world” is even more broad and immeasurable than “America’s” (which the court found to be a vague and broad general reference).

In addition, the advertiser argued that how “effective” an energy drink is depends upon intrinsic characteristics and personal preference – what is effective to one person may not be effective to another person. According to the advertiser, one person may find that caffeine makes an energy drink effective while another person may find that vinpocetine makes an energy drink effective.

Finally, the advertiser compared its use of the word “effective” to use of the word “better” in *Pizza Hut* where the court found the statement “Better Ingredients, Better Pizza” to be unquantifiable and concluded that “what makes one food ingredient ‘better’ than another comparable ingredient, without further description, is wholly a matter of individual taste or preference not subject to scientific quantification.” The advertiser argued that the term “effective” is also unquantifiable, adding that what makes an energy drink effective depends upon personal preference. Thus, the advertiser concluded, the statement “The World’s Most Effective Energy Drink” is puffery and not an actionable claim.

Decision:

Since the debut of Redbull in 1997, the beverage industry has been experiencing a shift from soft drinks and beer to functional, health and wellness oriented product categories. According to a beverage industry report by the Power Brands Beverage Specialists, functional beverages continue to be the hottest segment, and this category is led by energy drinks (such as Redline Princess) which reported a 53% growth in 2006 alone. Redline Princess (“RP”) is a ready-to-drink energy drink marketed specifically to women, which claims to enhance a female’s mood, energy and fat loss. Advertisements for the drink appear in health and fitness publications. In addition, the product is advertised and sold in nutrition stores, such as GNC and the Vitamin Shoppe, as well as mass distribution outlets like 7 Eleven.

The NAD inquiry focused on three advertising claims: (1) “A New Breakthrough Designed Especially for Women to Enhance: Mood, Energy and Fat Loss;” (2) “Mood, Energy & Fat Loss Matrix!” and (3) “The World’s Most Effective Energy Drinks.” In support of the first two claims the advertiser provided NAD with numerous articles and scientific studies on the individual ingredients in RP. The advertiser contended that the third claim is not a claim, but rather constitutes non-actionable puffery.

It is important to note that, when evaluating the message communicated by an advertising claim, NAD examines the claim in the context of the entire advertisement in which it appears, and an advertiser is obligated to support all reasonable interpretations of claims made in its advertising, including messages it may not have intended to convey.³¹

I. “Designed Especially for Women to Enhance: Mood, Energy and Fat Loss” and “Mood, Energy & Fat Loss Matrix!”

NAD’s evaluation of the advertiser’s substantiation is guided by the specific advertising claims at issue. Here, the claims at issue include very strong and specific health claims: “enhance mood, energy and fat loss.”

As noted above in the advertiser’s position, the performance claims were divided by the advertiser into three “core structure function” claims: enhanced mood, enhanced energy, and enhanced fat loss. The advertiser explained that, although no testing has been conducted on the product itself, caffeine is the key, most effective, ingredient in RP. Thus, the advertiser maintained that the scientific data on caffeine alone is sufficient to substantiate each of the core structure function claims, however, the advertiser also chose to submit scientific evidence on RP’s other active ingredients as additional support.³²

NAD has consistently held that the nature and extent of claims made by an advertiser should mirror the precision and specificity of the data relied on as substantiation.³³ It is important to note that although the Dietary Supplement Health and Education Act (“DSHEA”) allows structure function claims to appear on product packaging, so long as they are accompanied by the required DSHEA language,³⁴ both the Federal Trade Commission and NAD require that all advertising claims relating to a product’s impact on human health be supported by competent and reliable scientific evidence.³⁵

NAD first reviewed the claims in the context of the advertising and product packaging as a whole, taking into consideration the “Mood, Energy & Fat Loss Matrix” tagline, which is located just below the product name on both the product and product packaging. NAD determined that

³¹ See, Freeman Beauty Labs (Renewance Anti-Aging Chemical Peel), Report #4543R, *NAD/CARU Case Reports* (September 2006).

³² Specifically, the advertiser’s submission offered scientific studies on caffeine in support of its “Enhanced Energy” claim; scientific studies on caffeine, Vinpocetine, 5-HTP, PEA and St. John’s Wort in support of its “Enhanced Mood” claim; and scientific studies on caffeine, 5-HTP, and Yohimbine in support of its “Enhanced Fat Loss” claim.

³³ See, GlaxoSmithKline Consumer Healthcare (Aquafresh Advanced Toothpaste), Report #4769, *NAD/CARU Case Reports* (December 2007); POM Wonderful, LLC (Pom Wonderful® Pomegranate Juice), Report #4468, *NAD/CARU Case Reports* (April 2006).

³⁴ “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” Dietary Supplement Health and Education Act of 1994.

³⁵ *Dietary Supplements: An Advertising Guide for Industry*, FEDERAL TRADE COMMISSION, <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.pdf> (“FTC Guide”), at 3 (“When evaluating claims about the efficacy and safety of foods, dietary supplements and drugs, the FTC has typically applied a substantiation standard of competent and reliable scientific evidence.”).

one reasonable interpretation of the claims at issue is that the RP drink – as formulated for sale – has been shown to enhance mood, energy and fat loss. The advertiser provided numerous studies on RP’s active *ingredients* and their properties, however, there is no evidence in the record that the product itself will have this effect. The advertiser failed to show that the ingredients in RP, as combined and formulated for sale, generate the three claimed benefits (enhances mood, energy, and fat loss). Therefore, the NAD concluded that the claims must, at the very least, be qualified as ingredient claims.

NAD reviewed the advertiser’s evidence to determine whether the evidence is sufficient to substantiate the three performance claims at issue, if qualified as ingredient claims.³⁶ As noted above, the advertiser contended that its scientific data on caffeine alone is sufficient to substantiate the product performance claims. Therefore, NAD only analyzed the additional data provided where the evidence presented on caffeine alone was insufficient to support the claim.

A. RP’s Mood Enhancing Capability

According to the advertiser, RP contains 5 active ingredients which promote mood enhancement: caffeine, Vinpocetine, 5-HTP, PEA and St. John’s Wort. It is important to note that a majority of the studies submitted in support of the advertiser’s mood enhancement claim did not evaluate the subjects’ mood per se. Instead, many of the studies focused on mental functions the advertiser considered relevant to mood, such as: sleep deprivation, cognitive and motor function, memory and depression. Although NAD agreed with the advertiser that study results showing a significant effect on mental functions is relevant to mood, NAD did not agree that the advertiser’s performance claims mirrored the results of its supporting studies. Therefore, NAD recommended the advertiser modify its “enhanced mood” performance claim to more clearly reflect the results demonstrated by the scientific evidence offered as support.

i. Caffeine & Mood

A majority of the caffeine studies submitted by the advertiser investigated the ingredient’s effect on sleep deprivation and mental alertness – only two of the studies mentioned “mood” as a focal point: the Robelin and Rogers Study³⁷ and the Smith Study (See Advertiser’s Position). In

³⁶ When reviewing product performance claims based on ingredient testing, the NAD often looks to the guidelines provided by the FTC to dietary supplement manufacturers. The FTC Guide specifically states that advertisers “should make sure that the research on which they rely is not just internally valid, but also relevant to the specific product being promoted and to the specific benefit being advertised.” The guidelines list a set of questions that the manufacturers should ask themselves concerning substantiation for the advertised benefits of their products. These questions include: “How does the dosage and formulation of the advertised product compare to what was used in the study? Does the advertised product contain additional ingredients that might alter the effect of the ingredient in the study? Is the advertised product administered in the same manner as the ingredient used in the study? Does the study population reflect the characteristics and lifestyle of the population targeted by the ad? If there are significant discrepancies between the research conditions and the real life use being promoted, advertisers need to evaluate whether it is appropriate to extrapolate from the research to the claimed effect.” *Dietary Supplements: An Advertising Guide for Industry*, FEDERAL TRADE COMMISSION, BUREAU OF CONSUMER PROTECTION (April 2001), at 16, <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.shtm>.

³⁷ In the Robelin Study, the subjects, who were moderate consumers of caffeine (on average 453 mg/day), were first deprived of caffeine and then given one of four treatments morning, afternoon, and night: PPP, CPP, CCP, and CCC

addition, NAD noted that the Robelin Study, which concluded that “all treatments in which caffeine were delivered significantly increased energetic mood and improved psychomotor performance relative to placebo,” was the only study which demonstrated that caffeine had an actual effect on the subject’s mood.³⁸ NAD also questioned whether the fact that the subjects were first deprived of their normal caffeine intake made these results less convincing.

In response to these concerns the advertiser first emphasized that, according to Dictionary.com, the word ‘mood’ can have the following meanings: a state or quality of feeling at a particular time; a distinctive emotional quality or character; a prevailing emotional tone or general attitude; a frame of mind disposed or receptive, as to some activity or thing; a state of sullenness, gloom, or bad temper. The advertiser contended that it would thus stand to reason that the effect of caffeine on any number of parameters vis a vis mental function does indeed affect mood. The advertiser further stated that it believes that if caffeine has a positive effect on those who are sleep deprived, then it indeed benefits mood.³⁹

For the reasons stated above, NAD found that the data provided with respect to caffeine’s impact on mood was insufficient to support the advertiser’s mood enhancement claims and therefore looked to the advertiser’s additional evidence.

ii. Vinpocetine & Mood

According to the advertiser, the submission provided NAD with a plethora of data demonstrating that vinpocetine consumption has significant effects on both cognitive and motor function in humans (particularly with respect to short-term memory enhancement). However, NAD questioned whether the conditions and results of the vinpocetine studies provide support for mood enhancement as promoted in the advertisements and product packaging for RP.⁴⁰

While NAD recognized that the studies provided significant insight as to the overall effect of vinpocetine on the central nervous system, NAD was not persuaded that the testing conditions (for example the dosages and the study populations) were close enough to the ingredients and use instructions for the RP beverage, to support the advertiser’s extrapolation of the results.

(where P=Placebo and C=Caffeine). Each caffeine dosage receive was 1.2 mg caffeine per kg of body weight, which the advertiser explained, is the approximate level of caffeine in one serving of ground coffee.

³⁸ The Smith Study simply concluded that the subjects who consumed breakfast had a more positive mood.

³⁹ The advertiser went on to explain that it does not believe that pre-deprivation of caffeine makes the results of the Robelin Study ‘less’ or ‘more’ convincing. Instead, the advertiser stated that the deprivation of caffeine prior to the treatment was just one model to determine if caffeine affects mood. The advertiser argued that caffeine deprivation is but one perturbation out of many in which caffeine may have a significant impact, concluding that it simply depends on the experimental conditions upon which the person conducting the study wants to examine the supplement, drug, ingredient or combination thereof.

⁴⁰ For example: the 1985 Subhan and Hindmarch Study reported that only females treated with 40 mg vinpocetine (compared to treatments of 10 and 20 mg vinpocetine) demonstrated a significant improvement in memory; the 2007 Valikovics Study, which concluded that vinpocetine improved the cerebrovascular reserve capacity as well as favorably influenced cognitive status and general condition, was conducted on patients with ischemic stroke, mild cognitive impairment and chronic hyperfusion – which do not represent the target market for RP.

iii. 5-HTP, PEA, St. John's Wort & Mood

Of the 5 active ingredients listed to support mood enhancement, NAD found the studies on 5-HTP, PEA, and St. John's Wort to be the most relevant. As explained in detail in the advertiser's position above, these three ingredients have been shown to be effective in treating mild to moderately severe depression.

Although NAD found these studies provide evidence that 5-HTP, PEA, and St. John's Wort have a positive effect on mild to moderate depression, NAD was concerned with two significant points. First, the majority of subjects tested in the study were individuals who suffered from mild to moderate depression and, therefore, NAD questioned whether the study population reflected the RP target market. Second, NAD was concerned with whether or not the levels of 5-HTP, PEA and St John's Wort contained in RP were comparable to the dosages applied in the supporting studies.⁴¹

NAD has consistently held that product performance claims must accurately convey the nature and extent of the scientific research, as well as the relevance of such research, to the product. NAD noted that, in addition to its concern that the strength of the performance claim did not match the level of scientific support, the advertiser also failed to address the fact that the combination of ingredients may alter or diminish the efficacy of the individual ingredients – causing NAD to further question whether it was appropriate for the advertiser to extrapolate the findings of the studies in support of its product performance claims.

After a thorough review of the studies submitted on all 5 ingredients, NAD recommended that the advertiser discontinue any “enhanced mood” claims for the product itself. Further, in any future advertising, NAD recommended that the advertiser expressly qualify any ingredient claims in a way that communicates to consumers that the claim's support is based upon studies concluding that certain *ingredients* have been shown to be effective in the treatment of the specific cognitive functions or symptoms described in the studies (i.e., mood, mental fatigue, sleep deprivation, memory loss, and mild to moderate depression).

B. RP's Energy Enhancing Capability

NAD was also concerned about the truthfulness of the overall message communicated by the challenged advertising (i.e., that it is the combination of ingredients in the drink, rather than simply the added caffeine, which generates the drink's “enhanced energy”). Unlike the other claims in this case, the advertiser stated that the only RP ingredient related to the enhanced energy claim is caffeine. The advertiser submitted six studies on caffeine demonstrating the ingredient's ability to enhance exercise time to exhaustion as well as its function as an athletic performance aid. (See Advertiser's Position). Caffeine is a well known stimulant often used to

⁴¹ In the Sabelli and Javaid 1995 Study on PEA the subjects received 10-60 mg of PEA per day (in combination with 10mg/day selegiline to prevent rapid PEA destruction), the 1998 Miller Study on St. John's Wort stated that clinical studies on this ingredient typically utilize 300 mg three times a day and the Tangiano Study on 5-HTP used 900 mg of 5-HTP per day.

restore alertness or boost energy levels, thus NAD did not take issue with the concept that a drink made with caffeine would enhance energy.

However, NAD was troubled by the fact that one serving of RP (each bottle of RP is two servings) contains merely 125 mg caffeine (the amount of caffeine in a typical cup of coffee). In contrast, the studies submitted to the record in support of the enhanced energy claim employed much higher levels of caffeine. For example, the seminal study on caffeine performed by Dr. David Costill gave test subjects 330 mg/caffeine and the 1992 Collomp study used 250 mg caffeine. These dosage levels are at least twice the amount of caffeine found in RP. The other five studies applied a dosage of (2.5, 5, 7, 9 or 10) mg caffeine per kg body weight to each test subject. NAD converted kilograms to pounds in order to compare the approximate dosage levels in these studies to the level of caffeine in RP and found that even if the test subjects weighed 120lbs (35 lbs below the average female weight in the U.S.) only the 2.5 mg/kg of body weight dosage⁴² (Park et al., 2001) would be close enough to the RP 125 mg/caffeine to be relevant. The remaining studies used at least double (more often triple) the amount of caffeine found in one serving of RP.⁴³

According to the FDA stimulant monograph for caffeine, a dose of 100-200 mg caffeine taken every 3-4 hours “helps restore mental alertness or wakefulness.” The NAD recognized that the level of caffeine in one serving of RP is significant in that it falls within the FDA’s range. Thus, the advertiser may tout the fact that certain *ingredients* in RP can enhance energy.

C. RP’s Fat Loss Enhancing Capability

The advertiser did not submit any evidence that RP, as formulated for sale, enhances fat loss. Rather, the advertiser argued that three key ingredients: caffeine, yohimbine, and 5-HTP support the advertiser’s “enhanced fat loss” claim. The seriousness of the growing obesity epidemic in the U.S. and the potential vulnerability of the target audience have caused both the NAD and the FTC to carefully scrutinize weight and fat loss claims to ensure that they are truthful, accurate and supported by competent and reliable scientific evidence.

NAD reviewed the scientific evidence for each ingredient and concluded that while there is evidence that these ingredients may indirectly have an effect on fat loss, the level of supporting evidence was insufficient to provide a basis for the advertiser’s fat loss claims.

i. Caffeine & Fat Loss

⁴² NAD noted that 1 kilogram = 2.20462262 pounds, therefore a female weighing 120lbs or 54.5 kg would have received 136.25 mg caffeine in the Park Study.

⁴³ NAD noted that 1 kg is equal to approximately 2.2 lbs, thus a person weighing 120 lbs weighs approximately 54.5 kg. The second Costill Study used 9 mg caffeine/ kg of body weight (a subject weighing 120 lbs would receive 490 mg caffeine), Park 2001 used either 5mg or 2.5 mg caffeine/ kg of body weight (a subject weighing 120 lbs would receive 272.5 mg caffeine and 136.25 mg caffeine respectively), Anselme 1992 used 7mg caffeine /kg of body weight (a subject weighing 120 lbs would receive 381.5 mg caffeine), and Le Corre et al., 2004 used 5 or 10 mg caffeine / kg of body weight (a subject weighing 120 lbs would receive 272.5 mg or 545 mg caffeine respectively).

According to the advertiser, there is a plethora of data showing the lipolytic⁴⁴ and thermogenic⁴⁵ effects of caffeine. In particular the advertiser submitted four studies: The Dulloo Study; the Astrup Study; the Arciero Study; and the Acheson Study in support of its claim.⁴⁶

NAD does not question that caffeine may indirectly increase fat loss by increasing the body's metabolic rate. However, as with the advertiser's enhanced energy claims, NAD was concerned with the overall strength of the advertiser's evidence. Here again, NAD noted that RP contains a mere 125 mg caffeine per serving, yet two of the four studies submitted in support of the advertiser's fat loss claims used almost double that amount. Thus, although the advertiser was able to show that caffeine has the ability to increase the metabolic rate (which may indirectly lead to fat loss) there was no evidence that the 125 mg of caffeine in RP will sufficiently increase the body's metabolic rate to indirectly enhance fat loss.

ii. Yohimbine, 5-HTP & Fat Loss

The study submitted on yohimbine tested 20 elite male athletes who consumed two, 20 mg dosages of yohimbine a day, for 21 days. The studies on 5-HTP tested women with a body mass index ("BMI") of 30 – 40 at a dosage of approximately 645 mg 5-HTP per day, and 900 mg 5-HTP per day respectively.⁴⁷ As with the studies supporting mood enhancement, NAD was troubled by the uniqueness of the studies' subjects (elite male athletes) and the fact that the dosage levels indicated in the advertiser's supporting studies for yohimbine and 5-HTP did not mirror the dosage levels in the product.⁴⁸

After a thorough review of the advertiser's evidence on caffeine, yohimbine, and 5-HTP with respect to fat loss, the NAD concluded that the evidence was not sufficient to support the claims. Therefore, NAD recommended that the advertiser discontinue any fat loss claims for the product

⁴⁴ Lipolysis was defined by the advertiser as the splitting or breaking down of fatty acids.

⁴⁵ Thermogenesis is the process of heat production in organisms. There is exercise-associated thermogenesis and non-exercise associated thermogenesis; Thermogenesis can also be achieved by artificial means by increasing the body's metabolism, thereby increasing its core temperature. It is becoming common for people to use thermogenic substances to help control fluctuation in weight.

⁴⁶ The Dulloo Study, which applied 100 mg caffeine to test subjects, concluded that "caffeine at commonly consumed dosages can have a significant influence on energy balance and may promote thermogenesis in the treatment of obesity;" (2) The Astrup Study, which tested approximately 350 mg caffeine on young subjects and 295 mg caffeine on old subjects, concluded that caffeine increases energy expenditure in a dose-dependent manner; (3) The Arciero Study, which studied 12 men who consumed 200 mg caffeine, demonstrated a 7% increase in metabolic rate over three hours; and (4) The Acheson Study (where 8 men were given 10 mg caffeine per kg of body weight) concludes that although the role of caffeine in lipid metabolism is related in part to an increase in oxidation, there is not a linear relationship between caffeine ingestion and a pure increase in fatty acid burning.

⁴⁷ With respect to the 5-HTP studies, NAD noted that the BMI range of 30-40 is considered "obese" by the World Health Organization. A woman who is 5'4" and weighs 180 lbs would have a BMI of 30. This means that the first 5-HTP study, which applied 8mg 5-HTP /kg of body weight, would at the very least have used 645 mg 5-HTP as its daily dosage. The second 5-HTP study applied 900 mg 5-HTP per day. The dosages in these studies are very high and therefore the NAD questioned the relevance of these results as support for RP enhanced fat loss claim.

⁴⁸ In addition, NAD was disappointed that the advertiser did not address its concerns regarding the combination of ingredients forcing the NAD to question the appropriateness of the extrapolated findings.

itself and qualify any future ingredient claims by disclosing that the *ingredients* in RP may indirectly enhance fat loss by increasing metabolism.

II. “Designed Especially for Women”

The advertiser target markets its RP energy drink to women in an attempt to reach the largely untapped female market for energy drinks. NAD respects the fact that companies employ various types of marketing and advertising techniques in order to reach a certain portion or demographic of the market place. As with all claims, NAD first reviewed the “designed especially for women” claim in the context of the product packaging and print advertising to determine the message communicated to consumers. NAD concluded that the advertiser’s use of the word “designed” implies that the product formula or ingredients were somehow tailored to meet the particular needs of a woman. NAD then considered whether the advertiser provided sufficient evidence to support this implied claim.

NAD noted that the RP formula contains lower dosages of the active ingredients, which the advertiser explained was intended to compliment the female’s general lower body mass and address the common female concern that an energy drink will leave her feeling “jacked up”. In particular, RP contains a significantly lower amount of yohimbine than the other Redline energy drink products. Yohimbine, which is known for its energizing effect, can also cause anxiety, increased heart rate, dizziness and nausea – symptoms often acquainted with having too much caffeine and commonly described as feeling “jacked up.” By altering the ingredient levels in RP to match a female’s tolerance, NAD determined that the advertiser did in fact design RP for women.

Therefore, NAD found that the advertiser provided a reasonable basis for its claim, “designed especially for women.”

III. Puffery: The World’s Most Effective Energy Drinks

As a general rule, in determining whether an advertising slogan is an objectively provable claim, NAD examines the disputed language in context to determine whether it is likely to be understood as a factual claim for which an advertiser has objective proof, or puffery.⁴⁹ Whether a specific claim falls within puffery’s protective reach is largely dependent on what is communicated, i.e., what, if any, consumer expectations are created. Obvious hyperbole, exaggerated displays of a manufacturer’s pride in its product and other non-provable claims, the truth and accuracy of which cannot be determined, have been found to constitute puffery. Conversely, where an objective representation is made (i.e., termed in fact rather than opinion) regarding the performance or other tangible attributes of a product, that is sufficiently specific and material enough to create expectations in consumers, then substantiation for the claim is required.⁵⁰

⁴⁹ See, Alcoa, Inc. (Reynolds Handi-Vac Vacuum Sealer), Report #4823, *NAD/CARU Case Reports* (April 2008).

⁵⁰ See, Lenovo (United States), Inc., (Personal Computers), Report #4820, *NAD/CARU Case Reports* (March 2008); POM Wonderful, LLC (POM Wonderful Pomegranate Juice), Report #4468, *NAD/CARU Case Reports* (April 2006); Real TIME Media (Online Promotions), Report #3755, *NAD Case Reports*, (May 2001).

VITAL PHARMACEUTICALS, INC.

Redline Princess

Page: 19

In determining whether a claim is ‘puffery’ or an objective, measurable claim, NAD considers several factors including: whether the representations concern general matters that cannot be proven or disproved; whether the statements are distinguishable from representations of specific characteristics that are measurable by research or test; or whether the wording uses expressions of opinion that will be discounted by the buyer.⁵¹

NAD examined the phrase, “The World’s Most Effective Energy Drinks” and determined that, in the specific context in which the phrase appears it is unlikely to be interpreted as a statement of fact. In reaching this conclusion, NAD noted that its decision was dependent upon the fact that the phrase, “The World’s Most Effective Energy Drinks,” only appears on the home page of the Redline website (www.redlinrush.com), which depicts the entire Redline product line but does not contain any product performance claims (enhance mood, energy, and fat loss).

However, NAD cautioned the advertiser that use of the expression “most effective” may be problematic in other contexts. NAD explained that a slogan or tagline which specifically denotes RP as the “most effective” energy drink (whether in the world or in the universe) could be considered a statement of fact if the phrase “most effective” appeared alongside the tangible attributes listed in RP’s print advertisements and product packaging (i.e., enhance mood, energy, and fat loss). Under those circumstances, the advertiser would have to demonstrate that RP was more effective in those respects when compared to the leading energy drinks in the market.⁵²

Accordingly, NAD concluded that the claim, “The World’s Most Effective Energy Drinks,” as it appears, standing alone and without further description, in the monadic context on Redline’s home page is puffery.

Conclusion:

NAD found that, although the advertiser provided numerous studies on RP’s active ingredients and their properties, there is no evidence in the record that the product itself will “enhance mood,

⁵¹ Id.

⁵² In support of its argument that “The World’s Most Effective Energy Drinks” was puffery, the advertiser stated that how “effective” an energy drink is depends upon intrinsic characteristics and personal preference. The advertiser then compared its use of the word “effective” to use of the word “better” in *Pizza Hut* where the court found the statement “Better Ingredients, Better Pizza” to be unquantifiable, concluding that “what makes one food ingredient ‘better’ than another comparable ingredient, *without further description* (emphasis added), is wholly a matter of individual taste or preference not subject to scientific quantification.” NAD, however, did not fully agree with the advertiser’s argument. Instead, NAD stated that the Court in *Pizza Hut* reviewed the claim in two phases: standing alone and in the context of its advertising. NAD noted that while the Court held “Better Ingredients, Better Pizza” – standing alone – constituted non-actionable puffery it also concluded that: “The slogan, when used in combination with the comparison ads, gives consumers two fact-specific reasons why Papa John’s ingredients are ‘better.’ Consequently, a reasonable consumer would understand the slogan, when considered in the context of the comparison ads, as conveying the following messages: Papa John’s uses ‘better ingredients,’ which produces ‘better pizza’ because Papa John’s uses ‘fresh packed’ tomatoes, fresh dough, and filtered water. In short, Papa John’s has given definition to the word ‘better.’ Thus, when the slogan is used in this context, it is no longer mere opinion, but rather takes on the characteristics of a statement of fact.”

VITAL PHARMACEUTICALS, INC.

Redline Princess

Page : 20

energy, and fat loss” and consequently, NAD recommended that the advertiser’s product performance claims be discontinued.

After reviewing the advertiser’s evidence regarding RP’s individual ingredients, NAD agreed that certain ingredients in RP may have an effect, either directly or indirectly, on mood, energy and fat loss. Therefore, while the advertiser could not support its product performance claims, NAD found that the advertiser can support limited ingredient claims for RP. Accordingly, NAD recommended that the advertiser modify its claims to clearly convey that it is the ingredients in RP which provide advertised benefits. In particular, NAD stated that any future ingredient claims regarding “enhanced mood” should be qualified in order to communicate to consumers that the supporting evidence shows that certain *ingredients* in the product have been shown to be effective in improving certain specific cognitive functions or symptoms measured in the corresponding studies. In addition, NAD recommended that any ingredient claims regarding “enhanced fat loss,” disclose that the ingredients in RP, by increasing metabolic rate, may help facilitate fat loss.

NAD found that the advertiser provided a reasonable basis to support the claim, “designed especially for women.” Finally, NAD concluded that the claim, “The World’s Most Effective Energy Drinks,” in the monadic context in which it appears on Redline’s home page, is likely to be understood as puffery. However, NAD cautioned that in combination with any performance claims, the claim is likely to be viewed as an objectively provable claim and as such, would require support.

Advertiser’s Statement:

VPX is pleased that the NAD recognizes that “The World’s Most Effective Energy Drinks” is puffery and that VPX has provided a reasonable basis to support the claim “designed especially for women.” Further, VPX is pleased that the NAD recognizes the credibility of the scientific evidence underlying the ingredients used in REDLINE PRINCESS®. Although VPX disagreed with other aspects of the decision, VPX will consider NAD’s recommendations in all future advertising. (**#4868 KLF, closed 07/09/2008**)