

The evidence underpinning sports performance products: a systematic assessment

Journal:	BMJ Open
Manuscript ID:	bmjopen-2012-001702
Article Type:	Research
Date Submitted by the Author:	19-Jun-2012
Complete List of Authors:	Heneghan, Carl; Oxford University, Primary Health Care Howick, Jeremy; University of Oxford, Primary Care Health Sciences O'Neill, Braden; University of Oxford, Primary Care Health Sciences Gill, Peter; University of Oxford, Primary Care Health Sciences Lasserson, Daniel; University of Oxford, Department of Primary Care Health Sciences Cohen, Deborah; BMJ, Davis, Ruth; University of Oxford, Department of Primary Care Health Sciences Ward, Alison; University of Oxford, Department of Primary Care Health Sciences Smith, Adam; BMJ, Jones, Greg; BMJ, Thompson, Matthew; University of Oxford, Primary Health Care
Primary Subject Heading :	Sports and exercise medicine
Secondary Subject Heading:	Evidence based practice, Nutrition and metabolism, Sports and exercise medicine
Keywords:	SPORTS MEDICINE, PRIMARY CARE, EPIDEMIOLOGY

SCHOLARONE™ Manuscripts



Sports Adverts

The evidence underpinning sports performance products: a systematic assessment

Carl Heneghan, ¹Jeremy Howick, ¹Braden O'Neill, ¹Peter Gill, ¹Dan Lasserson, ¹Deb Cohen, ² Ruth Davis, ¹ Alison Ward ¹ Adam Smith, ² Greg Jones, ² Matthew Thompson, ¹

¹ Centre for Evidence-Based Medicine, Department of Primary Care Health Sciences, University of Oxford

² BMJ, London

Correspondence: Carl Heneghan

Diphc.ox.ac.uk carl.heneghan@phc.ox.ac.uk

Abstract 288

Word count 2,781

Abstract

Background

Claims regarding improved sports performance made by advertisers of a broad range of sports related products, and the quality of the evidence on which these claims are based is not well understood.

Methods

We analysed magazine adverts and associated websites of a broad range of sports products. We searched for references supporting the performance and/or recovery claims of these products. We critically appraised the methods in the retrieved references by assessing the level of evidence and the risk of bias. We also collected information on the included participants; adverse events; study limitations; the primary outcome of interest and whether the intervention had been retested.

Results

We viewed 1,035 web pages and identified 431 performance enhancing claims for 104 different products. We found 146 references that underpinned these claims. More than half (52.8%) of the websites that made performance claims did not provide any references, and we were unable to perform critical appraisal for approximately half (72/146) of the identified references. None of the references referred to systematic reviews (level 1 evidence). Of the critically appraised studies, 84% were judged to be at high risk of bias. Randomization was used in just over half of the studies (58.1%), allocation concealment was only clear in five (6.8%) studies; and blinding of the investigators, outcome assessors, or participants was only clearly reported as used in 20 (27.0%) studies. Only three of the 74 (2.7%) studies were judged to be of high quality and at low risk of bias.

Conclusion

The current evidence is not of sufficient quality to inform the public about the benefits and harms of sports products. There is a need to improve the quality and reporting of research a move towards using systematic review evidence to inform decisions.

Introduction

Exercise is important for improving overall health across a variety of conditions. [1] The promotion of exercise is therefore an important public health priority, particularly for the 'economically and socially disadvantaged'. [2]

Currently, the public are faced with a large number of adverts that make claims about enhanced performance and recovery for a wide range of products including drinks, supplements, clothing and footwear. Regulators require that marketing communications containing health claims must be supported by documentary evidence and 'must not mislead consumers by exaggerating the capability or performance of a product'. [3] In spite of this, some adverts for sports drinks have previously been shown to mislead the public into incorrectly concluding that the drinks contained no carbohydrates or additives. [4] In addition, whilst some supplements have been shown to potentially improve performance, many have no proven benefits and may cause serious side effects. [5] The marketing of sports products has become a multibillion dollar industry, [6] and the consumption of so called energy drinks is increasing year on year [7] but research in this area has previously been labelled as methodologically poor. [8]

The current confusion as to which products are actually beneficial for sports performance is highlighted by the European Food Safety Authority (EFSA) decision to approve certain products, such as carbohydrate-electrolyte drinks to enhance water absorption during exercising and maintain endurance performance, whilst not approving a variety of other products; including L-carnitine, glutamine or typrosine which claim to aid muscle recovery. [9] We therefore aimed to assess the extent and nature of claims regarding improved sports performance made by advertisers of a broad range of sports related products, and the quality of the evidence on which these claims are based.

Methods

In order to obtain a representative sample of adverts applicable to the general population, we searched the top 100 general magazines and the top 10 sport and fitness magazines in the UK and US for the month of March 2012 according to the Magazine Audit Bureau of Circulations (ABCs). This selection of magazines is distributed to over 30 million customers in the UK alone. We excluded magazines specifically aimed at body building. One reviewer (RD) examined each page of included magazines to identify adverts. All adverts were then assessed by second

reviewers (AW, CH, MT, RD) as either relevant to sports or not. A third round of reviews (CH, RD) assessed adverts that included specific performance enhancing claims.

Inclusion and exclusion criteria

We included oral sports drinks, oral supplements, footwear, and clothing or devices (such as wristbands). To be included, adverts had to make a claim related to sports performance (defined as improvement in strength, speed, endurance etc.), or enhanced recovery related to sports (e.g., reduced muscle fatigue). We excluded adverts related to purely weight loss, skin or beauty products, sports equipment (e.g. bicycles), and classified adverts. We therefore only included adverts from the actual manufacturer of products rather than suppliers

We then analysed the websites of any products making enhanced performance or recovery claims. A data extraction template (MS Word) was used to extract data from each web page, and five reviewers (BON, CH, DL, MT, PG) inserted page number, url and screen shots of all web pages viewed with the associated claims. To reduce errors we directly cut and paste any claims and searched the web pages for any references related to these claims. We compiled a database of all retrieved references and then two reviewers (AS, GJ) emailed all manufacturers with the claims and the associated references asking them 1) to confirm whether our list of claims and retrieved references was complete; 2) whether other data existed to support the claims; 3) If additional data was published could they provide us with the relevant references, and 4) If the research was unpublished, could they supply us with a copy of the report.

Data extraction:

We extracted the following data (from both the magazine and the websites) of included sports products into Microsoft Excel: product category (i.e. sports drinks, supplements, footwear, clothing or devices); website; number of pages viewed; number and type of enhanced performance claim(s); references cited for the claims; qualifiers related to the claim (e.g., such as 'should be used in conjunction with a healthy diet and training programme'); and whether the product was endorsed/backed by a sports person or team. One reviewer (JH) acted as custodian of the data and checked all entries for consistency.

Quality assessment

We obtained full text copies of all cited references and assessed them using the CEBM Levels of Evidence. [10] For treatment benefits the highest level of evidence for claim is a systematic

review of randomized controlled trials or an n-of-1-trial (Level 1) followed by randomized trials (Level 2) and non-randomized studies (level 3). The lowest level of evidence is mechanistic reasoning, which includes expert opinion and animal studies (Level 5).

We assessed whether a study was appropriate for critical appraisal (recording the reasons if it was not appropriate). Six reviewers (BON, CH, DL, JH, MT, PG) then recorded the presence or absence of the following elements of critical appraisal: a clear hypothesis, control group, power calculation, randomization, allocation concealment, intention to treat, blinding (investigator and/or subjects), and sports outcome (subjective or objective) that demonstrates improved performance or recovery. Extracted data was checked independently by a second reviewer. One reviewer (CH) then assessed included studies using the Cochrane method for risk of bias, assessing studies as high, unclear or at low risk of bias, which was checked by a second reviewer (JH). [11] Discrepancies were resolved by consultation with other reviewers.

We also collected information on the participants involved in the included trials (categorised as 'regular people' who do not exercise or compete seriously in sport; amateur athletes including 'regular people' who exercise seriously, and sports professionals); adverse events; whether study limitations were discussed; the primary outcome of interest and whether the intervention had been retested in a subsequent trial or test group.

We summarised data by raw counts and continuous data with medians and ranges, and for dichotomous data we presented percentage and associated 95% Confidence intervals. We analysed data using Microsoft Excel.

Results

We examined 92 magazines containing 1,807 adverts, of which 615 (34%) advertised sports products (Figure 1). After excluding 380 adverts which were not product specific (i.e. individual shop adverts) we included the remaining 235 advertised sports products in the analysis. From these, 54 (23%) different products made 113 enhanced performance or recovery claims. Of these, we found only 3 (2.7%) references for one product (ACCELERADE) t to back up these claims which were appropriate for critical appraisal, and 22 (42%) products which were endorsed by athletes. Six (12%) products made direct comparisons to other products in their advertised claims and three provided disclaimers. All of the latter were US based products, and cited the US Food and Drug

Administration (FDA) in disclaimers: 'these statements have not been evaluated by the FDA. This product is not intended to diagnose treat, or cure disease.'

We then assessed products' websites for claims (one product on reassessment was designated a dietary product) and viewed a total of 1,035 web pages (Web Appendix 1). From these we identified 431 (median 7, range o to 65) performance enhancing claims for 104 different products, and a total of 146 references (range o to 46) associated with these claims (Figure 1). More than half (52.8%) of the sites that made claims did not provide any references. One site (www.poweradegb.com/) provided approximately 1/3rd (46) of the references found, of which 24 (52%) were appropriate for critical appraisal.

We contacted 42 companies and received responses from 16, of which two were unwilling to share their research [Panache and New Balance], one provided a video of the product in use and said this was "sufficient" [Nike], one pointed to the work of one researcher but did not answer whether the company had any research on its actual product [Merrell]), one responded they would get back but didn't, one declined due to staff absence and one directed us back to their website (Web Appendix 1). In total we received additional referenced material from nine companies; obtaining two published [12, 13], one in press [14] and two unpublished studies that we included in the analysis. [15, 16] We also received four bibliographies: one of these was a comprehensive bibliography of Lucozade associated research (Web Appendix 2), which arrived outside of the time lock, and due to its size, we analysed separately in an associated article. [cross ref BMJ analysis piece]

We were unable to perform critical appraisal for approximately half (72) of the references identified (Figure 1). Of note, five references could not be identified despite extensive searching involving an information specialist, and eight were animal studies [17-24] including a comparative study of different diets on rat metabolism published in 1930. [21] None of the 74 studies which were critically appraised were systematic reviews (level 1 evidence), and approximately half of the studies were categorized as level 3 evidence (non-randomised studies). As a result, 84% of the critically appraised studies were judged to be at high risk of bias. The presence of this level of bias means the conclusions are likely to change based on future (high quality) research. [11]

Table 1 shows in the 74 studies the total number of participants was 2,031 (median 15): two thirds (1,310 65%) were male. Two studies provided a quarter of the participants (n= 505). [25, 26] Excluding these two the average number of participants per study was 16 (range 5 to 69). Nearly

half (48.6%) were classified as 'regular people' who exercise and 39.2% as endurance/serious athletes and 10.8% professional sports people (in one study it was unclear who the participants were. Nearly three times (423:146) as many sportspersons or teams endorsed products than evidence was made available.

Randomization was used in just over half of the studies (43/74, 58.1%), allocation concealment was only clear in five (6.8%) studies; and blinding of the investigators, outcome assessors, or participants was only clearly reported as used in 20 (27.0%) studies. The majority of studies (83%, 95% CI 73 to 92%) used a surrogate outcome (rather than a direct outcome of sports performance or recovery) and only two studies (2.7%, 95% CI o to 25%) repeated the intervention in the study protocol. [27, 28] Overall the majority of studies reported a clear hypothesis; but only four studies reported they used a power calculation (5%, 95% CI o to 28%), and very few studies (11%, 95% CI o to 33%) discussed limitations of their studies.

We were unable to perform meta-analysis of individual outcomes across specific products due to the heterogeneity, poor reporting and the sheer number of outcomes reported across the studies.

Three of the 74 (4.1%) studies were judged to be of high quality and at low risk of bias. [29-31] In the first of these, Berven et al, [29] the methods of blinding were clearly reported: 'capsules had the same size and appearance and were indistinguishable from the active capsules'. In addition, the study clearly reports intention to treat: 'clinical and laboratory data were analysed in all included subjects (based on "intention to treat"). In addition, a per-protocol analysis was performed'. In the second study, Roffe et al [31] clearly report the randomisation procedure: 'randomisation was performed in blocks of 10....The randomisation code was not known to the investigators who gave out the sachets. The code remained concealed from everyone except the pharmacist who prepared the sachets....' The third was one of the few studies to report a power calculation: 'A priori power analysis revealed power values of 0.14, 0.71, and 0.99 for small (0.25), moderate (0.75), and large effect sizes (1.25), respectively, for the n size used in the study. These findings indicate that the n size used in the present study was sufficient to detect significant differences among groups.' [30] Of note, all three of these studies reported no significant effects of the intervention.

Discussion

There is a striking lack of evidence to support the vast majority of sports related products which make claims related to enhanced performance or recovery, including drinks, supplements and footwear. Half of all websites for these products provided no evidence for their claims, and of those that do, half of the evidence is not suitable for critical appraisal. No systematic reviews were found and overall the evidence base was judged to be at high risk of bias. Half of the trials were not randomised and only 7% reported adequate allocation concealment. We found only three trials that were reported with sufficient details to be judged high quality and free from bias.

The absence of high quality evidence is worrying. For instance, investigations have shown that in trials which did not use allocation concealment (compared to those that did) the effect estimates were 40% larger, [32] and results fluctuate widely above and below the estimates. [33] In terms of blinding it is well known 'psychological effects could arise from participants' knowing that they have received a "promising" new treatment;' [34] in terms of assessors not being blinded this also presents substantial room for bias: 'outcome assessors with inclinations for or against any of the interventions being compared may make biased assessments.' [34] The placebo effect of carbohydrate drinks, which has been shown previously, makes blinding especially important. [35] Competitive endurance cyclists told they were receiving a carbohydrate sports drink, when in fact it was water, performed 2% better than whey they were told the truth. In addition, in a study that tested the effect of carbohydrate ingestion in male trained volunteers, increased time to exhaustion was significantly improved when participants and researchers knew the capsule content, but not in the double blind condition. [36]

Combining these problems with the fact no systematic reviews were found means it is virtually impossible for the public to make informed choice about the benefits and harms of advertised sports products based on the available evidence. Yet, a simple search of PubMed (http://www.ncbi.nlm.nih.gov/pubmed/) reveals a number of systematic reviews that could be used to better inform the public: a meta-analysis by Vandenbogaerde, included 88 randomized crossover studies of carbohydrate supplements with or without protein before and/or during exercise provided 155 estimates for performance effects. [37] Of concern is this study reports a funnel plot which shows 'asymmetrical scatter is very likely the result of a publication trend towards positive effects'. [37] Systematic review may come to conclusions that are different to those of individual studies. For instance, a systematic review of the effect of exercise-induced dehydration on time—trial performance concludes that relying in thirst sensation to gauge the need for fluid replacement maximises cycling time trial performance. [38]

We found that very few trials (2.7%) repeated the interventions under study conditions. In treatment trials repeating the intervention allow estimation of the individual responses takes account of regression to the mean and assesses the reliability of the effect measure. [39] The lack of power calculations in studies is also concerning, the sample should be large enough to be able to detect a statistically significant effect; however, the exact size of the study to detect a meaningful effect was seemingly left to chance in most studies. Moreover, many studies used a surrogate outcome of performance or recovery, and undertook studies within laboratory settings which limits the validity of the studies as "laboratory studies assessing the impact of certain interventions on athletic performance can produce results that have no relevance to the real athletic world." [40]

Some limitations of the present study are worth discussing. We attempted to identify a representative sample of products, but it is possible the products we analysed are at the worst end of the spectrum. To avoid 'cherry picking,' we undertook a search for a broad range of products. The number of adverts and the webpages we assessed required a number of reviewers for this task. We did not give the manufacturers much time to respond to requests for information, given more time a number may have provided more references. Our assessment of whether a claim was actually performance enhancing was subjective. Yet no manufacturer responded that any of the claims were incorrectly identified for their products. We also did not investigate heterogeneity of effects or publication bias as the number of outcomes and the substantial variation in these outcomes means it was not possible to combine or undertake such analyses

We therefore conclude that the current evidence is not of sufficient quality to inform the public about the benefits and harms of sports products. There is a need to improve the quality of the research conducted in this area and its reporting, and a move towards using systematic review evidence across the board for decision making.

Acknowledgements

We would like to acknowledge the BMA library for their help in obtaining full text papers and Mary Hodgkinson for help in compiling the databases of retrieved references.

Conflicts of interest

"All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

References

- 1. van Gelder Bm Fau Tijhuis, M.A.R., et al., *Physical activity in relation to cognitive decline in elderly men: the FINE Study.* (1526-632X (Electronic)).
- 2. Haskell Wl Fau Blair, S.N., J.O. Blair Sn Fau Hill, and J.O. Hill, *Physical activity: health outcomes and importance for public health policy.* (1096-0260 (Electronic)).
- code, C. Committee of Advertising Practice. 2012 25th May 2012]; Available from: http://www.cap.org.uk/The-Codes/CAP-Code-CAP-Code-
 ltem.aspx?q=CAP+Code+new General+Sections 03+Misleading+advertising Rules Exagger ation#c74.
- 4. News, M.E. *Sports drink ad misleading*. 25th May 2012]; Available from: http://menmedia.co.uk/manchestereveningnews/news/s/153/153627 sports drink ad mis leading.html.
- 5. Jenkinson Dm Fau Harbert, A.J. and A.J. Harbert, *Supplements and sports*. Am Fam, Physician, 2008. **78**(9): p. 1039-46.
- 6. Meadows-Oliver M Fau Ryan-Krause, P. and P. Ryan-Krause, *Powering up with sports and energy drinks*. (0891-5245 (Print)).
- 7. Grosz, A. and A. Szatmari, [The history, ingredients and effects of energy drinks]. Orv Hetil, 2008. **149**(47): p. 2237-44.
- 8. Coombes Js Fau Hamilton, K.L. and K.L. Hamilton, *The effectiveness of commercially available sports drinks.* (0112-1642 (Print)).
- 9. Starling, S. *EFSA delivers sports market blow: Consultant*. 29th May 2012]; Available from: http://www.nutraingredients.com/Regulation/EFSA-delivers-sports-market-blow-Consultant.
- * OCEBM Levels of Evidence Working Group: Jeremy Howick, I.C., Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, Hazel Thornton, Olive Goddard and Mary Hodgkinson. *The Oxford 2011 Levels of Evidence* 2011 30th May 2012]; Available from: http://www.cebm.net/index.aspx?o=5653.
- 11. Higgins, J.P., et al., *The Cochrane Collaboration's tool for assessing risk of bias in randomised trials.* BMJ, 2011. **343**: p. d5928.
- 12. Campbell, C., et al., *Carbohydrate-supplement form and exercise performance*. Int J Sport Nutr Exerc Metab, 2008. **18**(2): p. 179-90.
- 13. Menetrier A Fau Mourot, L., et al., *Compression sleeves increase tissue oxygen saturation but not running performance.* (1439-3964 (Electronic)).
- 14. Soop, M., et al., *Co-ingestion of whey protein and casein in a mixed meal demonstration of a more sustained anabolic effect of casein.* (1522-1555 (Electronic)).

- 15. Unknown, Effect of a Electrolyte replacement beverage compared with a commercially available Carbohydrate supplement on the rate of fat oxidation during moderate-intensity cycle ergometry exercise. unpublished 2010.
- 16. Unknown, Summary of the Study on the influence from compression sleeves worn during short-time intensive effort on lactatemia. Unpublished Compressport Medical Study, unknown.
- 17. Bounous, G. and P. Gold, *The biological activity of undenatured dietary whey proteins: role of glutathione.* Clin Invest Med, 1991. **14**(4): p. 296-309.
- 18. Harwood, J.P., et al., *Effect of long-term feeding of soy-based diets on the pancreas of Cebus monkeys*. Adv Exp Med Biol, 1986. **199**: p. 223-37.
- 19. Kitabatake, N. and Y.-l. Kinekawa, *Digestibility of Bovine Milk Whey Protein and β-Lactoglobulin in Vitro and in Vivo*. Journal of Agricultural and Food Chemistry, 1998. **46**(12): p. 4917-4923.
- 20. Ramamani, A., M.M. Aruldhas, and P. Govindarajulu, *Differential response of rat skeletal muscle glycogen metabolism to testosterone and estradiol*. Can J Physiol Pharmacol, 1999. **77**(4): p. 300-4.
- 21. Samuel, E. and I. Kugelmaa, *Comparative Studies of the Influence of Acid-Forming and Base-Forming Diets on the Metabolism of Rats.* American Journal of Diseases of Children, 1930. **39**(4).
- 22. Sharma, V., et al., Evaluation of the Anabolic, Aphrodisiac and Reproductive Activity of Anacyclus Pyrethrum DC in Male Rats. Scitia Pharmacueutica, 2008.
- 23. Sharma, V., et al., Effects of petroleum ether extract of Anacyclus pyrethrum DC. on sexual behavior in male rats. Zhong Xi Yi Jie He Xue Bao, 2010. **8**(8): p. 767-73.
- 24. Zabala, A., et al., trans-10,cis-12 Conjugated linoleic acid inhibits lipoprotein lipase but increases the activity of lipogenic enzymes in adipose tissue from hamsters fed an atherogenic diet. Br J Nutr, 2006. **95**(6): p. 1112-9.
- 25. Flakoll, P.J., et al., *Postexercise protein supplementation improves health and muscle soreness during basic military training in Marine recruits.* J Appl Physiol, 2004. **96**(3): p. 951-6.
- 26. Gaullier, J.M., et al., Six months supplementation with conjugated linoleic acid induces regional-specific fat mass decreases in overweight and obese. Br J Nutr, 2007. **97**(3): p. 550-60.
- 27. Goodin, S., et al., *Clinical and biological activity of soy protein powder supplementation in healthy male volunteers.* Cancer Epidemiol Biomarkers Prev, 2007. **16**(4): p. 829-33.
- 28. Lukaski, H.C. and F.H. Nielsen, *Dietary magnesium depletion affects metabolic responses during submaximal exercise in postmenopausal women.* J Nutr, 2002. **132**(5): p. 930-5.
- 29. Berven, G., et al., *Safety of conjugated linoleic acid (CLA) in overweight or obese human volunteers.* European Journal of Lipid Science and Technology, 2000. **102**(7): p. 455-462.
- 30. Kreider, R.B., et al., *Effects of conjugated linoleic acid supplementation during resistance training on body composition, bone density, strength, and selected hematological markers.* J Strength Cond Res, 2002. **16**(3): p. 325-34.
- 31. Roffe, C., et al., *Randomised, cross-over, placebo controlled trial of magnesium citrate in the treatment of chronic persistent leg cramps.* Med Sci Monit, 2002. **8**(5): p. CR326-30.
- 32. Schulz Kf Fau Grimes, D.A. and D.A. Grimes, *Allocation concealment in randomised trials:* defending against deciphering. (0140-6736 (Print)).
- 33. Schulz, K.F., Subverting randomization in controlled trials. (0098-7484 (Print)).
- 34. Schulz Kf Fau Chalmers, I., D.G. Chalmers I Fau Altman, and D.G. Altman, *The landscape and lexicon of blinding in randomized trials.* (1539-3704 (Electronic)).
- 35. Clark, V.R., et al., *Placebo effect of carbohydrate feedings during a 40-km cycling time trial.* Med Sci Sports Exerc, 2000. **32**(9): p. 1642-7.

- 36. Nassif, C., et al., *Double blind carbohydrate ingestion does not improve exercise duration in warm humid conditions.* J Sci Med Sport, 2008. **11**(1): p. 72-9.
- 37. Vandenbogaerde Tj Fau Hopkins, W.G. and W.G. Hopkins, *Effects of acute carbohydrate* supplementation on endurance performance: a meta-analysis. (0112-1642 (Print)).
- 38. Goulet, E.D., *Effect of exercise-induced dehydration on time-trial exercise performance: a meta-analysis.* (1473-0480 (Electronic)).
- 39. Hopkins, W., *Research Designs: Choosing and Fine-tuning a Design for Your Study.* SPORTSCIENCE, 2008. **12**: p. 12-21.
- 40. Noakes, T., Waterlogged: The Serious Problem of Overhydration in Endurance Sports. 2012, Human Kinetics Publishers. p. 94.



41 42

Figure 2: Flow chart

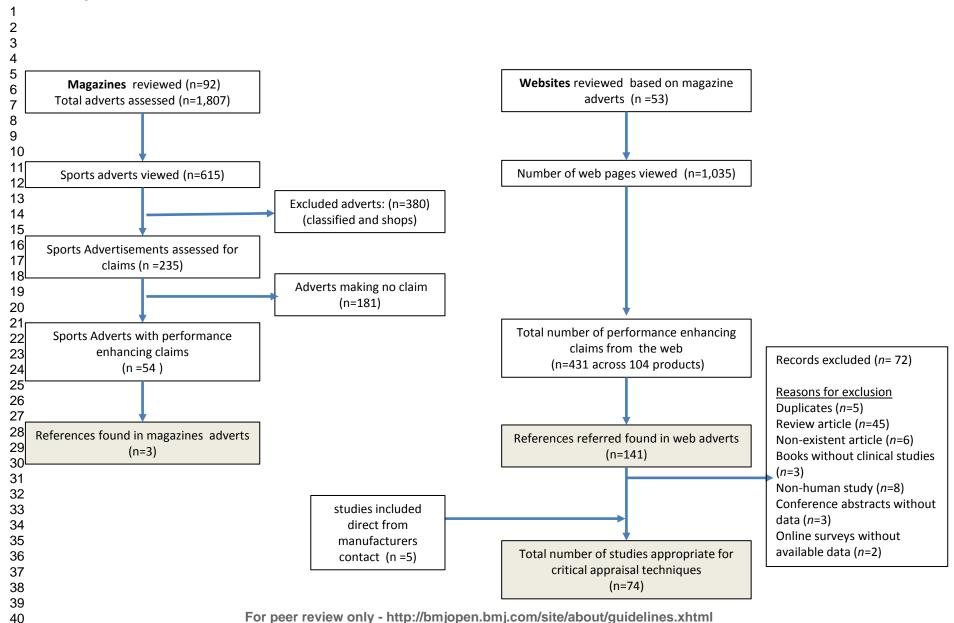


Table 1 Sports adverts study quality

Study component	N =74	% (95% CI)
Number of participants	2031 (Median 15)	Range (5 to 387)
Number of males	1310	64.5 (61.9 to 67.1)
Study quality		
Control Group	55	74.3 (62.8 to 85.9)
Randomization	43	58.1 (43.4 to 72.9)
Allocation Concealment	5	6.8 (0 to 28.8)
Intention to treat	22	29.7 (10.8 to 48.8)
Blinding (investigators, outcome assessors, or participants)	20	27.0 (7.6 to 46.5)
Surrogate sports outcome	61	82.4 (72.9 to 92.0)
Repeat of the intervention	2	2.7 (0 to 25.2)
Reporting		
Clear Hypothesis	66	89.2 (81.7 to 96.7)
Power Calculation	4	5.4 (0 to 27.6)
Adverse events reported	6	6.8 (0 to 32.3)
Study limitations discussed	8	10.8 (0 to 32.3)
Level of Evidence		
1	0	0
2	32	42.1 (25.0 to 59.2)
3	33	43.4 (26.5 to 60.3)
4 or 5	9	11.8 (0 to 33.0)

Web Appendix 1: Web products reviewed and website addresses

Product	Number of products (total 104)	Website
Vega Sport:	7	vegasport.com/
Prepare: Preworkout Energizer		
Sustain: Electrolyte Hydrator, Endurance Bar, Endurance Gel		
Recover: Performance Protein, Protein Bar, Recovery Accelerator		
T-100 Testo Booster	1	en.olimpsupplements.com/
Scott Race Rocker and Grip 2 Shoes	2	www.scottsports.com/global/en/
Reflex Nutrition Diet Protein	1	www.reflexnutrition.com/
Reebok Zig Activate shoe	1	www.finishline.com/reebokshoes
Panache Sports Bra	2	www.panachelingerie.com/sports/
Nike Lunar Eclipse shoes: LunarEclipse+2; LunarEclipse Shield	2	nikerunning.nike.com/nikeos/p/nikeplus/language_tunnel/
Merrell Barefoot: Run, Train, Water, Life, Kids	5	www.merrell.com/UK/en/Barefoot
Maxifuel: Viperactive ,Recovermax, Powerboost	17	www.maxifuel.com
Focus system: Viper Boost, Viper Boost Bar, Viper Boost Capsules, Viper Boost Gel		www.maxifuel.com/maxifuelranges/focus
Energy system: Viper Active, Viper Active Capsules, Viper Active Gel, Viper Active Bars, Viper Active Sachets, Creatamax Capsules, Electro Tabs		www.maxifuel.com/maxifuelranges/energy
Recovery system: Protrient, Ache Free, BCAAs, Immune Support, Recovermax, Sports Vitamins		www.maxifuel.com/maxifuelranges/recovery
GNC Ultra Mega Women's Vitapaks: Women's Ultra Mega Active; Ultra Mega 50 Plus; Ultra Mega Menopause; Ultra Mega® Green Women's Vitapak; Ultra Mega® Joint; Ultra Mega™ Wellness Vitapak®; Ultra Mega® Energy; Ultra	9	www.gnc.com/home/index.jsp
Mega® Heart; Ultra Mega® Green Vegetarian Vitapak® Compressport Full Socks	1	compressport.uk.com/blog/
PureProtein	. 1	www.myprotein.com/uk/
Accelerade advanced sports drink & Hydro	2	www.nyprotein.com/uk/ www.pacifichealthlabs.com
Gatorade G series Pro (3 products)	3	www.gatorade.co.uk/
01 PRIME, 02 PERFORM, 03 RECOVER		
K-SWISS Blade Max series training shoes	1	www.kswiss.com
Kinetica Protein shake	1	www.kinetica-sports.com
Run Sure Wave Inspire 8 Mizuno	1	www.mizuno.co.uk
Powerade: Powerade ION 4, Powerade zero, Powerade energy	3	www.poweradegb.com/
ProPeptide Advanced protein supplement	1	www.cnpprofessional.co.uk/
PWXcompression clothing 2XU	1	www.2xu.com/uk
SixStar Whey protein elite series	1	www.sixstarpronutrition.com/
Sports Jelly Beans	1	
Zoot Ultra TT 5.0	1	www.zootsports.com
ZV7 Energy gels	1	zipvitsports.com
Vitabiotics: Mass gainer, Ultra whey protein, Ultra rehydration recovery	3	www.vitabiotics.com/Wellman/
USN Body & Lifestyle (12 week new body starter pack)	1	www.usn.co.uk/
Premium 8 h Casein	1	www.usn.co.uk/
Predator Nutrition:	4	www.predatornutrition.com/
Triazole, Triazole/Activate Extreme, Anabeta, CRAZE		
Product Platinum Hydrobuilder	1	www.onacademy.eo.uk/
New Balance	1	www.newbalance.co.uk/
Myoprotein	1	www.myprotein.com/uk
MET- Rx Mass Gainer	1	www.metrx.eo.uk/
Lucozade: Lucozade Sport, Sport Lite, Sport Pro Muscle protein bar, Sport jelly	6	www.lucozade.com/
Beans, Sport Body Fuel Powder, Sport Body Fuel Gel		
ASICS Gel Volt 33	1	www.intersport.co.uk/
SMARTEC XcelR8	1	www.smarttecnutrition.com/
ZEROHIGH 5	1	www.highfive.co.uk/zero_INT.php#tested

1	www.reebok.com
	www.neebok.com www.maxitone.com/sculptresscapsules
	www.vitabiotics.com/wellwoman/
	www.maximuscle.com/
-	http://www.maximuscle.com/cyclone
1	www.aquasphereswim.com/uk/
1	www.trionz.co.uk
1	www.runnersworld.co.uk/puma
1	www.healthaid.co.uk
1	www.refelex-nutrition.com
3	www.powerbar.co.uk
1	www.sci-mx.co.uk/
	www.phd-supplements.com
	www.gasparinutrition.co.uk/
1	www.bodybuildingwarehouse.co.uk/
	1 1 1 3 1 1 1

Web Appendix 1 - sports company correspondence

1. Contents

- 2. Summary
- 3. Original enquiry email
- 4. Company correspondence
 - a. GSK
 - b. <u>Vegasport</u>
 - c. Panache
 - d. Compressport
 - e. Pacific Health Labs
 - f. PE Science
 - g. New Balance
 - h. Powerbar
 - i. Nike
 - j. <u>Merrell</u>
 - k. GNC
 - I. Kinetica
 - m. Zip Vit Sport
 - n. Sci-MX Nutrition
 - o. Body Building Warehouse
 - p. <u>DS</u>
 - q. Pharma Blend 6HR
 - r. <u>TrionZ Bracelets</u>
 - s. Zero High 5
 - t. 2XU PWX compression tights
 - u. Gatorade G Series Pro
 - v. K-Swiss
 - w. ProPeptide Advance
 - x. Sports Jelly Beans
 - y. Asics Gel Volt 33
 - z. Aqua Sphere Energize compression-wear
 - aa. Powerade

Summary

Companies contacted: 42

Replied: 27

Number providing references: 9

Number providing references for actual product(s) enquired about: 6

Original enquiry email

Dear xxx,

I am writing on behalf of a team of researchers from the BMJ (British Medical Journal) and the Centre of Evidence Based Medicine at Oxford University. In the run up to the 2012 Olympics we are undertaking a piece of research analysing the evidence for sports health products. This will appear in the BMJ. Since we are on a very tight deadline we would appreciate your answers by the end of the week (18th May).

So far, we have used pieces of published research where possible. But we are aware that this might be the complete picture.

On your website you have listed the following references to scientific articles as evidence for

[Product names here]

Because we are trying to evaluate the evidence base across a range of products fairly, we would like to be sure that this represents a complete list of scientific articles that you have used to demonstrate how these products work.

[Found references here]

Do you think you could tell us:

- a. If this is a complete list?
- b. If not, what other data you have used to support your claims?
- c. Is this published or unpublished?
- d. If the research is published could you provide us with the relevant references?
- e. If your research is unpublished, would you be willing to share it with us so we can fairly evaluate how your product works?

Please note, we are aiming to capture everything as accurately and fairly as we can. If you are unable to provide us with further information we will also note this in our research.

Don't hesitate to contact us for further information, but we would appreciate a prompt response.

Kind regards

Company correspondence

a. GSK

Products

Lucozade Sport

Lucozade Sport Lite

Lucozade Sport Pro Muscle protein bar

Lucozade Sport jelly Beans

Lucozade Sport Body Fuel Powder

Lucoazde Sport Body Fuel Gel

MAXITONE SCULPTRESS

Maximuscle

Cyclone Maximuscle

"Focus system": Viper Boost, Viper Boost Bar, Viper Boost Capsules, Viper Boost

Gel (4 products)

"Energy system": Viper Active, Viper Active Capsules, Viper Active Gel, Viper

Active Bars, Viper Active Sachets, Creatamax Capsules, Electro Tabs (7 products)

"Recovery system": Protrient, Ache Free, BCAAs, Immune Support, Recovermax,

Sports Vitamins (6 products)

MAXIFUEL Viper Active and Recovermax

Contact

Maria Potter

maria.a.potter@gsk.com

Correspondence

To: "ASmith@bmj.com" <ASmith@bmj.com>

From: Maria Potter <maria.a.potter@gsk.com>

Date: 05/31/2012 5:36PM Subject: BMJ Research

Dear Adam

I am working through your questions. I will get back to you next week.

Kind regards,

Maria

From: Adam Smith/BMJ

Cc: Maria Potter <, maria.a.potter@gsk.com>

Subject: Re: BMJ Research

Dear Maria,

Thank you for you help in sending over the references for your products. As you can imagine, asking a library to collate all these papers will take quite some time. I imagine you have PDFs all of these as a dossier already.

Do you think you could send them over? If you don't have them, we would also be grateful if you could send summaries.

We were also wondering what kind of methods you have employed to check the quality of the studies. Do you think you could share that information with us?

And lastly, do you think you could tell us which of these studies actually use your products (rather than just the active ingredient)?

If none of them do, which use the active ingredient in the same doses as contained within your products?

We would be grateful for some guidance on this.

Thanks for your help,

Adam

To: Maria Potter < maria.a.potter@gsk.com>

From: Adam Smith/BMJ Date: 05/23/2012 08:44PM Subject: Re: BMJ Research

Dear Maria,

Thanks for the info. If I need anything else, I'll be in touch once my colleagues and I have taken a look through.

Many thanks,

Adam Smith BMJ Research asmith@bmj.com

To: "ASmith@bmj.com" <ASmith@bmj.com> From: Maria Potter <maria.a.potter@gsk.com>

Date: 05/23/2012 11:41AM Subject: BMJ Research

Dear Adam,

Further to our conversation please find attached the information that you requested. I hope that the following information helps you with your enquiry.

All the Maxifuel and Lucozade Sport products mentioned in the attached are based on well researched ingredients and the references listed on the website provide an example for the consumer. The main ingredients in this range are carbohydrates, caffeine and protein all of which have approved EFSA health claims and a large amount of research papers to support the benefit for fuelling, focus and recovery. Attached is a more comprehensive list of references that apply to each product in turn based on the ingredients found in the formulation.

As mentioned on the phone please come back to me if you require comment or further details. In addition, I would appreciate it if you could let me know once you are aware of the publication date.

Kind regards Maria

Maria Potter

Communications Director, Consumer Healthcare Great Britain & Ireland GSK Consumer Healthcare

GlaxoSmithKline GSK House, 980 Great West Road Brentford Middlesex TW8 9GS

T +44 (0)208 047 5479 M +44 (0)7920 568781 www.gsk.com | GSKvision on YouTube | Follow us on Twitter

b. Vegasport

Products

Pre-Workout energizer Electrolyte Hydrator Endurance Bar Endurance Gel Performance Protein Protein Bar Recovery Accelerator

Contact

Jessica Malach
Public Relations Manager
C 604 653-5350
T 604 945-3133 x 366 | T 1 866 839 8863 | F 604 945 3233
Ejessica.malach@myvega.com | myvega.com

Correspondence

To: Jessica Malach <, Jessica.Malach@myvega.com>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM

Subject: RE: BMJ research deadline for information

Hi Jessica,

Thanks for the help. The absolute deadline will be end of the day on Thursday (your time). Hope to hear from you before then.

Kind regards
Adam Smith
BMJ Researcher
asmith@bmj.com
07816125827

-----Jessica Malach < Jessica. Malach@myvega.com > wrote: ----

To: Adam Smith <ASmith@bmj.com>

From: Jessica Malach < Jessica. Malach@myvega.com>

Date: 05/22/2012 10:31PM

Subject: RE: BMJ research deadline for information

HI Adam.

Thanks for sending the study information over. Before I go any further, I need approval from senior management. What is your absolute latest for receiving the information if it is approved?

Thank you, Jessica

----Forwarded by Adam Smith/BMJ on 05/31/2012 05:00PM ----

To: Adam Smith/BMJ@BMJ From: Adam Smith/BMJ Date: 05/25/2012 05:22PM

Cc: Jessica Malach <, Jessica.Malach@myvega.com>, Krystal LaFrance <,

krystal@myvega.com> Subject: RE: BMJ research

(See attached file: CEBM research.doc)

(See attached file: CEBM research protocol.doc)

Hi Jessica and Krystal,

Thanks for agreeing to provide the info.

Please find attached a letter and full research protocol, as requested.

Kind regards Adam Smith BMJ Researcher asmith@bmj.com

----Adam Smith/BMJ wrote: ----

To: Jessica Malach < Jessica. Malach @myvega.com >

From: Adam Smith/BMJ Date: 05/18/2012 06:59AM

Cc: Krystal LaFrance <krystal@myvega.com>

Subject: RE: BMJ research

Hi Krystal,

I'm waiting on my colleagues and will get back to you on this. Should be today.

Many thanks,

Adam

-----Jessica Malach < Jessica. Malach@myvega.com > wrote: ----

To: "asmith@bmj.com" <asmith@bmj.com>

From: Jessica Malach < Jessica. Malach@myvega.com>

Date: 05/16/2012 09:29PM

Cc: Krystal LaFrance <krystal@myvega.com>

Subject: RE: BMJ research

HI Adam,

I'm the Public Relations Manager for Vega and this request has just come to me. I've confirmed with our QA team that it would be possible for us to provide more information to your questions below; however, before we do so, I would like a copy of your research proposal, including the credentials of the researchers involved, name of your supervisor and a formal letter from the BMJ requesting this information with a summary of how it will be presented should it be included in the article. Depending on the nature of how this information will be published, we may require a non-disclosure agreement to be signed.

I appreciate your deadline for information is May 18; however, asking us to submit this information in four days is not feasible unless we can obtain the information above from you. Furthermore, I would like to express now that it would not be fair nor representative to suggest we are unable to provide further information as noted in your final sentence from the email below, if you cannot help meet our needs for information expressed above or extend your deadline: "Please note, we

are aiming to capture everything as accurately and fairly as we can. If you are unable to provide us with further information we will also note this in our research. Don't hesitate to contact us for further information, but we would appreciate a prompt response."

The timing and nature of your request is unusual compared to other requests we've had from medical journals which typically come by way of formal letter, and thus we may need more time and information from you to help out.

Vega has great respect for the British Medical Journal and we look forward to assisting you with your research as best we can!

Thank you, Jessica

c. Panache

Panache Sports Bra

Contact

Jonathan Kirkby instinct pr ltd d: +44 20 7401 0479

t: +44 20 7401 0478 m: +44 7843255917

e: jonathan.kirkby@instinct-pr.com

Correspondence

To: Jonathan Kirkby - Instinct PR <, jonathan.kirkby@instinct-pr.com>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM Subject: Re: BMJ research

Hi Jonathan,

Thanks for the extra info. Just a couple of more Qs to make sure I'm being thorough.

Could you explain a little more the rationale behind not publishing the research?

As you know, publishing research is standard practice in the science world, so are there specific aspects of this product or market sector besides its competitive nature that inform the decision not to publish?

Thanks for the continued help.

Adam

To: Adam Smith <ASmith@bmj.com>

From: Jonathan Kirkby - Instinct PR < jonathan.kirkby@instinct-pr.com>

Date: 05/18/2012 11:37AM Subject: Re: BMJ research

Hi Adam,

I can confirm that the research that was conducted by Progressive Sports based in Loughborough is not published.

Thanks,

Jonathan
Jonathan Kirkby
Founder & Director

instinct pr ltd
Unit 232
Great Guildford Business Square
30 Great Guildford Street
London
SE1 0HS

d: +44 20 7401 0479 t: +44 20 7401 0478 m: +44 7843255917

e: jonathan.kirkby@instinct-pr.com

w: www.instinct-pr.com twitter: @instinctpr

On 18 May 2012, at 11:27, Adam Smith wrote:

Hi Jonathan,

So, to confirm, the research is not published in any academic literature? Is it peer reviewed?

Thanks,

Adam

To: Adam Smith <ASmith@bmj.com>

From: Jonathan Kirkby - Instinct PR <jonathan.kirkby@instinct-pr.com>

Date: 05/18/2012 10:12AM

Subject: Re: BMJ research

Hi Adam,

Panache does have research they're just keen to keep it to themselves at the moment. As a market leader I'm sure you understand that they wish to remain there and not openly give their research out.

Thanks,

Jonathan
Jonathan Kirkby
Founder & Director

instinct pr ltd Unit 232 Great Guildford Business Square 30 Great Guildford Street London SE1 0HS

d: +44 20 7401 0479 t: +44 20 7401 0478 m: +44 7843255917

e: jonathan.kirkby@instinct-pr.com

w: www.instinct-pr.com twitter: @instinctpr

On 18 May 2012, at 06:53, Adam Smith wrote:

Hi Jonathan,

Could you confirm whether the company has research and just does not wish to share it, or whether there is no research?

Also, any reasons why they'd rather not share it would be helpful.

Many thanks,

Adam

-----Jonathan Kirkby - Instinct PR <jonathan.kirkby@instinct-pr.com> wrote: -----

To: Adam Smith <ASmith@bmj.com>

From: Jonathan Kirkby - Instinct PR < jonathan.kirkby@instinct-pr.com>

Date: 05/17/2012 04:19PM Subject: Re: BMJ research Hi Adam,

I've just heard back from the client to say that they don't want to share their research data at this stage.

Thank you for thinking of us.

Jonathan Jonathan Kirkby Founder & Director

instinct pr ltd Unit 232 Great Guildford Business Square 30 Great Guildford Street London SE1 0HS d: +44 20 7401 0479

d: +44 20 7401 0479 t: +44 20 7401 0478 m: +44 7843255917

e: jonathan.kirkby@instinct-pr.com

w: www.instinct-pr.com twitter: @instinctpr

d. Compressport

Product

Compressport Full Socks

Correspondence

To: COMPRESSPORT MEDIA <, media@compressport.com>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM Subject: Re: BMJ research

Dear Valerie,

Many thanks. Do you have research for Compressport Full Socks too? Specifically, research behind these claims:

1) ensures venous return and recovery; 2) improve your performance; p3) protect muscles from oscillation and impact shock waves; 4) reduces muscle damage

Do you think you could tell us:

what data and research have you used to support your claims over Compressport Full Socks?

Is this published or unpublished?

If the research is published could you provide us with the relevant references? If your research is unpublished, would you be willing to share it with us so we can fairly evaluate how your product works?

Kind regards

Adam Smith BMJ Research asmith@bmj.com

From:

Date: 05/25/2012 05:22PM Subject: Re: BMJ research

(See attached file: Etude Medicale CSI - English-2fev.pdf)

(See attached file: Etude Medicale CSI.pdf)

(See attached file: Compression Sleeves Increase Tissue Oxygen.pdf)

Dear Adam,

In answer to your request please find attached:

- LEDUC study in French
- LEDUC study in English (Summary)
- -MENETRIER study in English

You could contact the authors if you want.

- Olivier LEDUC = oleduc@skynet.be
- Arnaud MENETRIER:

Explorations Fonctionnelles Respiratoires, 2 Place Saint Jacques, 25030 Besan on, France. T l.: +33(0)3 81 21 87 50 – 06 31 46 18 33. E-mail: arnaud.menetrier@laposte.net

Please be aware that these studies have been done with the R2 products.

Let me know if you need more information.

Regards.

Valerie LAUR

From:

Date: 05/25/2012 05:22PM Subject: Re: BMJ research

Dear Adam,

I don't understand why do you link the product Compressport Full Socks to the two studies done with the product Compressport R2? Could you please explain to me?

Regards.

Valerie LAUR

To: COMPRESSPORT MEDIA <, media@compressport.com>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM Subject: Re: BMJ research

Thanks Valerie.

Adam

To: Adam Smith < ASmith@bmj.com>

From: COMPRESSPORT MEDIA < media@compressport.com>

Date: 05/20/2012 09:56PM Subject: Re: BMJ research

Dear Sir,

I will be able to send you the info at the end of the week.

Regards. Valerie LAUR

Le 21 mai 2012 00:35, Adam Smith a crit:

Dear sir/madam,

I haven't heard back from you regarding the below. When will you be able to send me the relevant info?

Kind regards

Adam Smith BMJ Research

asmith@bmj.com

e. Pacific Health Labs

Products

Accelerade advanced sports drink & Hydro

Contact

Steve Kuchen

Vice President & CFO | PacificHealth Laboratories, Inc: We Power Your Passion. 732-739-2900 X 603 | pacifichealthlabs.com | Twitter | Facebook | Youtube | Blog

Correspondence

To: "Adam Smith" < ASmith@bmj.com>

From: "Stephen P. Kuchen" <skuchen@pacifichealthlabs.com>

Date: 05/21/2012 02:36PM Subject: RE: RE: BMJ research

Please see our website at www.pacifichealthlabs.com.

Click on each product on the right side. On each product page, you will see a tab for Studies.

Hope this helps, please keep me informed and updated on your project.

Regards,

Steve Kuchen

Vice President & CFO | PacificHealth Laboratories, Inc: We Power Your Passion. 732-739-2900 X 603 | pacifichealthlabs.com | Twitter | Facebook | Youtube | Blog

Steve Kuchen

Vice President & CFO | PacificHealth Laboratories, Inc: We Power Your Passion. 732-739-2900 X 603 | pacifichealthlabs.com | Twitter | Facebook | Youtube | Blog

From: Adam Smith [mailto:ASmith@bmj.com]

Sent: Monday, May 21, 2012 6:44 AM

To: Stephen P. Kuchen

Subject: Re: RE: BMJ research

Hi Steve,

Do you have another colleague who could help? Or give me an idea of what, if any, research is published?

Many thanks,

Adam

----"Stephen P. Kuchen" <skuchen@pacifichealthlabs.com> wrote: ----

To: "Adam Smith" < ASmith@bmj.com>

From: "Stephen P. Kuchen" <skuchen@pacifichealthlabs.com>

Date: 05/20/2012 07:16PM Subject: RE: BMJ research

We will have to decline, I sent to our research team but he is out of the country

for a few weeks. Steve Kuchen

Vice President & CFO | PacificHealth Laboratories, Inc: We Power Your Passion. 732-739-2900 X 603 | pacifichealthlabs.com | Twitter | Facebook | Youtube | Blog

----Original Message----

From: Adam Smith [mailto:ASmith@bmj.com]

Sent: Sun 5/20/2012 10:36 AM

Cc: Stephen P. Kuchen Subject: Re: BMJ research

Dear Stephen,

I haven't heard back from you regarding the below. When will you be able to send me the relevant info?

Kind regards

Adam Smith BMJ Research asmith@bmj.com o7816125827

f. PE Science

Product

Anabeta

Contact

Josh Poole support@pescience.com

Correspondence

To: Josh Poole <, josh@pescience.com>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM

Subject: Re: RE: British Medical Journal research

Many thanks, Josh.

Adam

----Josh Poole <josh@pescience.com> wrote: ---To: "asmith@bmj.com" <asmith@bmj.com>
From: Josh Poole <josh@pescience.com>

Date: 05/23/2012 11:55PM

Subject: RE: British Medical Journal research

This website published an article on the extract today:

http://ergo-log.com/spanish-chamomile-t-booster.html

To: "asmith@bmj.com" <asmith@bmj.com>
From: Josh Poole <josh@pescience.com>

Date: 05/23/2012 08:26PM

Subject: RE: British Medical Journal research

Hello Adam,

Thank you for contacting us. I am well aware of BMJ, a major journal.

The study sent this morning is a key study that you are missing from the list.

http://www.ncbi.nlm.nih.gov/pubmed/22473789

We are changing our writeup to gauge this new research, which actually tests serum levels of testosterone changes in the animal model. Previous studies did not test serum testosterone levels, they just tested groups taking the extract compared to animals taking testosterone, and noted the anabolic effects with a testosterone-like effect.

The beauty of a supplement that can be anabolic without lowering, and in this case actually increasing testosterone is it gets rid of the major issue with synthetic anabolics -- HPTA suppression.

The most interesting thing about the research in the original animal studies is that in the extract group that gained an equal amount of weight compared to the testosterone group, the prostate weight gain was insignificant which is very

important. Prostate weight gain is a key marker in determining how androgenic something is, whereas bodyweight gains is a key marker of how anabolic a substance can be.

This shows anacyclus may have abilities to gain body weight independent of testosterone increase. One theory is that it may increase muscle glycogen retention (or reduce muscle glycogen depletion), and it has been studied for its hyperglycemic effect in animals:

http://www.idosi.org/ejbs/3%284%2911/4.pdf

http://www.academicjournals.org/jmpr/PDF/pdf2012/30%20Apr/Selles%20et%20al.pdf

We have had hundreds of users come back to us saying that when they take 2-3 capsules of AnaBeta with a high carbohydrate meal they will get hypoglycemic feeling that they do not normally get. So it may be possible this is one of its mechanism of action, perhaps through GLUT4, but it is something we will be looking into in the future.

There has been a number of new studies on this ingredient just in the past 9-12 months, and we expect it to continue since we released the ingredient to the supplement market. If you have any questions regarding specific claims or need any specific info feel free to ask.

Also, in closing, here is one study that highlights the safety of the extract in the animal model:

http://pharmacologyonline.silae.it/files/newsletter/2011/vol1/015.gautam.pdf

If you would like me to send some bottles just for curiosities sake, let me know! I hope this email helps your research and did not create more work!

-Josh

g. New Balance

New Balance trainers

Contact

Jo Green, PR company jo@sx-media.com

Correspondence

To: <, Jo@sx-media.com> From: Adam Smith/BMJ Date: 05/25/2012 05:22PM Subject: RE: BMJ research

Hi Jo,

Thanks for letting me know. Could you provide more detail as to why?

Specifically:

Is there any scientific research behind "lighter lower to the ground ride without sacrificing cushioning"?

If so, could you detail why New Balance can't provide it or point me to it online?

Thanks,

Adam

----"Jo Green" <Jo@sx-media.com> wrote: ----

To: "Adam Smith" <ASmith@bmj.com> From: "Jo Green" <Jo@sx-media.com>

Date: 05/28/2012 10:59AM Subject: RE: BMJ research

Hi Adam

Further to our conversation I'm afraid New Balance are unable to provide the data you are looking for on this occasion.

Please do let me know if we can help with anything else in the future.

Good luck with your study.

Kind regards

Jo

----Adam Smith/BMJ wrote: ----

To: jo@sx-media.com From: Adam Smith/BMJ Date: 05/15/2012 08:42AM Subject: Re: BMJ research

Dear Jo,

Sorry I couldn't answer your query straight away yesterday, when I didn't have the right document to hand. The claim I'm referring to is: "lighter lower to the ground ride without sacrificing cushioning".

With this in mind, please could you send us: what data you have used to support your claims? Is this published or unpublished? If the research is published could you provide us with the relevant references? If your research is unpublished, would you be willing to share it with us so we can fairly evaluate how your product works?

Any other questions, please let me know.

Thanks, Adam

h. Powerbar

Powerbar All in One, Whey isolate, Muscle up & Charger

Contact

Corinne Mäder corinne.maeder@powerbar.de EU Sport Nutrition Science Specialist PowerBar Europe GmbH Zielstattstraße 42 D-81379 München Phone: +49 (0)89 50 20 07 15

Correspondence

To: Corinne M der <, corinne.maeder@powerbar.de>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM

Cc: 'Selena Murray' <, selena.murray@powerbar.de>

Subject: AW: Fw: BMJ research

Thanks Corinne. If I need anything else I'll be in touch.

Adam

----Corinne M der <corinne.maeder@powerbar.de> wrote: ----

To: asmith@bmj.com

From: Corinne M der <corinne.maeder@powerbar.de>

Date: 05/21/2012 12:21PM

Cc: 'Selena Murray' <selena.murray@powerbar.de>

Subject: AW: Fw: BMJ research

Dear Adam,

Please find attached our literature overview and science background for the PowerBar Products ALL IN ONE, MUSCE UP, WHEY ISOLATE and CHARGER.

- If not, what other data you have used to support your claims? Our Product a. claims are EFSA based
- Is this published or unpublished? For the 4 products we have used published papers
- If the research is published could you provide us with the relevant references? => Please find attached the lit overview
- If your research is unpublished, would you be willing to share it with us so we can fairly evaluate how your product works? Unfortunately we are not allowed to share unpublished data's

If you need any further product or science information please do not hesitate to contact me- I will be happy to support you!

May I kindly ask you to send me the BMJ-publication afterwards?

Kind regards, Corinne

Corinne M der **EU Sport Nutrition Science Specialist** PowerBar Europe GmbH Zielstattstra e 42 D-81379 M nchen

Phone: +49 (0)89 50 20 07 15

Online: http://www.powerbarstore.de

Facebook: http://www.facebook.com/PowerBarEurope

From: Adam Smith [mailto:ASmith@bmj.com]

Sent: 20 May 2012 15:41

Cc: selena.murray@powerbar.de Subject: Re: Fw: BMJ research

Importance: High

Dear Selena,

I haven't heard back from you regarding the below. When will you be able to send me the relevant info?

Kind regards

Adam Smith

BMJ Research asmith@bmj.com 07816125827

i. Nike

Products

Nike LunarEclipse Nike LunarEclipse Shield

Contact

Ryan Greenwood Ryan.Greenwood@nike.com Head of PR & Communications, Nike UK & Ireland +44 (0)7919 927 502

Correspondence

To: <, Ryan.Greenwood@nike.com>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM

Subject: Re: Nike enquiry re: Lunar Eclipse shoes

Dear Ryan,

Thanks for getting back to me. I just want to confirm something. There's no scientific research, published or unpublished, on which the claims and explanations draw?

Thanks,

Adam

From: Adam Smith <ASmith@bmj.com>
To: Nike <ryan.greenwood@nike.com>

Subject: Re: Nike enquiry re: Lunar Eclipse shoes

Dear Ryan,

Thanks for getting back to me. I just want to confirm something. There's no scientific research, published or unpublished, on which the claims and explanations draw?

Thanks,

Adam

----"Greenwood, Ryan" < Ryan. Greenwood@nike.com > wrote: ----

To: Adam Smith <ASmith@bmj.com>

From: "Greenwood, Ryan" < Ryan. Greenwood@nike.com>

Date: 05/28/2012 04:58PM

Subject: Nike enquiry re: Lunar Eclipse shoes

Dear Adam

Further to your recent enquiry, we believe that the explanation we have already provided sufficiently substantiates the claims you have questioned. I've copied our original response below.

The ride's perfect"

In this context, "the ride's perfect" refers to the sensation runners feel in the smooth Lunarlon cushioning and the stability provided by the dynamic fit system.

"Adapts to every stride"

The use of "adapts to every ride" is a reference to the dynamic fit system, which is a Nike innovation. Featuring soft material that wraps the midfoot and arch from under the foot and connects to the laces, the fit system reduces the space between foot and shoe. It moves with the foot as you run, thereby providing a personal fit. This is in contrast with conventional shoe constructions that pull from the outside edge of the shoe's sole unit.

Attached is a video showing how the dynamic fit system moves with the motion of the foot. Watch the silver line drawn on the shoe in the video. It is marked on the fit system while the shoe is at rest. The exterior mesh panel has been cut away to expose the fit system. When the runner runs, that silver line pulls away from the sole unit bite line & shows how the fit system moves with the foot through the foot strike.

https://www.wetransfer.com/dl/oZ9zgM4J/1a7cfo6fd42d161ea1f8fe7a883bee28162db3af3ce779937edf82a48856o656o82ed9fb3892587

https://www.wetransfer.com/dl/JTt5BM67/1ebe7e43a1d851acd721856f69c55e027ea4f2ba5oo5d1fo6o41oo21e879439fc6a2629738924fa>

Ryan Greenwood Head of PR & Communications, Nike UK & Ireland +44 (0)7919 927 502 To: <, Ryan.Greenwood@nike.com>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM Subject: Re: Nike questions

Great, thanks Ryan.

Any idea how come these wordings weren't in your PR materials?

Adam

To: "ASmith@bmj.com" <ASmith@bmj.com>

From: "Greenwood, Ryan" < Ryan. Greenwood@nike.com>

Date: 05/22/2012 08:53PM Subject: BMJ/NIKE

Hi Adam

Please see below for a further explanation of the terms referenced in the ad.

Regards

Ryan

"The ride's perfect"

In this context, "the ride's perfect" refers to the sensation runners feel in the smooth Lunarlon cushioning and the stability provided by the dynamic fit system.

"Adapts to every stride"

The use of "adapts to every ride" is a reference to the dynamic fit system, which is a Nike innovation. Featuring soft material that wraps the midfoot and arch from under the foot and connects to the laces, the fit system reduces the space between foot and shoe. It moves with the foot as you run, thereby providing a personal fit. This is in contrast with conventional shoe constructions that pull from the outside edge of the shoe's sole unit.

Attached is a video showing how the dynamic fit system moves with the motion of the foot. Watch the silver line drawn on the shoe in the video. It is marked on the fit system while the shoe is at rest. The exterior mesh panel has been cut away to expose the fit system. When the runner runs, that silver line pulls away from

the sole unit bite line & shows how the fit system moves with the foot through the foot strike.

https://www.wetransfer.com/dl/oZ9zgM4J/1a7cfo6fd42d161ea1f8fe7a883bee28162db3af3ce779937edf82a48856o656082ed9fb3892587

https://www.wetransfer.com/dl/JTt5BM67/1ebe7e43a1d851acd721856f69c55e027ea4f2ba5005d1f060410021e879439fc6a2629738924fa>

From:

Date: 05/25/2012 05:22PM Subject: Re: Nike questions

Hi adam

We will aim to have a response by Monday.

Ryan

Ryan Greenwood Head of PR & Communications, Nike UK & Ireland +44 (0)7919 927 502

----"Greenwood, Ryan" < Ryan. Greenwood@nike.com > wrote: ----

To: Adam Smith <ASmith@bmj.com>

From: "Greenwood, Ryan" < Ryan. Greenwood@nike.com>

Date: 05/21/2012 02:20PM Subject: Re: Nike questions

Hi Adam

I'm hoping to have a response for you by this evening. Apologies for the delay.

Ryan

Ryan Greenwood Head of PR & Communications, Nike UK & Ireland +44 (0)7919 927 502

From: Adam Smith <ASmith@bmj.com>
To: Nike <ryan.greenwood@nike.com>

Subject: Re: Nike questions

Hi Ryan,

The ad text is available here, page 2:

http://issuu.com/larryeder1958/docs/ao-fall-winter-2011

The bottom right hand corner states:

Even the most innovative technology won't help much if your shoe doesn't fit. So for the ike LunarEclipse+, we combined the soft, smooth lunarlon cushioning runners lover with the pitch-perfect stability of dynamic support. Then wrapped it all up with the new dynamic fit system, which tailors the shoe perfectly to your foot and adapts to every stride. So the fit's personal, and the ride's perfect."

We're looking for the research behind these claims. Would you be able to get back to me today or early next week?

Many thanks,

Adam

----"Greenwood, Ryan" < Ryan. Greenwood@nike.com> wrote: ----

To: Adam Smith <ASmith@bmj.com>

From: "Greenwood, Ryan" < Ryan. Greenwood@nike.com>

Date: 05/18/2012 09:00AM Subject: Re: Nike guestions

No problem – thanks for the update.

Ryan Greenwood Head of PR & Communications, Nike UK & Ireland +44 (0)7919 927 502

From: Adam Smith <ASmith@bmj.com>
To: Nike <ryan.greenwood@nike.com>

Subject: Re: Nike questions

Ryan,

Apologies for the delay - I'm waiting on colleagues and will get back to you on this. We can obviously give you a little more time, into next week. I hope to get back to you today.

Thanks,

Adam

----"Greenwood, Ryan" < Ryan. Greenwood@nike.com > wrote: ----

To: "ASmith@bmj.com" <ASmith@bmj.com>

From: "Greenwood, Ryan" < Ryan. Greenwood@nike.com>

Date: 05/16/2012 07:05PM Subject: Re: Nike questions

Hi Adam

Apologies to chase you on this but it would be great to know where you saw these claims made as I can't see them in our PR materials.

Ryan

Ryan Greenwood Head of PR & Communications, Nike UK & Ireland +44 (0)7919 927 502

From: <Greenwood>, Nike <ryan.greenwood@nike.com>

To: "ASmith@bmj.com" <ASmith@bmj.com>

Subject: Nike questions

Hi Adam

Please can you let me know where you've seen the claims made that you referenced in yesterday's note-namely: the ride's perfect adapts to every stride

Ryan

Sent via iPhone

j. Merrell

Products

Merrell Barefoot: "Run", "Train", "Water", "Life", "Kids"

Contact

Simon Vingoe
Marketing Manager
T +44 (0)207 860 0122
M +44 (0)782 687 0690
simon.vingoe@wwwinc.com

Correspondence

Hi Adam,

I have spoken with the USA and they do not know of any published research on Barefoot trainers.

Thanks

Simon

From: Adam Smith [mailto:ASmith@bmj.com]

Sent: 01 June 2012 12:44 To: Vingoe, Simon

Subject: RE: BMJ research

Thanks Simon. I got the attachment too. I'll be in touch if I need anything else.

Adam

To: Adam Smith < ASmith@bmj.com>

From: "Vingoe, Simon" <Simon.Vingoe@wwwinc.com>

Date: 06/01/2012 08:59AM Subject: RE: BMJ research

Hi Adam,

We do not have any proprietary research on the trainers which we can supply. I have attached some more of the Lieberman work if of use. I have asked the PD team in the US if there is any publicly available research on Barefoot trainers generally but I have to say I am not aware of any.

Thanks

Simon

To: Adam Smith <ASmith@bmj.com>

From: "Vingoe, Simon" <Simon.Vingoe@wwwinc.com>

Date: Wednesday, May 30, 2012 10:27PM

Subject: RE: BMJ research

Hi Adam,

I am up in Scotland tomorrow and so OK if I come back to you on Friday?

Cheers

Simon

From: Adam Smith [mailto:ASmith@bmj.com]

Sent: 30 May 2012 20:56 To: Vingoe, Simon

Subject: RE: BMJ research

Hi Simon,

Thanks for this.

Has there been any research done on the actual trainers? If so, could you send me the relevant journal papers or point me in the right direction online?

Thanks,

Adam

To: Adam Smith < ASmith@bmj.com>

From: "Vingoe, Simon" <Simon.Vingoe@wwwinc.com>

Date: 05/28/2012 11:10PM Subject: RE: BMJ research

Hi Adam,

Having checked with the States I can confirm that our claims were taken from the work of Daniel Lieberman at the Harvard Skeletal Biology Lab and his study into Biomechanics of Foot Strikes

& Applications to Running Barefoot or in Minimal Footwear.

Please see http://www.barefootrunning.fas.harvard.edu/index.html

I am happy to assist further if you need any more information from me and so please do not hesitate to ask. I know from our conversation your timings are tight and so wanted to get back to you asap.

Regards

Simon

From: Adam Smith [mailto:ASmith@bmj.com]

Sent: 28 May 2012 11:07 To: Vingoe, Simon

Subject: RE: BMJ research

OK, thanks Simon. Keep me posted.

Adam

----"Vingoe, Simon" <Simon.Vingoe@wwwinc.com> wrote: ----

To: Adam Smith < ASmith@bmj.com>

From: "Vingoe, Simon" <Simon.Vingoe@wwwinc.com>

Date: 05/28/2012 10:57AM Subject: RE: BMJ research

Hi Adam,

Its a bank hol in the US today and so I will have to aim to get the info you need from them tomorrow.

Thanks

Simon

To: simon.vingoe@wwwinc.com

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM Subject: RE: BMJ research

Hi Simon,

Thanks for the call just now. Original email and requests below. Specifically, the claims we're looking at research for are:

- 1) Helps you find the natural way you were born to run;
- 2) forefoot plate and Vibrant sole provides traction and protection for a smoother ride.

The relevant products are listed in the original email below.

As discussed, I'd need a reply by the end of next Tuesday, either with or without the research I requested.

Thanks,

Adam

From:

Date: 05/25/2012 05:22PM Subject: FW: Medical research

Hi Adam,

Nice to talk to you thought might be worthwhile dropping you my contact details.

Regards

Simon

Simon Vingoe Marketing Manager

T +44 (0)207 860 0122 M +44 (0)782 687 0690 simon.vingoe@wwwinc.com merrell.com

Wolverine Europe Ltd Kings Place 90 York Way London N1 9AG

----Adam Smith/BMJ wrote: ----

From: Adam Smith/BMJ Date: 05/25/2012 04:43PM

Cc: "Woolham, Vikki" < Vikki. Woolham@wwwinc.com>

Subject: RE: BMJ research

Hi Vikki,

Just to let you know, I still haven't heard from your colleagues.

I'd need a reply by the end of next Tuesday, either with or without the research I requested.

Kind regards

Adam Smith BMJ Research asmith@bmj.com o7816125827

----Adam Smith/BMJ wrote: ----

To: "Woolham, Vikki" < Vikki. Woolham@wwwinc.com>

From: Adam Smith/BMJ Date: 05/21/2012 11:54AM Subject: RE: BMJ research

OK Vikki. Thanks for the help.

Adam

----"Woolham, Vikki" < Vikki. Woolham@wwwinc.com> wrote: ----

To: Adam Smith <ASmith@bmj.com>

From: "Woolham, Vikki" < Vikki. Woolham@wwwinc.com>

Date: 05/21/2012 11:49AM Subject: RE: BMJ research

Hi Adam

I have sent this to them they have just returned from conference so are quite busy I am sure they will read this email at some point.

Kind Regards

Vikki

Vikki Woolham . Receptionist Central Services

Wolverine Europe Ltd . A Division of Wolverine Worldwide, Inc

Kings Place . 90 York Way . London . N1 9AG P: +44 (0) 20 7860 0100 . F: +44 (0) 20 7860 0500

From: Adam Smith [mailto:ASmith@bmj.com]

Sent: 21 May 2012 11:47 To: Woolham, Vikki

Subject: RE: BMJ research

Thanks Vikki. Do you have an idea of when they'll be back and therefore when I might expect a reply? Sorry to press you on this, I'm just trying to check how soon I can pull everything together.

Thanks for your help.

Adam

----"Woolham, Vikki" < Vikki. Woolham@wwwinc.com > wrote: ----

To: Adam Smith <ASmith@bmj.com>

From: "Woolham, Vikki" < Vikki. Woolham@wwwinc.com>

Date: 05/21/2012 08:46AM Subject: RE: BMJ research

Hi adam this has been sent our merrell marketing guys have been in the USA I am

sure they will see it when they get back

Kind Regards

Vikki

Vikki Woolham . Receptionist Central Services Wolverine Europe Ltd . A Division of Wolverine Worldwide, Inc Kings Place . 90 York Way . London . N1 9AG P: +44 (0) 20 7860 0100 . F: +44 (0) 20 7860 0500

k. GNC

Products

"GNC Ultra Mega Women's Vitapaks: GNC Women's Ultra Mega Active; GNC Women's Ultra Mega 50 Plus; GNC Women's Ultra Mega Menopause; GNC Ultra Mega Green Women's Vitapak; GNC Women's Ultra Mega Joint; GNC Women's Ultra Mega Wellness Vitapak; GNC Women's Ultra Mega Energy; GNC Women's Ultra Mega Heart; GNC Ultra Mega Green Vegetarian Vitapak (9 products)"

Contact

Laura Brophy
Ibrophy@marketcompr.com

Main: 212-537-5177 x2 | Mobile: 203-331-7618

Greg Miller

gmiller@marketcompr.com

Correspondence

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM

Cc: Greg Miller <, gmiller@marketcompr.com>, Laura Brophy <,

Ibrophy@marketcompr.com> Subject: Re: BMJ research

Hi Laura and Greg,

Further to our phone call, I haven't yet received any articles or a response regarding my request. The initial deadline has far passed. Would you be able to get this to me by the end of today?

Kind regards

Adam Smith BMJ Research asmith@bmj.com

----Adam Smith/BMJ wrote: ----

To: Laura Brophy < lbrophy@marketcompr.com>

From: Adam Smith/BMJ Date: 05/15/2012 08:54AM

Cc: Greg Miller <gmiller@marketcompr.com>

Subject: Re: BMJ research

Hi Laura,

Feel free to give me a call today (Tuesday). I'm available 9am - 1pm EST on 07816125827. Unfortunately I don't have any similar articles I could send you, so let's just discuss on the phone.

Kind regards

Adam Smith BMJ Research asmith@bmj.com o7816125827

-----Laura Brophy < lbrophy@marketcompr.com > wrote: -----

To: Adam Smith <ASmith@bmj.com>

From: Laura Brophy lbrophy@marketcompr.com

Date: 05/14/2012 08:28PM

Cc: Greg Miller <gmiller@marketcompr.com>

Subject: Re: BMJ research

Adam,

Please let me know a good time for us to chat on the phone regarding your request. Since you are ahead of our time, maybe tomorrow morning EST? Do you have example of of other articles that are similar in nature that you can email me ahead of a call? Also, when and where are your articles published? Thank you and best regards,

Laura

LAURA BROPHY

Director of Client Services and New Business Development marketcom pr | "Whatever your story is, we can help you tell it." lbrophy@marketcompr.com | Main: 212-537-5177 x2 | Mobile: 203-331-7618 www.marketcompr.com | 36 East 23rd Street, Suite 602 New York, NY 10010

I. Kinetica

Product

Kinetica Protein shake Supplement

Contact

Hugo Youngman Brand Manager hyoungman@kinetica-sports.com M +44 (0) 7584 194831 T +44 (0) 2031708591

Correspondence

To: Hugo Youngman <, hyoungman@kinetica-sports.com>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM Subject: Re: Kinetica Sports

Hi Hugo,

Thanks for calling yesterday - sorry I couldn't get back to you there and then as I was out at a conference.

Specifically, we're looking for the research that supports these claims:

- 1) support and sustain lean muscle, before during or after workout
- 2) giving your body everything it needs to succeed

We've found the 7 references included below in my first email, so we'd be looking for all other data and research beyond these 7 papers, as per the questions in the original email below.

Hopefully this narrows down the scope somewhat. Could you say realistically whether you'd be able to get things to me - if not today, in the first half of next week?

Kind regards

Adam Smith BMJ Research asmith@bmj.com

-----Hugo Youngman <hyoungman@kinetica-sports.com> wrote: ----

To: Adam Smith <ASmith@bmj.com>

From: Hugo Youngman < hyoungman@kinetica-sports.com>

Date: 05/24/2012 03:45PM Subject: Kinetica Sports

Hi Adam,

Thanks for taking the call today. Just to confirm that you will revert with any more specific information that we can provide.

BR

Hugo Youngman

Brand Manager

M +44 (0) 7584 194831 T +44 (0) 2031708591 S hugoyoungman

Kinetica Sports
One Lyric Square
Hammersmith
London W6 oNB

From: Adam Smith [mailto:ASmith@bmj.com]

Sent: 20 May 2012 15:37 Cc: Hugo Youngman Subject: Re: BMJ research

Importance: High

Dear Hugo,

I haven't heard back from you regarding the below. When will you be able to send me the relevant info?

Kind regards

Adam Smith BMJ Research asmith@bmj.com o7816125827

m. Zip Vit Sport

Product

ZV7 Energy gels

Contact

Ben

media@zipvitsport.com

Correspondence

To: Media <, media@zipvitsport.com>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM Subject: Re: BMJ research Thanks Ben. Could you give me an idea of when I could expect to hear more from you? By mid-week this week is best.

Many thanks,

Adam

----Media <media@zipvitsport.com> wrote: ----

To: Adam Smith <ASmith@bmj.com> From: Media <media@zipvitsport.com>

Date: 05/20/2012 04:08PM Subject: Re: BMJ research

Dear Adam,

I will try to look at this for you next week

Best regards

Ben

Sent from my iPhone

On 20 May 2012, at 15:38, Adam Smith < ASmith@bmj.com> wrote:

Dear sir/madam,

I haven't heard back from you regarding the below. When will you be able to send me the relevant info?

Kind regards

Adam Smith BMJ Research asmith@bmj.com

n. Sci-MX Nutrition

Product

Sci-Max (Omni MX hardcore)

Contact

Tim.Green@sci-mx.co.uk

Correspondence

To: Tim Green <, Tim.Green@sci-mx.co.uk>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM Subject: Re: BMJ research

Thanks Tim. Hope to hear from you soon.

Adam

-----Tim Green <Tim.Green@sci-mx.co.uk> wrote: ----

To: Adam Smith < ASmith@bmj.com>

From: Tim Green <Tim.Green@sci-mx.co.uk>

Date: 05/21/2012 03:42PM Subject: Re: BMJ research

Hi

I have passed this on internally. If we are able to assist someone will be in touch. I shall chase up again.

Thanks.

Tim

Sent from my iPhone

On 20 May 2012, at 15:41, "Adam Smith" <ASmith@bmj.com> wrote:

Dear Tim,

I haven't heard back from you regarding the below. When will you be able to send me the relevant info?

Kind regards

Adam Smith BMJ Research asmith@bmj.com

o. Body Building Warehouse

Product

Warrior Blaze Supplement

Contact

Kieran Fisher Kieran@bodybuildingwarehouse.co.uk

Correspondence

To: Kieran Fisher <, Kieran@bodybuildingwarehouse.co.uk>

From: Adam Smith/BMJ Date: 05/25/2012 05:22PM

Cc: Kim McIntyre <, Kim.McIntyre@bodybuildingwarehouse.co.uk>

Subject: RE: BMJ

Hi Kieran,

That should be fine. Can I expect it next Thurs/Fri?

Thanks,

Adam

-----Kieran Fisher <Kieran@bodybuildingwarehouse.co.uk> wrote: -----

To: Adam Smith < ASmith@bmj.com>

From: Kieran Fisher < Kieran @bodybuildingwarehouse.co.uk>

Date: 05/17/2012 03:10PM

Cc: Kim McIntyre < Kim. McIntyre@bodybuildingwarehouse.co.uk>

Subject: RE: BMJ

Hi Adam,

Happy to help but I'll need till next week – it's a big expo this weekend, then next week I'm in Geneva for another expo. I will be back next Thursday.

Does that work for you? I'd like to help but I need more than a couple days notice as this is our first ever trade show, and we need it to go well.

All the best,

Kieran

Bodybuilding Warehouse www.BodybuildingWarehouse.co.uk Great deals on Gaspari, BSN, CNP, Nutrisport, Applied Nutriceuticals & more!

The information contained in this E-Mail is intended for the named recipient(s). It may contain certain privileged and confidential information, or information which is otherwise protected from disclosure. If you are not the intended recipient, you must not copy, distribute or take any action in reliance on this

information. The content of this message, including any attachments to it, is the property of KBF Enterprises Ltd. unless otherwise specifically noted by an approved officer of KBF Enterprises Ltd.

From: Adam Smith [mailto:ASmith@bmj.com]

Sent: 15 May 2012 16:54

To: Kieran Fisher Cc: Kim McIntyre Subject: RE: BMJ

Hi Kieran,

My research is for an article in the BMJ looking at the evidence for a number of sports health products. I can't say anything more than that because we don't know what the research will raise.

I don't think that any research you provide could be seen to oppress a consumer's freedom of choice. The point of research is to do the opposite, no?

As mentioned previously, this is the relevant research we've found so far, and we're hoping you can help by pointing us to further research about, or of relevance to, the Warrior Blaze Supplement.

1. Westerterp-Plantenga MS. Green tea catechins, caffeine and body-weight regulation. Physiol Behav. 2010 Apr 26;100(1):42-6. Epub 2010 Feb13. http://www.ncbi.nlm.nih.gov/pubmed/20156466

Thanks,

Adam

----Kieran Fisher <Kieran@bodybuildingwarehouse.co.uk> wrote: ----

To: Adam Smith <ASmith@bmj.com>

From: Kieran Fisher < Kieran @bodybuildingwarehouse.co.uk>

Date: 05/15/2012 01:12PM

Cc: Kim McIntyre <Kim.McIntyre@bodybuildingwarehouse.co.uk>

Subject: RE: BMJ

HI Adam,

What will the research be used for? How were the products selected? Can you give me a couple examples of other products you're reviewing? I'm aware that legislation is quite relaxed in the US and much less so in, perhaps, Norway. Obviously I'm in favour of freedom of choice and consumers having the right to do what they want with their own bodies, so I'm concerned any help I provide being misused to oppress this.

In terms of research, I can provide this as that product is a collection of very simple ingredients – anyone with access to the internet could do the same, and I'm happy to help if I can get a better idea of your goals.

Thanks,

Kieran

Bodybuilding Warehouse www.BodybuildingWarehouse.co.uk Great deals on Gaspari, BSN, CNP, Nutrisport, Applied Nutriceuticals & more!

The information contained in this E-Mail is intended for the named recipient(s). It may contain certain privileged and confidential information, or information which is otherwise protected from disclosure. If you are not the intended recipient, you must not copy, distribute or take any action in reliance on this information. The content of this message, including any attachments to it, is the property of KBF Enterprises Ltd. unless otherwise specifically noted by an approved officer of KBF Enterprises Ltd.

From: Adam Smith [mailto:ASmith@bmj.com]

Sent: 15 May 2012 07:49

To: Kieran Fisher Cc: Kim McIntyre Subject: RE: BMJ

Hi Kieran,

We're looking at a range of sports-related products from many companies. As mentioned in my original email, the research is for the BMJ and will be published in the same. Our work is in conjunction with the Centre of Evidence Based Medicine at Oxford University. The BMJ and the Centre are funding the research.

How will the research benefit the industry? That's hard to say until we've done the research and collected lots of references for lots of products. I wouldn't want to make conclusions about anything until we've done the research.

Can you send me the research you mention, or specific research on Warrior Blaze Supplement?

Thanks,

Adam

-----Kieran Fisher <Kieran@bodybuildingwarehouse.co.uk> wrote: ----To: "ASmith@bmj.com" <ASmith@bmj.com>

From: Kieran Fisher < Kieran @bodybuildingwarehouse.co.uk>

Date: 05/14/2012 06:37PM

Cc: Kim McIntyre <Kim.McIntyre@bodybuildingwarehouse.co.uk>

Subject: RE: BMJ

Hi Adam,

What will the research be used for and how will the industry benefit?

There's a lot of research out there which shows how effective use of sports supplementation can help individuals get into better shape safely, than with training and diet alone, however I've got to admit I've never thought the mainstream medical community a friend to our industry. In most cases the attitude seems to be "if it works, make it a medicine and restrict its sale"......which is exactly what has happened to Yohimbe (safe, effective, and now classed as a medicine), Milk Thistle (safe, effective, and now classed as a medicine), DHEA and more....

Why are you interested in that specific product and what other products are you looking at? Who is the research for and what will it be used for? Who is paying for the research?

Thanks,

Kieran

Bodybuilding Warehouse www.BodybuildingWarehouse.co.uk
Great deals on Gaspari, BSN, CNP, Nutrisport, Applied Nutriceuticals & more!

p. DS

Products

Triazole Triazole/Activate Extreme CRAZE

Contact

Rob

rob@getds.com

Correspondence

To: <, info@getds.com> From: Adam Smith/BMJ Date: 05/25/2012 05:22PM

Subject: Re: Inquiry from GetDS.com

Many thanks Rob.

Adam

----rob@getds.com wrote: ----

To: Adam Smith <ASmith@bmj.com>

From: "info@getds.com" Sent by: rob@getds.com Date: 05/23/2012 07:08PM

Subject: Re: Inquiry from GetDS.com

Hi Adam,

The references for our products are all clearly listed at the bottom of the FAQ pages.

The blood work charts shown for Triazole and Activate Xtreme were compiled inhouse, using data provided by testers - many of whom are people not involved with the company.

We are currently in the process of working out a schedule for the next 12-18 months for double-blind placebo controlled studies for our products with an outside research group. We have a completed (but unpublished) pilot-study on Triazole for safety and efficacy, and studies on Craze for both acute and long-term use are about to get underway. We are looking to get similar studies started for both Activate Xtreme and Lean Xtreme in the near future.

Hope this helps your research.

Regards,

To: <, info@getds.com> From: Adam Smith/BMJ Date: 05/25/2012 05:22PM

Subject: Re: Inquiry from GetDS.com

Dear DS,

Thanks for getting back to me - our dialogue shows exactly why research is important. I'll contact PES with regard to Anabeta.

Meanwhile, could you help with the rest of my enquiry, regarding your products? Specifically, Triazole, Triazole/Activate Extreme and CRAZE.

What other data you have used to support your claims about these products? Is this published or unpublished?

If the research is published could you provide us with the relevant references? If your research is unpublished, would you be willing to share it with us so we can fairly evaluate how your product works?

Since I'm on a very tight deadline, I'd need all the relevant references and papers by the end of 24 May. If you are unable to provide us with further information we will also note this in our research.

Kind regards

Adam Smith BMJ Research asmith@bmj.com o7816125827

Hi Adam,

Thanks for getting in touch with us. Very glad to see you are looking to be as accurate as possible, as Anabeta is not a product we produce! Additionally, we do not use the core ingredient for that product - anacyclus - in any of our products. Anabeta, and all of the references you cut and pasted into your email, is from a company called PES. We have no affiliation to this company, but I have ran a quick google search and found that you can contact them at this URL: http://pescience.com/contacts/

Regards,

--

q. Pharma Blend 6HR

Contact

Jason Rickaby
Managing Director
PhD Nutrition Ltd
j.rickaby@phd-supplements.com
0845 6589858

Correspondence

Message sent Friday May 25th Hi Jason,

Thanks for your help on this. I appreciate things are changing. Do you think you could help me by telling me a bit more about the changes?

You said that: "the website will be (as the majority of the industry is) changing quite dramatically and there are only around 200 claims that can be used to

support inclusive ingredients (such as vitamins and minerals, protein etc) and any further claims- be it labelling or advertisement (web and offline) must fall within this criteria."

What does this mean for you as a company? Will you have to change your website and your adverts?

"Any product related claims outside the approved claims must then be supported with bespoke and specific product research analysis, which we are currently looking to choose a partner to work with on. Our R&D consultant is currently speaking with a number of universities for this purpose."

I'd love to hear more about this. Does this mean you'll have to test your product specifically or just find research to support what's in it? What are you hoping to do in future?

Where you say: "in relation to having specific product research on the product in question, we don't have any."

Have there not been any product specific tests to date? Thanks again,
Greg
BMJ Researcher
greg.jones@bmj.com

HI Greg

Thanks for the clarification below.

At this moment in time, the website will be (as the majority of the industry is) changing quite dramatically.

Whilst sports nutrition has relied upon ingredient led research to lead product claims and labelling, it no longer can do after September 2012, when the health food claims come into action.

This means, that at this point, there are only around 200 claims that can be used to support inclusive ingredients (such as vitamins and minerals, protein etc) and any further claims- be it labelling or advertisement (web and offline) must fall within this criteria. Any product related claims outside the approve claims must then be supported with bespoke and specific product research analysis, which we are currently looking to choose a partner to work with on. Our R&D consultant is currently speaking with a number of universities for this purpose.

So, in relation to having specific product research on the product in question, we don't have any.

I hope this helps in some way?

Kind Regards,

Jason Rickaby Managing Director PhD Nutrition Ltd 0845 6589858 Innovation For The Modern Athlete www.phd-supplements.com www.phd-femme.com

From: Greg Jones [mailto:Greg.Jones@bmj.com]

Sent: 15 May 2012 10:38

To: J.rickaby@phd-supplements.com

Subject: RE: Evidence enquiry re: Pharma Blend 6HR

Hi Jason,

I have attached a copy of our research so far, which includes some screenshots and details of the references and where they appear.

I hope that clarifies where the information has come from.

Regards,

Greg

BMJ Researcher greg.jones@bmj.com

-----Jason Rickaby <j.rickaby@phd-supplements.com> wrote: ----

To: "'Greg Jones'" < Greg. Jones @bmj.com>

From: Jason Rickaby <j.rickaby@phd-supplements.com>

Date: 05/15/2012 09:28AM

Subject: RE: Evidence enquiry re: Pharma Blend 6HR

http://www.phd-supplements.com/store/p/51/1/blend,-Pharma-Blend.html

Hi Greg

Thanks for the enquiry, above is the Pharma Blend 6HR product as shown on the PhD website.

Can you show/guide me where the links to the reference articles are?

Kind Regards,

Jason Rickaby Managing Director PhD Nutrition Ltd 0845 6589858 Innovation For The Modern Athlete www.phd-supplements.com www.phd-femme.com

r. TrionZ Bracelets

Contact

wendydignan@btinternet.com jasmin@trionz.co.uk paul@trionz.co.uk

Correspondence

Message sent Friday May 25th Hi Wendy,

Sorry for taking so long to respond but we have had a wealth of data to get through during this research. We are looking at identifying the research behind each claim that is made and assessing the scientific rigour with which it has been conducted. We are also keen to determine whether the research is on the product itself or constituents of the product.

If you have a list of any research that relates to the Trion Z bracelets then we would be keen to examine this, as well as any other information you might want to offer from your own research that might support or diminsh the claims of their effectiveness.

We have a lot of research to assess so we would appreciate any references as soon as possible, only if you have access to them of course.

Many thanks, and good luck with your research!

Greg

BMJ Researcher greg.jones@bmj.com

----"Wendy Dignan" <wendydignan@btinternet.com> wrote: ----

To: <greg.jones@bmj.com>

From: "Wendy Dignan" < wendydignan@btinternet.com>

Date: 05/15/2012 12:18PM

Cc: "Jasmin Brady" <jasmin@trionz.co.uk>, <paul@trionz.co.uk>

Subject: Re Trion Z evidence

Hi Greg

I am currently a final year student on the doctorate of health psychology at Staffordshire University. For my doctoral research I will be working with Trion Z and Collantotte magnetic bracelets and running a clinical trial to establish their effectiveness. I am just about to submit an ethics form to the University board. I have been passed your email regarding an evidence base for claims on the website regarding effectiveness. I am assuming that you are gathering any published or grey data for a systematic review? Any data that I have found is very much in the public domain and I haven't come across any grey data at this point.

I would however be very interested in your review. When are you hoping to submit to the BMJ?

Many thanks

Wendy Dignan

s. Zero High 5

Contact

Raphael Deinhart raph@highfive.co.uk

Correspondence

Hi Greg,

Sorry for not getting back to you sooner. The reason the study has not been published is because it is already well established research and the lead researcher felt that it didn't warrant publishing at the time.

Kind Regards, Raph

Raphael Deinhart Events and Marketing

High5 Advanced Endurance Nutrition | Race Faster | Recover Faster | Research Proven

www.highfive.co.uk | www.twitter.com/high5nutrition | www.facebook.com/High5Nutrition

On 23/05/2012 16:50, "Greg Jones" < Greg. Jones@bmj.com> wrote:

Hi Raph,

Thanks for getting back to me regarding the Zero High 5 research. I wanted to ask whether you could find out why the study you sent wasn't published? Have you had any luck contacting the lead researcher, as it might be useful to ask them this question.

Many thanks,

Greg

BMJ Researcher greg.jones@bmj.com

----Raphael Deinhart <raph@highfive.co.uk> wrote: ----

To: Greg Jones < Greg. Jones @bmj.com>

From: Raphael Deinhart <raph@highfive.co.uk>

Date: 05/15/2012 02:53PM

Subject: Re: Evidence enquiry re: Zero High 5

Hi Greg,

My colleague has tried to contact you but unfortunately the email got sent back.

Attached is the study from the original ZERO research. The study was not published. I will speak to the lead researcher in this and see if she can provide you any additional information.

Kind Regards Raph

Raphael Deinhart Events and Marketing

High5 Advanced Endurance Nutrition | Race Faster | Recover Faster | Research Proven www.highfive.co.uk | www.twitter.com/high5nutrition | www.facebook.com/High5Nutrition

t. 2XU PWX compression tights

Contact

Charlotte Bates charlotte@tclsports.co.uk

Correspondence

Message received Weds May 23rd:

Here is what is publically available. Anything else I may have to request permissions for on your behalf.

http://www.2xu.com/pwx/pwx-research.asp

Many Thanks,

Charlotte Bates

TCL Sports

Twyford House
Unit 1B
21 London Road
Twyford
Berkshire
RG10 9EH

Tel 0118 932 1556

Email sent Weds May 23rd:
Hi Charlotte Twyford House

Hi Charlotte,

Thanks for getting back to me with the references and studies. There is one in particular that we would like to investigate - it's page 24 of 29 of the RMITIAS presentation copy.pdf - do you know where we might be able to get hold of the paper that these results are from, or would you happen to have a copy that you could send?

Many thanks for your help,

Greg

BMJ Researcher greg.jones@bmj.com

From: Charlotte Bates [mailto:charlotte@tclsports.co.uk]

Sent: 15 May 2012 11:30

To: 'Greg Jones'

Cc: mikemartin@tclsports.co.uk

Subject: RE: Evidence enquiry re: 2XU PWX compression tights

Dear Greg,

Thank you for your email.

I very much doubt that that is anything close to a complete list of academic research on the benefits of compression, which is well documented. Regarding 2XU Compression specifically, our claims are predominantly based on the last of those articles (the one on endurance cyclists), alongside ongoing research at the Australian Institute of Sport. I have attached some documents relating to the AIS studies, how the products are tested and how we use the information from the research that may be of use to you.

What will you be doing in this article exactly? Are you testing the products, or simply evaluating the existing research?

Would you be able to send this article on to us when it's finished please? Thank you! J

We also deal with a sports nutrition product – GU Energy – and Newton Running, the leading natural running shoe, in case we can be of further assistance to you in these areas also.

Many Thanks,

Charlotte Bates

TCL Sports

Twyford House Unit 1B 21 London Road Twyford Berkshire RG10 9EH

Tel 0118 932 1556

u. Gatorade G Series Pro

Contact

Megan Hess

Megan.Hess@imgworld.com

Correspondence

Hi Megan,

If you could get the relevant references to me as soon as possible that would be greatly appreciated. We have begun our examination of the evidence from other products so we want to make sure we can dedicate an appropriate amount of time to each producer.

Many thanks,

Greg

BMJ Researcher greg.jones@bmj.com

----"Hess, Megan" < Megan. Hess@imgworld.com > wrote: ----

To: Greg Jones < Greg. Jones @bmj.com>

From: "Hess, Megan" < Megan. Hess@imgworld.com>

Date: 05/30/2012 02:10PM

Subject: RE: Evidence enquiry re: Gatorade G series Pro

We can get you something by the end of this week,

Is that ok?

Many thanks

From: Greg Jones [mailto:Greg.Jones@bmj.com]

Sent: 30 May 2012 09:46

To: Hess, Megan

Subject: Fw: Evidence enquiry re: Gatorade G series Pro

Dear Megan,

Here is the original email, sent on the 5th May. Please bear in mind my previous email, which aims to collect only those studies that test the product itself or the constituent components at the same levels at which they appear in the drinks. If you have any further questions then please email me or contact me on my mobile (07792 154497) as I am away from the office at the moment.

Greg

BMJ Researcher greg.jones@bmj.com

[original email was attached here]

Email from Megan Hess received Tuesday May 29th Can you please send me through the original email as I did not receive it.

Many thanks

From: Greg Jones [mailto:Greg.Jones@bmj.com]

Sent: 29 May 2012 09:33

To: Hess, Megan

Subject: Evidence enquiry re: Gatorade

Dear Megan Hess,

I contacted you a couple of weeks ago about a piece of research the BMJ is doing into the evidence behind claims made by sports nutrition and equipment. I have not received a reply from Gatorade so far and we are starting our assessment of evidence this week.

I wanted to give you a final opportunity to add any further evidence to the claims made about Gatorade. We are specifically interested in research that either tests Gatorade itself, or at least involves testing of the constituent components at the same quantities as they are found in the sports drinks.

If you have any research that demonstrates this then please send it by tomorrow afternoon so that we may be as fair and accurate as possible in our assessment of each product's claims.

Many thanks,

Greg

BMJ Researcher greg.jones@bmj.com

v. K-Swiss

Contact

Sarah Robins srobins@k-swiss.co.uk

Correspondence

Email sent May 23rd Dear Sarah,

Apologies for not being available recently - I have been away from the office and have not had time to catch up on these emails.

I am at the BBC's Media City tomorrow but could find some time to call during the day if that suits. If you want to give me a convenient time for you then I will do my best to get in touch then.

With regards to the original email, apologies if it wasn't directed at the appropriate person initially. We are looking specifically at the K-Swiss Blade Max series training shoes.

As I mentioned, we are working to a tight schedule so I would ideally like to get hold of any references that you might wish to send by the end of the week. I appreciate that I haven't been available for clarification but I hope the general

idea of our research is clear - identifying and assessing the research that backs up any claims made about a product.

Regards,

Greg

BMJ Researcher greg.jones@bmj.com

----"Sarah Robins" <srobins@k-swiss.co.uk> wrote: ----

To: <Greg.Jones@bmj.com>

From: "Sarah Robins" <srobins@k-swiss.co.uk>

Date: 05/18/2012 04:24PM

Subject: Re: Evidence enquiry re: K-Swiss Blade Max series Training shoes

Hi Greg,

I hope you are well.

I received your message this week via Nick Crook and have not had a chance to respond to your enquiry.

Can you leave this with me until early next week?

Is this research completely focused on training shoes or encompassing other sports equipment as well?

Also, I wondered how you got Nick's details as being a contact for K-Swiss since he has not worked at K-Swiss for over 2 years?

Many thanks

Sarah

w. ProPeptide Advance

Contact

Philip Connolly philip@comproteins.com PO Box 1532 778 Jagerhorn Drive Lake Arrowhead, CA 92352 Tel 1.909.336.4774 Mobile 1.909.215.2814

Correspondence

Email received May 24th: Hello Greg,

Sorry that I didn't respond yesterday, but I was on airplanes most of the day. You are correct in your assumption that we rely on the studies for each of the individual ingredients when putting together a formula for a product. I would always be skeptical of any studies that are run to "prove" the superiority of one brand over another ... the study would have been paid for by the marketing company, would likely be a biased study, and, at least in the USA, would not be considered valid by the US FDA. Met Rx and EAS both tried to run such studies and then model claims for their products based on study results but the FDA and the Federal Trade Commission disallowed both companies from structuring claims based on their "biased" studies ... mostly due to lack of a good control with which to compare. On the other hand, the FDA and FTC do allow claims to be made for individual components in a product as long as the studies are independently generated, double blind, pacebo controlled studies and the methodology can pass review by a standards board.

I am attaching a copy of one last study just released this month that shows the metabolic fate of consumption of a blend of micellar casein and native whey proteins produced by filtration of skim milk. The study basically upholds previous studies such as Boirie et al. from 1997. As I stated in my 1st email to you, we based our sustained release of amino acids claim on the original Boirie study ... but there have been many confirming studies run since then, such as: Tome and Bos in 2000, Dangin et al in 2001, and LaCroix et al in 2006. Because of regulations here in the USA, we do not make claims unless we have at least 3 studies to show efficacy.

As far as proving the products themselves, we have always relied on friendly athletes to "test" the products for us. Many athletes are very aware of the metabolic effects of every product they ingest. Many have been known to keep consumption/performance diaries so that they can refer to their personal data to solve problems in the future. We have relied on their feedback before launching a product. In the case of ProPeptide and Pro MR, some sports organizations have kept their own "before and after" records of athlete performance and have praised the two products ... we have tried to convince them to share their information, but they are, understandably, reluctant to do so. The world of sports is entwined with big money these days and nobody wishes to give away their "secrets" to the competition.

Philip Connolly PO Box 1532 778 Jagerhorn Drive Lake Arrowhead, CA 92352 Tel 1.909.336.4774 Mobile 1.909.215.2814 ---- Original Message -----From: Greg Jones

To: Philip Connolly

Sent: Wednesday, May 23, 2012 8:45 AM

Subject: Re: Sports Health Products - CNP Professional Response

Dear Philip,

Thank you for your emails and the references you supplied - I think there were more than enough for us to look through.

However, so far we have found it difficult to find references that specifically test the two products: PropPeptide Advanced and ProPeptide Protein Supplements. Would you be able to point out any research that deals with the products rather than the components of the product? Are there any references that do this or are the products using the claims made for the individual ingredients?

Many thanks for your help,

Greg

BMJ Researcher greg.jones@bmj.com

----"Philip Connolly" < Philip@comproteins.com> wrote: ----

To: <greg.jones@bmj.com>

From: "Philip Connolly" < Philip@comproteins.com>

Date: 05/17/2012 08:20PM

Cc: "Debbie Kayes" <Debbie@cnpprofessional.co.uk>, <SusanWilson@firstmilk.co.uk>, "Garry Medlock"

<garry@cnpprofessional.co.uk>

Subject: Sports Health Products - CNP Professional Response

Hello Greg,

My name is Philip Connolly. I own a company in the USA called Commercial Proteins Corporation and I am the technical consultant to CNP Professional, a sports nutrition company recently purchased by First Milk. Mr. Kerry Kayes of CNP Professional requested that I respond to you directly concerning your inquiries about evidence for sports health products. I am a Biochemist/Molecular Biologist by education and have 30+ years of experience in Research & Development of milk based proteins plus some experience with development and uses of vegetable sourced proteins. More than 20 USA and other country patents bear my name as the inventor of protein manufacturing processes and also protein applications. I have helped to formulate sports nutrition products for such giants

in the industry as Met Rx (the original Met Rx products), EAS, VPX, and Weider Global Nutrition to name a few. I have also helped to formulate some of the best selling Ready-to-Drink high protein shakes in the USA. I have much experience in the sports nutrition field.

Your email inquiry concerned ProPeptide Advanced, so I will limit my response to ProPeptide and its sister product Pro MR. Both products contain many ingredients in common. The main idea behind development of ProPeptide and Pro MR was the protein blend. Over the years, there has existed anecdotal evidence that consumption of larger amounts of proteins is good for athletes. The types of proteins traditionally utilized in sports nutrition have always been those that supplied the highest quality of nutrition to human beings. Consequently, those proteins that displayed a high PER (Protein Efficiency Ratio) and, later, a high Biological Value, have always been prized as the best proteins for an athlete. When we were putting together the protein blend for ProPeptide and Pro MR, we wanted to include only those proteins that imparted the highest quality nutrition for athletes. Therefore we used a blend of the following proteins: Milk Protein Concentrate, Whey Protein, Egg White, and Hydrolyzed Whey Protein.

We settled on this particular mix of proteins because all are well recognized in sports nutrition as providing benefits to athletes. After deciding on a mix of proteins, we had to determine the proper ratio of the proteins. Just before ProPeptide and Pro MR were formulated, a landmark study was published in The Proceedings of the National Academy of Sciences (USA) in 1997 by Yves Boirie et. al. The study was performed at the European Center for Human Nutrition Research in Clermont, France. This study attempted to answer the question of which type of protein was more efficiently utilized by a young, athletically fit human body - a fast digesting protein (in this study, a native whey protein filtered directly from skim milk) or a slow digesting protein (casein in its native structure known as a casein micelle that was also filtered directly from skim milk). The results of the study caused a great uproar in sports nutrition. Those companies that had devoted themselves to selling only whey protein were upset because some of the study results seemed to show that casein was a more efficiently used protein by the body. Companies that sold products containing a mix of casein and whey proteins hailed the study results as proof that they had been right along. In truth, though, the results of the study showed that both fast and slow digesting proteins provide unique benefits to a young athletic body. Consumption of whey protein triggered a pronounced beginning of protein synthesis (the process by which the body creates new muscle tissue). Consumption of casein did not trigger protein synthesis as significantly as did whey protein, but did result in prolonged elevated amino acid levels in the bloodstream compared to whey protein. Without plentiful supplies of amino acids in the bloodstream, protein synthesis cannot occur. Therefore, the study pointed out the obvious ... that while whey protein strongly triggered protein synthesis, it's effect was transitory compared to casein and while casein did not trigger protein synthesis as strongly as whey protein, its effects lasted much longer and protein synthesis was able to proceed for at least 7 hours after consumption of casein.

While most people were trying to declare one protein or the other as the victor from the Boirie study, we saw the true meaning of the results. Both proteins are of great benefit to athletes. But at what ratio? For the answer to that, we had to turn again to anecdotal evidence. We looked at human maternal breast milk and the ratio of casein to whey proteins. Maternal breast milk in all mammals is species specific ... i.e., the milk for each species contains protein ratios specific for that species. Cow's milk proteins are roughly comprised of 82% casein and 18% whey proteins. Human maternal milk is roughly 50% casein and 50% whey proteins. We reasoned that the human infant is the fastest growing stage of human development. If the ratio of 50% casein and 50% whey proteins was perfect for fast growing human infants, then it would also be ideal for promoting tissue growth and repair in athletes. So, we settled on a blend of 50% casein and 50% whey proteins for the main part of the ProPeptide and Pro MR blend and added some egg white (always considered a superior protein for athletes due to its high biological value and high levels of sulfur containing amino acids) as well as a small amount of hydrolyzed whey protein (to get amino acids into the bloodstream even faster of a faster start to protein synthesis).

Then we had to decide on protein sources. For egg white and hydrolyzed whey protein, the choices were easy because egg white is a standard product worldwide and we were looking for a whey protein of about 20% degree of hydrolysis. For the casein source, we followed the Boirie study and decided to use only casein in its micellar form (as opposed to those products out there that also use casein or caseinates). One other finding of the Boirie study was that the prolonged, slow release of amino acids into the bloodstream from micellar casein provided a protective effect against catabolism during and after exercise. Milk Protein Concentrate is the name given to the milk protein that has been filtered straight from skim milk without addition of any chemicals to the milk or any pH adjustments. The protein resulting from the skim milk filtration process is as undenatured as one can get ... casein in its native, micelle structure and whey proteins in their native, undenatured state.

Because the milk source is bovine, the milk protein concentrate only contained 18% whey protein. In order to achieve our desired ratio of 50% whey protein and 50% casein, we had to source the ideal whey protein. That is where the Bounous and Gold paper that you referenced in your email inquiry comes into play. Gustav Bounous is a medical doctor from Montreal, Canada. He used to travel the International Dairy Federation circuit giving lectures about his medical findings for the immune supporting benefits of whey protein. To make his long story short enough for this email, Bounous noticed that some whey proteins helped his cancer and AIDS patients to recover better from treatment while others did not seem to be very effective. At a loss to understand what was going on, he approached Dr. Phil Gold at Montreal University to find out why he was experiencing a difference in whey protein benefits. Phil Gold correctly assumed that the differences were most likely due to processing variations in the whey proteins ... that some whey proteins were more chemical and/or heat denatured than others. Thus, Gold devised an experiment wherein he compared a "perfect" whey protein - made by filtering whey protein direct from skim milk with very low heat treatments - which he dubbed "Product X", to some commercially available

whey proteins manufactured as a byproduct of cheese production (from New Zealand, USA, and even Europe). As a control for their experiment, they used casein ... because everyone knows that casein is not supposed to have any immune supporting properties (right? I'm being sarcastic here). The results of the study showed that Product X had a significant effect supporting the immune system while the commercially available whey proteins were not much more effective at immune support than the control casein. Over the years, whey protein purveyors worldwide have slaughtered the true meaning of the results of the Bounous and Gold study, trying to convince everyone that any whey protein will support the immune system like Phil Gold's Product X. We, however, wanted to do things right and, so, set out to find a whey protein that was low heat treated and filtered directly from skim milk. That is the whey protein with which we formulated ProPeptide and Pro MR ... as close to Phil Gold's Product X as one can get.

Now we had our protein blend ... micellar structure casein, native, undenatured whey proteins filtered directly from skim milk, egg white and hydrolyzed whey protein. It was time to add in a few helpful ingredients. The first item we looked at was glutamine. Much has been written about the amino acid glutamine over the years. While it is a non-essential amino acid from a dietary standpoint, it is an essential amino acid in the human body ... even more essential for an athlete. It has been reported that glutamine comprises as much as 50% of the total amino acids present in the average human body. Our bodies can manufacture the amino acid glutamine from 4 or 5 other amino acids as our bodies require more glutamine. When people are under great stress (defined as people suffering from prolonged, chronic illness or hard training athletes), their bodies become depleted of glutamine. These people need to supplement their diets with additional glutamine. Published studies show that such people need a supplemental quantity of about 20 grams of glutamine per day. Then, there is the question of what form of glutamine ... L-glutamine as is commonly used in sports nutrition or peptide bonded glutamine? There are literally 100's of studies concerning efficient absorption of free amino acids versus di- and tri- peptides through the human intestinal uptake system (many of which were performed by D.B. Silk et. al.). Each of these studies concluded that di-and tri- peptides are more efficiently absorbed into the blood stream than are free amino acids, like Lglutamine, when consumed in the presence of other proteins/amino acids or even carbohydrates and fats. As confirmation of these facts, in 2003 a study published in Nutrition Journal by Preiser et. al. showed a difference in body utilization of L-Glutamine and peptide bonded glutamine. We, therefore, opted to use peptide bonded glutamine in ProPeptide and Pro MR. We add 3 to 4 grams of supplemental glutamine, in the form of peptide bonded glutamine, to every serving of ProPeptide and Pro MR.

How much protein should an athlete consume in one serving? This question stirs great debates in sports nutrition. When Met Rx was first marketed, there were nutritionists who declared that the human body wasn't capable of processing 37 grams of protein in one meal. Today, there exist sports nutrition products that exceed 60 grams of protein in one serving. We settled on our quantity of protein per serving by striving to supply only as much protein as the body can efficiently

assimilate from any one meal. There have been a few studies released in the past that show that the body can only efficiently assimilate about 15 grams to 20 grams of whey protein per dose and so we set our whey protein dose at 15 grams to 20 grams per serving. Since our protein blend was to be 50% whey protein and 50% casein, we also added 15 grams to 20 grams micellar form casein per serving. Then, we added the egg white, hydrolyzed whey protein and even the protein content from the peptide bonded glutamine supplementation. That brought us to the present protein content per serving of ProPeptide and Pro MR. We have one unique twist in ProPeptide and Pro MR ... probiotic organisms. What good does it do a body to consume large amounts of nutrients if the body cannot efficiently absorb those nutrients? Athletes, especially, have a difficult time maintaining good intestinal health. As was stated earlier, athletes are easily depleted of glutamine because their bodies will use glutamine to restore glycogen stores after hard training and also will utilize glutamine in the energy cycle should the body run out of glucose. Glutamine plays an important role in maintaining the intestinal lining ... the site of nutrient uptake system of nutrients after digestion. It is said that the human body replenishes that intestinal lining every 72 hours. Without sufficient glutamine, the body cannot replenish and restore the lining efficiently. Therefore, we decided to include some other protective mechanism for the intestine and included probiotic organisms in ProPeptide and Pro MR. The probiotic organisms provide two benefits for athletes. One is promotion of intestinal health by killing off more harmful organisms in the intestine such as yeast and mold. Two, the probiotic organisms assist in more efficient digestion

Other ingredients that we add, such as salt (sodium) and potassium, serve less significant functions but are still important to sports nutrition as metabolic electrolytes. A few ingredients are added to increase the appeal of the products to consumers without adding benefit to athletes. And because the powders are dusty, it is necessary to coat the powders with a fat containing product to decrease dustiness. Lecithin has always been used for such a purpose because it is considered a healthy phospholipid and we have also added medium chain triglycerides ... because they are not readily utilized to manufacture stored fat in the body but are metabolized in the liver for energy and provide an energy punch of 9 Kcals per gram of energy as opposed to 4 Kcals of energy per gram of carbohydrate.

and harvesting of nutrients from all foods consumed.

That, basically, gives you a brief description of the reasoning behind our formulating of ProPeptide and Pro MR. I realize that one would look at the length of this email and think that it isn't so brief, but ... trust me ... this is brief compared to what detail I could discuss about the science behind our products. I am attaching a large bibliography taken from what I have amassed over the years concerning nutritional properties of proteins and their effects on the human body. The list is by no means complete. If, after reading my email and looking over the list, you still have questions please feel free to contact me. I love to talk proteins and am here to help.

Kind Regards, Philip Connolly PO Box 1532 778 Jagerhorn Drive Lake Arrowhead, CA 92352 Tel 1.909.336.4774 Mobile 1.909.215.2814

x. Sports Jelly Beans

Contact

Victoria Reeves Jelly Belly-UK PR Best House 4-5 Alban Park Hatfield Road St Albans AL4 OJJ

T: 01727 829010 M: 07860 436649

Correspondence

Message received May 15th Dear Greg

Thank you for writing. Attached is our research which I hope you'll find interesting and relevant. In Please do not hesitate to let me know if I can be of further assistance.

Thanks for thinking of Jelly Belly Sport Beans in this context.

Kind regards

Victoria

Victoria Reeves Jelly Belly-UK PR Best House 4-5 Alban Park Hatfield Road St Albans AL4 OJJ

T: 01727 829010 M: 07860 436649

www.jellybelly-uk.com

y. Asics Gel Volt 33

Contact

Liz Austen
liz@asics.co.uk
Cathy McGinnis
C.McGinnis@asics.co.uk

Correspondence

To: Greg.Jones@bmj.com

From: Liz Austen < liz@asics.co.uk>

Date: 05/16/2012 05:07PM

Cc: Cathy McGinnis < C.McGinnis@asics.co.uk>

Subject: Re: Fw: Evidence enquiry re: ASICS Gel Volt 33

Dear Greg,

I have been passed your email from Susan at Intersport. I am happy to talk to you about this, however you have not provided a telephone number. I feel that for the short deadline you have it might be best to have a conversation.

Please provide a number, or give me a call on the numbers below.

As a quick answer see below:

- ASICS have our own Research and Design Centre at our Head office in Japan. This is ASICS Institute of Sport Science where we do our material testing and development, quality control, innovation and design and product testing. In order for ASICS to develop new concepts and technologies we do background research taking in to account published research, and our own research results.

The testing done in Japan if it is published is normally done so in Japanese. However some of the researchers have attended international conferences to speak about sports footwear and research. Tsuyoshi Nishiwaki and Kenta Moriyasu are two of ASICS top sports engineers in our R&D centre. We also use a lot of research gathered from Melborne University and Simon Bartold is our International Research consultant who also has some published research.

I'll happily speak to you to see if I can help answer any questions.

Kind Regards,

Liz Austen Product Manager - Footwear ASICS ASICS UK 01925 241041 07876 355852

z. Aqua Sphere Energize compression-wear

Contact

Lindsey Taylor <u>ltaylor@aqualung.fr</u>

Correspondence

Email sent May 25th Dear Lindsey,

Thank you for your help in sending over the articles relating to your products. What we are looking to compile are the studies that directly test your compression-wear, rather than the studies that discuss any benefits of compression on exercise. Do you think you could send any specific research that you have? If you don't have any, we would also be grateful if you could send any summaries relating to your products specifically.

We were also wondering what kind of methods you might have employed to check the quality of any studies. Do you think you could share that information with us?

It would be useful to have the fabric manufacturers contact details, although my assumption would be that they do not conduct any testing outside of quality control. Would this be correct?

Thanks for your help,

Greg

BMJ Researcher greg.jones@bmj.com

----TAYLOR Lindsey < ltaylor@aqualung.fr> wrote: ----To: "greg.jones@bmj.com" <greg.jones@bmj.com>

From: TAYLOR Lindsey < ltaylor@aqualung.fr>

Date: 05/21/2012 02:18PM

Subject: Compression-wear range

Hi Greg,

I'm sorry I don't have more time to help you with your research - I was out of the office when your email came through last week, and now we have started are Sales Conference which lasts all week.

Anyway, I've taken 5 minutes out to try to help - there are a number of studies available on line, here are just a couple of articles which may be of use to you:

http://www.pponline.co.uk/encyc/the-benefits-of-compression-clothing-35846 http://greatist.com/fitness/compression-clothing-exercise/#

You could also contact the fabric manufacturers - please let me know if you need their details?

If you wish we can discuss over the phone.

Thanks and kind regards Lindsey

aa. Powerade

Contact

Helen Munday hmunday@coca-cola.com Laura Misselbrook lmisselbrook@coca-cola.com

Correspondence

Email; received May 31st: Dear Greg,

Thanks for our discussion yesterday.

As promised here is some additional information that I think will help you.

As I explained in our discussion, as sports drinks are classified as foods, the regulations that govern foods are in play here rather than ones that govern other materials. As such there is no need to conduct clinical trials, as the SCF report that we talked about, has set compositional standards for drinks such as Powerade ION4. The findings of the SCF were then further evaluated by EFSA (European Food Safety Authority) who are the competent authority to scientifically substantiate evidence and indeed claims. In our conversation we talked about the scientific evaluation of the evidence. In it is our view that having been reviewed by both SCF and EFSA, the body of evidence has been assessed as scientifically robust by the highest possible authority.

I have previously sent you the EFSA review but I now include pertinent extracts from both the SCF report and the EFSA review. Plus I attach the full SCF report as promised.

Extracts from the EU Scientific Committee for Foods (SCF) - Report of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort especially for sportsmen (SCF/NUT/SPORT/5 Final 2001).

Council Directive 89/398/EEC on foodstuffs intended for particular nutritional uses, as amended by Council Directive 1999/41/EC, foresees the adoption, by the Commission, of a specific directive on foodstuffs for particular nutritional uses intended to meet the expenditure of intense muscular effort and especially for sportsmen. In order to prepare this specific directive the Commission asked the Scientific Committee for Food (SCF) for advice on the nature, the essential composition where necessary, and any other specific requirements concerning the labelling and the appropriate use of such foodstuffs. The Committee reviewed the scientific literature in the area of sport nutrition as well as a number of consensus reports that were prepared by various sport organisations and came to the conclusion that the concept of a well-balanced diet is the basic nutritional requirement for athletes. Nevertheless, taking the aspects of intense muscular exercise in consideration such as intensity, duration and frequency as well as specific constraints like time and convenience, individuals can benefit from particular foods or food ingredients beyond the recommended dietary guidelines for the general population. As the increased energy need of these individuals is the most apparent difference, the food intake is higher. This can lead to differences in food choice and eating pattern as well as gastro-intestinal distress. Specially adapted nutritious foods or fluids may help to solve specific problems so that an optimal nutritional balance can be reached. These beneficial effects are not only limited to athletes who are taking regular intense prolonged muscular exercise, but are also intended for other target groups, for example for occupational jobs with hard physical work or with extreme environmental conditions, as well as for individuals with irregular physical high intensity or fatiguing leisure time activities. In relation to these general considerations, four food categories have been identified, reviewed and where applicable, essential requirements were formulated.

Carbohydrate-electrolyte solutions (C.E.S.):

The two factors that have been considered to contribute most to the onset of fatigue in exercise are the depletion of the body's carbohydrate reserve and the onset of dehydration, as a consequence of the loss of water and electrolytes in sweat. Compared to water as a control drink, a substantial body of scientific evidence supports the suggestion that during prolonged exercise drinks containing carbohydrates and electrolytes, in particular sodium, improve the performance.

The optimum carbohydrate concentration in the drink depends on a number of factors, among others the need for water (hot/cold conditions) and the intensity and type of exercise (gastrointestinal absorptive capacity, osmolality (rate of gastric emptying as well as water absorption in the small intestine), type of carbohydrate simple vs. polymers). Therefore a range from 80-350 kcal (335 - 1470 kJ) CHO/1000ml CES drink is advised. The only electrolyte added to drinks consumed during exercise that is known to confer physiological benefit is sodium. A sodium concentration of 20-50 mmol/l (460 - 1150 mg/l) will stimulate

carbohydrate and water uptake maximally in the small intestine and will help to maintain extracellular fluid volume.

End of extract from the SCF report

EXTRACT FROM EFSA OPINION

These guidelines have been taken into account and in effect by the EFSA Scientific Opinion on the substantiation of health claims related to carbohydrate-electrolyte solutions and reduction in rated perceived exertion/effort during exercise (ID 460, 466, 467, 468), enhancement of water absorption during exercise (ID 314, 315, 316, 317, 319, 322, 325, 332, 408, 465, 473, 1168, 1574, 1593, 1618, 4302, 4309), and maintenance of endurance performance (ID 466, 469) pursuant to Article 13(1) of Regulation (EC) No 1924/20061.

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to carbohydrate-electrolyte solutions and reduction in rated perceived exertion/effort during exercise, enhancement of water absorption during exercise, and maintenance of endurance performance. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food which is the subject of the health claims is carbohydrate-electrolyte solutions. The Panel considers that carbohydrate-electrolyte solutions are sufficiently characterised in relation to the claimed effects.

Ø Enhancement of water absorption during exercise
The claimed effects are "water and electrolyte balance", "rehydration", "nutrient
absorption", "hydration", "better/faster fluid delivery with a combination of
carbohydrates than with glucose alone", "electrolyte balance/rehydration",
"potassium/water/electrolyte-balance; diuretic", "ergogenic role in sports and
exercise", and "contains essential electrolytes for better recovery". The target
population is assumed to be active individuals performing endurance exercise.
The Panel considers that an enhancement of water absorption during exercise
may be a beneficial physiological effect.

The evidence provided by consensus opinions/reports from authoritative bodies shows that glucose electrolyte solutions with an osmolality which is isotonic or slightly hypotonic with respect to plasma (i.e. 200-330 mOsm/kg water) maximise the rate of water uptake.

The Panel concludes that a cause and effect relationship has been established between the consumption of carbohydrate-electrolyte solutions and an enhancement of water absorption during exercise.

The Panel considers that in order to bear the claim a carbohydrate-electrolyte solution should contain 80-350 kcal/L from carbohydrates, and at least 75 % of the energy should be derived from carbohydrates which induce a high glycaemic response, such as glucose, glucose polymers and sucrose.

In addition, these beverages should contain between 20 mmol/L (460 mg/L) and 50 mmol/L (1,150 mg/L) of sodium, and have an osmolality between 200-330 mOsm/kg water.

The target population is active individuals performing endurance exercise.

Ø Maintenance of endurance performance

The claimed effects are "endurance; increased endurance capacity; increased endurance performance; delayed fatigue" and "endurance in heat". The target population is assumed to be active individuals performing endurance exercise. The Panel considers that maintenance of endurance performance is a beneficial physiological effect.

The evidence provided by consensus opinions/reports from authoritative bodies shows that there is good consensus on the role of beverages containing carbohydrates and electrolytes (in particular sodium) in maintaining performance during prolonged endurance exercise, relative to plain water.

The Panel concludes that a cause and effect relationship has been established between the consumption of carbohydrate-electrolyte solutions and maintenance of endurance performance.

The Panel considers that in order to bear the claim a carbohydrate-electrolyte solution should contain 80-350 kcal/L from carbohydrates, and at least 75 % of the energy should be derived from carbohydrates which induce a high glycaemic response, such as glucose, glucose polymers and sucrose.

In addition, these beverages should contain between 20 mmol/L (460 mg/L) and 50 mmol/L (1,150 mg/L) of sodium, and have an osmolality between 200-330 mOsm/kg water.

The target population is active individuals performing endurance exercise.

END OF EXTRACT

Thus you can see, that under these provisions, if you have an appropriately formulated product, the benefits are sufficiently characterised to make relevant claims.

So you can understand how Powerade ION4 fits into the compositional standards I present to you the following summary.

Composition

Minimum quantity specified

Powerade ION4

Maximum quantity specified

Carbohydrate

At least 75% of the energy from metabolisable carbohydrate

3.9g glucose and fructose Sodium 460 mg/l 510 mg/l 1150 mg/l Energy 80 kcal/l 160 kcal/l 350 kcal/l Osmolality 200 mOsm/kg water 275 mOsm/kg water 330 mOsm/kg water

Thus you can see that we are authorised to make claims for carbohydrateelectrolyte drinks.

I additionally wanted to clarify the testing of Powerade ION4. Whilst there is no explicit requirement to do this, given the compositional standards I have described, the work that we have conducted with researchers does contribute to the body of evidence and has given us assurances to the efficacy of our products. The paper by Watson, Shirreffs and Maughan that I have already sent is a good example of this. You will see that we used a number of variants to establish the efficacy of the level of carbohydrate and sodium that our product contains. We could not use the commercially available product as this would have not been possible in the experimental design but the functional ingredients were those used in our formulation and you will see in the acknowledgement ('The study was carried out in relation to the product Powerade and was funded in part by the Coca-Cola Company') that this was conducted in support of our development programme.

If you have any further questions please don't hesitate to contact me and I would be most grateful if you would let me know the timings on the issue of the report and when we might have sight of it. We have also been contacted by the BBC about a Panorama programme they are currently compiling and they mentioned a BMJ study. Is this the same piece of work that they are referencing?

Kind regards,

From: Greg Jones [mailto:Greg.Jones@bmj.com]

Sent: 25 May 2012 15:47

To: Helen Munday; Laura Misselbrook Subject: RE: Evidence enquiry re: Powerade

Dear Helen,

Thank you for you help in sending over the references for Powerade. As you can imagine, asking a library to collate all the papers we have received will take quite some time. I imagine you have PDFs of all of these as a dossier already: if that is the case then would you be able to send them over? If you don't have them, we would also be grateful if you could include any summaries.

We were also wondering what kind of methods you have employed to check the quality of the studies. Do you think you could share that information with us?

And lastly, do you think you could tell us which of these studies actually uses the Powerade drinks? If none of them do, which studies use the active ingredient in the same doses as contained within Powerade? We would be grateful for some guidance on this.

Many thanks for your help,

Greg

BMJ Researcher greg.jones@bmj.com

To: Laura Misselbrook "Greg.Jones@bmj.com" <Greg.Jones@bmj.com>

From: Helen Munday hmunday@coca-cola.com>

Date: 05/18/2012 04:42PM

Subject: RE: Evidence enquiry re: Powerade

Dear Dr. Jones,

Sports drinks are among the best-researched food and beverages products in the world. There is a wealth of scientific research that can be relied upon to formulate an efficacious beverage that can serve a variety of purposes.

These include:

- · supply of substrate (carbohydrates),
- · prevention of dehydration,
- electrolyte replacement,
- pre-exercise hydration,
- post-exercise rehydration

The Coca-Cola Company takes its responsibilities towards efficacy and claims very seriously and we work within a strict regulatory environment to ensure that all claims we make, can be fully substantiated and bring benefits to consumers.

We would refer you to the material on our website www.poweradegb.com which we feel clearly describes the efficacy of our lead sports drink POWERADE ION4 to our consumers, although we believe that you are probably aware of this as the list of references you have sent us, appears to be taken from this source.

Whilst this represent a thorough overview of the body of science that supports the efficacy of products such as POWERADE ION4, it is important to recognise that research in the field of sports nutrition is active and developing rapidly. As such, The Coca-Cola Company works closely with eminent experts in this field to ensure that all our products are firmly grounded in science and we make only claims which can be substantiated by scientific evidence.

In addition to the references that you have cited we can add the following reference that has been published since the last update of our website and supports our product's efficacy. These studies have either been commissioned by ourselves, or sometimes have been independently conducted using our product. In any event, all have been through a thorough peer review process. In the last 2 years we have commissioned and published the following series of studies, which have been published as one paper in the official journal of the American College of Sports Medicine.

1. Watson P, van Langen F, Quigley J and Maughan RJ. Effect of Dilute CHO Beverages on Performance in Cool and Warm Environments. Med. Sci. Sports Exerc., Vol. 44, No. 2, pp. 336–343, 2012.

We would like to point out that POWERADE ION4 is an isotonic sports drink aimed at individuals taking part in intense physical exercise. It has been formulated, and is marketed, in complete accordance with Directive 2009/39/EC (recast of Directive 89/398/EEC) relating to foodstuffs for particular nutritional uses (PARNUTS).

With regard to sports drinks, PARNUTS refers to the "Report on Composition and Specification of Food Intended to meet the Expenditure of Intense Muscular Effort, Especially Sportsmen" issued by the Scientific Committee on Food (SCF), adopted in 2000 and corrected in 2001, which was prepared at the request of the European Commission. The SCF report is the most authoritative analysis of the role and benefits of sports drinks and sets out guidelines on the composition and specification of foods and beverages intended to meet the expenditure of intense muscular effort and in particular to allow for efficient hydration. Our product has been formulated in strict compliance with these guidelines.

In addition, more recently the European Food Safety Authority has published the scientific opinion on the substantiation of claims in relation to carbohydrate-electrolyte solutions, more commonly known as sports drinks. This opinion addresses the scientific substantiation of health claims in relation to carbohydrate-electrolyte solutions and reduction in rated perceived exertion/effort during exercise, enhancement of water absorption during exercise, and maintenance of endurance performance. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders. See attachment.

As an example, in evaluating the substantiation of the efficacy of an isotonic sports drink such as POWERADE ION 4 it is essential to bear in mind that such a beverage is intended for use by a person who, as a result of engaging in sustained, high intensity exercise, has lost substantial quantities of water and minerals (electrolytes) through perspiration. A substantial body of scientific evidence, taken as a whole, establishes that for such a person, drinking an isotonic sports drink that contains not only water, but also appropriate quantities of sodium and carbohydrates, will result in his/her consuming a higher volume of fluid, and retaining it better, than if he/she drank plain water alone. In other words, under such circumstances an appropriately formulated isotonic sports drink, such as POWERADE ION4, "hydrates better than water."

The extract from the website that demonstrates our scientific basis, is as follows:

When you're exercising hard and desperately need a drink, it's natural to head for the nearest bottle of water. But although it'll quench your thirst, it isn't always the best way to rehydrate your body during or after exercise. Here's why:

- Water doesn't have adequate minerals and carbohydrates. 4,7,9,10-16, 19-20, 26
- Water shuts down the thirst receptors prematurely, before you've replaced the fluid your body has lost through sweat. 1,3,9,12,20,21
- · Water doesn't have flavour. 1-3,21,25
- Water doesn't have the performance benefits of a sports drink. 5,6,8,12-16,20-25
- Therefore, sports drinks have the advantage of containing sodium which helps your body retain and use the fluid you've drunk more effectively, as well as carbohydrates to help recover muscle fuel stores.
- Sports drinks are specially formulated to replenish both fuel and mineral needs to help you sustain physical and mental performances at your best.

We would direct you to the website http://www.poweradegb.com/hydration-and-performance/hydration/water-is-not-enough to view this information (including the references cited) and the sports context in which it is presented.

Finally I would add that we have a European Scientific Advisory Board on Sports Science and Nutrition composed of academics and practical experts in the field, and this Board advices us on all aspects of sports science and nutrition which may or may not be in the public domain at that time, but it is always our intent to publish any research outcomes in support of our products.

Yours sincerely,

From: Laura Misselbrook Sent: 18 May 2012 11:46 To: Greg.Jones@bmj.com

Cc: Helen Munday

Subject: FW: Evidence enquiry re: Powerade

Dear Greg -

Thank you for your note below.

I work in the Public Affairs & Communications team here – and wanted to let you know that we have received your enquiry regarding the research analysis you are pulling together. We have a response and will share with you by end of day today.

I am looping my colleague Helen Munday in who is Director Scientific and Regulatory Affairs at The Coca-Cola Company and will come back to you on this.

Regards –

Laura