The evidence underpinning sports performance products: a systematic assessment

Carl Heneghan,1 Jeremy Howick,1 Braden O’Neill,1 Peter J Gill,1 Daniel S Lasserson,1 Deborah Cohen,2 Ruth Davis,1 Alison Ward,1 Adam Smith,2 Greg Jones,2 Matthew Thompson1

ARTICLE SUMMARY

Article focus
- The marketing of sports products has become a multibillion-dollar industry, but research in this area has previously been labelled as methodologically poor.
- We aimed to assess the extent and nature of claims regarding improved sports performance made by advertisers for a broad range of sports-related products and the quality of the evidence on which these claims are based.

Key messages
- 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. The promotion of exercise is therefore an important public health priority, particularly for the ‘economically and socially disadvantaged’. 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
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. In addition, while some supplements have been shown to potentially improve performance, many have no proven benefits and may cause serious side effects. The marketing of sports products has become a multibillion-dollar industry, and the consumption of the so-called energy drinks is increasing year on year, but research in this area has previously been labelled as methodologically poor.

The current confusion as to which products are actually beneficial for sports performance is highlighted by the European Food Safety Authority decision to approve certain products, such as carbohydrate—electrolyte drinks to enhance water absorption during exercising and maintain endurance performance, while not approving a variety of other products; including L-carnitine, glutamine or tyrosine, which claim to aid muscle recovery.

We therefore aimed to assess the extent and nature of claims regarding improved sports performance made by advertisers for 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 the USA for the month of March 2012 according to the Magazine Audit Bureau of Circulations. 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 and RD) as either relevant to sports or not. A third round of reviews (CH and 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 (eg, reduced muscle fatigue). We excluded adverts related to purely weight loss, skin or beauty products, sports equipment (eg, 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, DSL, MT and PJG) 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 and 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 were 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 (ie, 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 (eg, 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 Centre for Evidence-Based Medicine (CEBM) Levels of Evidence. For treatment benefits, the highest level of evidence for claim is a systematic review of randomised controlled trials or an N-of-1 trial (level 1) followed by randomised trials (level 2) and non-randomised 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, DSL, JH, MT and PJG) then recorded the presence or absence of the following elements of critical appraisal: a clear hypothesis, control group, power calculation, randomisation, allocation concealment, intention to treat, blinding (investigator and/or subjects) and sports outcome (subjective or objective) that demonstrates improved performance or recovery. Extracted data were 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). 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% CIs. We analysed data using Microsoft Excel.

RESULTS

We examined 92 magazines containing 1807 adverts, of which 615 (34%) advertised sports products (figure 1). After excluding 380 adverts, which were not product specific (ie, individual shop adverts), we included the remaining 235 advertised sports products in the analysis. From these, 54 (23%) different products made 115 enhanced performance or recovery claims. Of these, we found only three (2.7%) references for one product (ACCELERADE) to back up these claims, which were appropriate for critical appraisal, and 22 (42%) products that were endorsed by athletes. Six (12%) products made direct comparisons with other products in their advertised claims and three provided disclaimers. All 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 1035 web pages (web appendix 1). From these, we identified 431 (median 7, range 0–65) performance-enhancing claims for 104 different products, and a total of 146 references (range 0–46) associated with these claims (figure 1). More than half (52.8%) of the sites that made claims did not provide any references. One site (http://www.poweradegb.com/) provided approximately one third (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 that 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 that they would get back but did not, 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 press14 and two unpublished studies that we included in the analysis (Effect of an electrolyte replacement beverage compared with a commercially available carbohydrate supplement on the rate of fat oxidation during moderate-intensity cycle ergometry exercise, 2010; Summary of the study on the influence from compression sleeves worn during short-time intensive effort on lactatemia). We also received four bibliographies: one of these was a comprehensive bibliography of Lucozade-associated...
research (web appendix 2), which arrived outside the time lock, and due to its size, we analysed separately in an associated article.14a

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 studies15—22 including a comparative study of different diets on rat metabolism published in 1930.19 None of the 74 studies, which were critically appraised, were systematic reviews (level 1 evidence), and approximately half of the studies were categorised 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 that the conclusions are likely to change based on future (high-quality) research.11

Table 1 shows that in the 74 studies, the total number of participants was 2031 (median 15): two thirds (1310, 65%) were men. Two studies provided a quarter of the participants (n=505).23, 24 Excluding these two, the average number of participants per study was 16 (range 5—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. Randomisation 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 0 to 25%) repeated the intervention in the study protocol.23, 26 Overall, the majority of studies reported a clear hypothesis; but only four studies reported that they used a power calculation (5%, 95% CI 0 to 28%), and very few studies (11%, 95% CI 0 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.27 In the first of these, the methods of blinding by Berven et al27 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 al29 clearly reported 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.

<table>
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<tr>
<th>Study component</th>
<th>N=74</th>
<th>% (95% CI)</th>
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<tr>
<td>Number of participants</td>
<td>2031 (median 15)</td>
<td>Range 5—387</td>
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<tr>
<td>Number of men</td>
<td>1310</td>
<td>64.5 (61.9 to 67.1)</td>
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<td>Control group</td>
<td>55</td>
<td>74.3 (62.8 to 85.9)</td>
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<tr>
<td>Randomisation</td>
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<td>58.1 (43.4 to 72.9)</td>
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<td>6.8 (0 to 28.8)</td>
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<td>Intention to treat</td>
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<td>29.7 (10.8 to 48.8)</td>
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<td>Blinding (investigators, outcome assessors or participants)</td>
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<td>27.0 (7.6 to 46.5)</td>
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<td>Surrogate sports outcome</td>
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<td>2</td>
<td>32</td>
<td>42.1 (25.0 to 59.2)</td>
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<td>33</td>
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<tr>
<td>4 or 5</td>
<td>9</td>
<td>11.8 (0 to 33.0)</td>
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These findings indicate that the n size used in the present study was sufficient to detect significant differences among groups. 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 that 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 that did not use allocation concealment (compared with those that did) the effect estimates were 40% larger, and results fluctuate widely above and below the estimates. In terms of blinding, it is well known that “psychological effects could arise from participants’ knowing that they have received a ‘promising’ new treatment; 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.” The placebo effect of carbohydrate drinks, which has been shown previously, makes blinding especially important. Competitive endurance cyclists told that they were receiving a carbohydrate sports drink, when in fact it was water, performed 2% better than when 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.

Combining these problems with the fact no systematic reviews were found means that 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 reveals a number of systematic reviews that could be used to better inform the public: a meta-analysis by Vandenbogaerde, included 88 randomised crossover studies of carbohydrate supplements with or without protein before and/or during exercise provided 155 estimates for performance effects. Of concern is that this study reports a funnel plot, which shows “asymmetrical scatter is very likely the result of a publication trend towards positive effects”. Systematic review may come to conclusions that are different from 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.

We found that very few trials (2.7%) repeated the interventions under study conditions. In intervention trials restesting the intervention allows estimation of individual responses, takes account of regression to the mean and assesses the reliability of the effect measure. 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.”

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 web pages 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 that 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.

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**Contributors** DC and CH conceived the project and drafted the initial protocol. DC, CH and MT contributed to the finalisation of the protocol. RD, CH, MT and AW reviewed the magazine articles. BON, PJG, DSL, MT and CH reviewed the websites, and BON, PJG, DSL, MT, JH and CH appraised retrieved articles. RD maintained the magazine database and JH the Web database. AS and GJ contacted manufacturers and compiled responses. All authors contributed to the writing of the draft and approved the final manuscript. CH is the guarantor of the data.

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**Competing interests** None.

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The evidence underpinning sports performance products

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The corresponding author is happy to supply a copy of the data or the list of websites and/or references upon request.

REFERENCES


16. Forty years of Lucozade sports performance research and little insight gained. BMJ 2012. doi:10.1136/bmj.e4797


Correction

Heneghan C, Howick J, O’Neill B, et al. The evidence underpinning sports performance products: a systematic assessment. BMJ Open 2012;2:e001702. There is a typographical error in the abstract (it is correct in the main body of the text). The last line of the results section of the abstract should read “Only three of the 74 (4.1%) studies were judged to be of high quality and at low risk of bias.”

BMJ Open 2012;0:e001702corr1. doi:10.1136/bmjopen-2012-001702corr1
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Summary
Companies contacted: 42
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:
If this is a complete list?
If not, what other 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?

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

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
Company response

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.

BMJ follow up

Thank you for your 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.

Vegasport

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

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!

BMJ follow up

Thanks for agreeing to provide the info.

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

Company response

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?

BMJ follow up

Thanks for the help. The absolute deadline will be end of the day on Thursday (your time).
Panache

Panache Sports Bra (represented by Instinct PR)

Company response

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

BMJ follow up

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

Company response

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.

BMJ follow up

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

Company response

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

BMJ follow up

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.

**Compressport**

Product
Compressport Full Socks

**Company response**

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?

AND

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
- Arnaud MENETRIER:

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

Let me know if you need more information.

**BMJ follow up**

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; 3) 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?

Pacific Health Labs

Products
Accelerade advanced sports drink & Hydro

Company response

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.

PE Science

Product
Anabeta

Company response

This website published an article on the extract today:

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

AND

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


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


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:

**New Balance**

New Balance trainers (represented by PR company SX-media)
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?

Company response

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

BMJ follow up

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?

Powerbar

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

Company response

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

a. If not, what other data you have used to support your claims? Our Product claims are EFSA based
b. Is this published or unpublished? For the 4 products we have used published papers
c. If the research is published could you provide us with the relevant references? => Please find attached the lit overview

d. 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!

---

**Nike**

Products
Nike LunarEclipse
Nike LunarEclipse Shield

**Company response**

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

AND

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.

**BMJ follow up**

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.

AND

The ad text is available here, page 2:


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.”

**Company response**

“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/0Z9zgM4J/1a7cf06fd42d161ea1f8fe7a883bee28162db3af3ce779937edf82a488560656082ed9fb3892587>

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

**BMJ follow up**

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

**Company response**

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.

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<https://www.wetransfer.com/dl/oZ9zgM4J/1a7cf06fd42d161ea1f8fe07a883bee28162db3af3ce779937edf82a488560656082ed9fb3892587>

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

**BMJ follow up**

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?

---

**Merrell**

**Products**

**Correspondence**

**BMJ email**
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.

**Company response**

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

**BMJ follow up**

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?

**Company response**

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.

AND

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

**GNC (PR Market com)**

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
BMJ follow up

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?

Kinetica

Product
Kinetica Protein shake Supplement

BMJ follow up

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?

Zip Vit Sport

Product
ZV7 Energy gels
BMJ follow up

Could you give me an idea of when I could expect to hear more from you? By mid-week this week is best.

Sci-MX Nutrition

Product
Sci-Max (Omni MX hardcore)

Company response

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

Body Building Warehouse

Product
Warrior Blaze Supplement

Company response

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?

BMJ follow up
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?

Company response

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.

BMJ follow up

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.

DS

Products
Triazole
Triazole/Activate Extreme
CRAZE

Company response

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 in-house, 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.

AND

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/

BMJ follow up

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?

Pharma Blend 6HR
PhD Nutrition Ltd

Company response

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?

BMJ follow up

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.

Company response

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.

**BMJ follow up**

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?

---

**TrionZ Bracelets**

**Company response**

**BMJ follow up**
Company response

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?

BMJ follow up

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 diminish 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.

Company response

BMJ follow up

Company response

BMJ follow up

Zero High 5
Company response

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.

BMJ follow up

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.

Company response

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.

2XU PWX compression tights

Company response

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?

**BMJ follow up**

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?

**BMJ follow up**

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

**Gatorade G Series Pro**

**BMJ follow up**

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.

**Company response**

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

Company response

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

BMJ follow up

We are looking specifically at the K-Swiss Blade Max series training shoes.

ProPeptide Advance

Company response

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 for 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 L-glutamine, 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 and harvesting of nutrients from all foods consumed. 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. 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.

**BMJ follow up**

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?

**Company response**
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, placebo 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.

Sports Jelly Beans

Company response

Thank you for writing. Attached is our research which I hope you'll find interesting and relevant. Please do not hesitate to let me know if I can be of further assistance.
Asics Gel Volt 33

Company response

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 Melbourne University and Simon Bartold is our International Research consultant who also has some published research.

Aqua Sphere Energize compression-wear

BMJ follow up

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?
Powerade

Company response

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.


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

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 ION 4, “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 advises 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.

BMJ follow up

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.

Company response

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
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 1924/2006.

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.
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 carbohydrate-electrolyte 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.
### Table 1 Sports adverts study quality

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