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Attorneys for Plaintiff

IN UNITED STATES DISTRICT COURT
DISTRICT OF MONTANA, BILLINGS DIVISION

ALL AMERICAN PHARMACEUTICAL AND NATURAL FOODS CORP., **Plaintiff,** **v.** **MARK J. TALLON, ROBERT CHILD, CR-TECHNOLOGIES, LLP,** **Defendants.**	**COMPLAINT** **JURY TRIAL REQUESTED** **Case No.: CV-09-67-BLG-RFC** **Honorable Judge** **Richard F. Cebull**

Plaintiff, All American Pharmaceutical and Natural Foods Corp. ("All American"), files this Complaint against Defendants, Mark J. Tallon ("Tallon"), Robert Child ("Child"), CR-

Technologies, LLP ("CR-Tech") (collectively "Defendants"), and in support of its Complaint alleges:

NATURE OF ACTION AND PARTIES

1. This is a complaint for damages and equitable relief for commercial disparagement under Section 43(a) of the Lanham Act, for intentional interference with economic relations, and for business libel, arising from Defendants' statements and actions regarding a product marketed by All American called Kre-Alkalyn® ("Kre-Alkalyn").

2. All American is a corporation organized and existing under the laws of the State of Montana, with its principal place of business at 2376 Main Street, Billings, Montana 59105.

3. Upon information and belief, CR-Tech is a limited liability partnership organized and existing under the laws of the United Kingdom, which transacts business and maintains a presence throughout the United States, including Montana.

4. Upon information and belief, Tallon and Child reside in the United Kingdom, are co-founders of CR-Tech and members of its advisory board, and have an economic interest in CR-Tech.

5. CR-Tech's principal product is CREASAFE®, which is a delivery system for creatine monohydrate ("CM").

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this matter pursuant to 15 U.S.C. § 1121(a) because this is a case arising under the Lanham Act,15 U.S.C. § 1051, *et seq*., and particularly 15 U.S.C. § 1125, as well as pursuant to 28 U.S.C. § 1331, because this matter involves a federal question.

7. This Court has personal jurisdiction over Defendants under Rule 4(B) of Montana's Rules of Civil Procedure because Defendants, having engaged in activities so as to harm All American, have committed acts resulting in the accrual within Montana of this tort action, and have transacted business within Montana.

8. Venue is proper in this judicial district as to Defendants pursuant to 28 U.S.C. § 1391(d), because an alien may be sued in any district.

FACTS

9. All American is a leading manufacturer of dietary, food and nutritional supplements, and has been in business since 1984.

10. Under US Patent 6,399,661 ('661 Patent), All American produces a creatine nutritional supplement which is marketed as Kre-Alkalyn. Creatine aids in the process of creating energy usable by muscles. The main challenge with creatine supplementation systems is the ability to deliver creatine in a form usable to the human body, rather than to have it immediately convert to creatin*ine*, a toxic by-product. The invention underlying the '661 Patent relates to an oral creatine supplement and the method of making this supplement which method includes mixing an alkaline powder with a powdered creatine until the pH of the mixture is in the alkaline range of 7-14, but which does not result in the formation of substantial creatin*ine*. As discussed in the '661 Patent, the then-known creatine supplements are dissolved in acidic solutions naturally occurring in the stomach having a pH range of 3-6 and research has shown that at these pH ranges, the rate of conversion of creatine to creatin*ine* is almost instantaneous.

11. Practicing the '661 Patent, Kre-Alkalyn is marketed as not converting to creatin*ine* before reaching muscles, but rather converts to creatin*ine* only after metabolizing in the muscles, which can dispose of creatin*ine* more effectively than the kidneys and digestive system.

12. All American holds the trademark for Kre-Alkalyn under Trademark Registration Number 2627498, which Mark is and has been used in commerce at all times relevant to this action.

13. All American markets and sells Kre-Alkalyn throughout the United States, and has done so since August 15, 2000.

14. Defendants have disparaged the beneficial effects of Kre-Alkalyn by claiming that under conditions similar to those found in the human stomach, Kre-Alkalyn converts to creatin*ine* at a rapid rate. Moreover, Defendants claim, that under similar conditions, creatine monohydrate ("CM"), the most widely available form of creatine, converts to creatin*ine* at a substantially slower rate.

15. Virtually simultaneously with these claims, Defendants began marketing CREASAFE. CREASAFE, or CM, is a delivery system for creatine monohydrate and upon information and belief is intended to compete directly with Kre-Alkalyn which occupies a significant part of the relevant market.

16. On January 16, 2006, Defendants filed a US application (No. 78792435) to register CREASAFE as a recognized US trademark, which application was granted on July 7, 2008 (Registration No.3249999509). Defendants announced the filing of the registration application as follows:

> CR-Technologies recently received notice of registration for the mark "CREASAFE" (#78792435) from the United States Patent and Trademark Office.
>
> "This is great news for both CR-Technologies and for our customers," says Dr. Mark J Tallon, co-founder of CR-Technologies. "In addition to strengthening CR-Technologies' portfolio of novel ingredients, the CREASAFE brand offers our customers a reassurance and guarantee that they are using a premium ingredient differentiated from other creatine products by cutting-edge science and technology. This offers a very strong USP to the end user wanting a branded ingredient that delivers on marketing promises."
>
> For additional information, please contact CR-Technologies today.

(See http://www.cr-technologies.net/inthenews.html.)

17. As part of its trademark application, on April 21, 2008, Defendants filed a Notice of Statement of Use, representing that the date of first use of the mark CREASAFE in commerce was October 6, 2007.

18. CREASAFE as marketed by Defendants, is intended to compete directly with Kre-Alkalyn.

Defendants Announce CREASAFE as they Denounce Kre-Alkalyn

19. Defendants posted a "news item" dated August 14, 2007, to their website entitled "CR-Technologies launches CREASAFE®" (the "CREASAFE Launch Announcement"). (*See* http://www.cr-technologies.net/creasafe.html, a copy of which is attached hereto as Exhibit A.)

20. The CREASAFE Launch Announcement indicates that CREASAFE, the result of "two years of research and development," is a delivery system for creatine monohydrate ("CM").

The CREASAFE Launch Announcement, in part, reads as follows:

> CREASAFE® is the first product release which utilizes the novel application of this delivery technology and represents the result of two

> years of research and development into the enhancement and optimization of creatine monohydrate - sports nutrition's most efficacious ingredient.

(*See* http://www.cr-technologies.net/inthenews.html.)

21. In another news posting on Defendants' website, entitled "Kre-alkalyn® supplementation has no beneficial effect on creatine–to–creatin*ine* conversion rates" ("Abstract"), Defendants abstracted their "research" on Kre-Alkalyn further claiming that "[t]his research was presented at the 4th Annual International Society of Sports Nutrition Conference (Las Vegas, USA)." The 4th Annual International Society of Sports Nutrition Conference ("ISSN") took place between June 10-12, 2007 in Las Vegas. (A copy of the "Abstract" is attached here as Exhibit B; also *see* http://www.cr-technologies.net/inthenews.html). It is believed that although the posting is dated June 19, 2007, it was actually posted to the CR-Tech website on August 13, 2007, the day before the CREASAFE Launch Announcement was made.

22. Upon information and belief, Tallon and Child's "presentation" at the Conference consisted of nothing more than Tallon and Child standing in front of a poster which had the contents of the Abstract printed on it (the "Poster Presentation"). This was not a full conference presentation as implied in the Abstract.

23. The Abstract asserts that "an independent commercial laboratory" tested the relative stabilities of Kre-Alkalyn and creatine monohydrate ("CM") in acidic conditions "that replicate those of the stomach" and found that not only did Kre-Alkalyn convert to creatin*ine*, it did so at a significantly higher rate than CM, which converted to creatin*ine* at a relatively insignificant rate.

24. The Abstract simultaneously undermines Kre-Alkalyn's claims while claiming that there is no problem with CM, and concludes that CM is the better alternative. The Abstract, in its entirety, reads as follows:

Kre-alkalyn® supplementation has no beneficial effect on creatine-to-creatinine conversion rates

Tallon MJ[1] and Child R[2]. Kre-alkalyn® supplementation has no beneficial effect on creatine-to-creatinine conversion rates. [1]University of Northumbria, Sport Sciences, Northumbria University, Northumberland Building, Newcastle upon Tyne, United Kingdom.[2]Department of Life Sciences, Kingston University, Penrhyn Rd, Kingston-upon-Thames, United Kingdom.

All American Pharmaceutical and Natural Foods Corp. (Billings, MT, USA) claim that Kre-alkalyn® (KA) is a "Buffered" creat*ine*, is 100% stable in stomach acid and does not convert to creatinine. In contrast, they also claim that creatine monohydrate (CM) is highly pH labile with more than 90% of the creat*ine* converting to the degradation product creatinine in stomach acids. To date, no independent or university laboratory has evaluated the stability of KA in stomach acids, assessed its possible conversion to creatinine, or made direct comparisons of acid stability with CM. This study examined whether KA supplementation reduced the rate of creatine conversion to creatinine, relative to commercially available CM (Creapure®). Creatine products were analyzed by an independent commercial laboratory using testing guidelines recommended by the United States Pharmacopeia (USP). Each product was incubated in 900ml of pH 1 HCL at 37± 1°C and samples where [sic] drawn at 5, 30 and 120 minutes and immediately analyzed by HPLC (UV) for creatine and creatinine. In contrast to the claims of All American Pharmaceutical and Natural Foods Corp., the rate of creatinine formation from CM was found to be less than 1% of the initial dose, demonstrating that CM is extremely stable under acidic conditions that replicate those of the stomach. This study also showed that KA supplementation actually resulted in 35% greater conversion of creatine to creatinine than CM. In conclusion the conversion of creatine to creatinine is not a limitation in the delivery of creatine from CM and KA is less stable than CM in the acid conditions of the stomach.

This research was presented at the 4th Annual International Society of Sports Nutrition Conference (Las Vegas, USA).

(See http://www.cr-technologies.net/inthenews.html.)

25. Based on research conducted by All American as well as independent studies commissioned by All American, upon information and belief, the Abstract includes false and/or misleading representations of fact regarding the efficacy of Kre-Alkalyn as compared to CM .

26. Upon information and belief, the Abstract is intended to disparage Kre-Alkalyn so as to support the launch of CREASAFE and hype it as a competing and superior product.

27. Positioned alongside the text of both the CREASFE Launch Announcement and the Abstract is an image of the "Nutrition Business Journal."

28. Upon information and belief, the Nutrition Business Journal is a publication that is respected in the market in which Kre-Alkalyn and CREASAFE compete.

29. Upon information and belief, neither of the postings has any relationship to the Nutrition Business Journal, but rather Defendants have placed the image next to the postings in an effort to mislead the viewer into believing that there is a relationship between the Journal and the postings in order to imbue the postings with credibility.

Defendants Engage in Calculated Campaign to Undermine Kre-Alkalyn and Elevate CM

30. Upon information and belief, Defendants posted a press release days after the ISSN Conference which included the Abstract to the "Natural Products Industry Center" website ("Press Release"). (*See* http://www.npicenter.com/anm/templates/newsATemp.aspx?articleid=18806&zoneid=28, a copy of which is attached hereto as Exhibit C).

31. Defendants' Press Release includes the headline "Creatine Efficacy ***Headlines*** At Sports Nutrition Meeting" (emphasis added), and includes the following:

> The studies presented at the ISSN annual conference showed that both CEE [creatine-ethyl-ester] and Kre-alkalyn do not confer any advantages

> beyond that of creatine monohydrate [CM] and where [sic] in fact [sic] less stable when exposed to conditions similar to those found during digestion. These studies should help increase consumer awareness of creatine products without safety data, which carry unsubstantiated marketing claims. More importantly these investigations further enhance the reputation of creatine monohydrate [CM] as a safe and efficacious ingredient.

(*See id.*)

32. Upon information and belief, based on research conducted by All American as well as independent studies commissioned by All American, the Press Release includes false and/or misleading representations of fact regarding the efficacy of Kre-Alkalyn.

33. Upon information and belief, far from "headlining" at the ISSN Conference, Defendants' "presented research" was but an insignificant part of the ISSN Conference, and Defendants' involvement consisted of nothing more than the Poster Presentation mentioned above.

34. Upon information and belief, Defendants encouraged the proliferation of the Press Release on various websites and message boards.

35. A Google search of the address to the Press Release results in dozens of separate websites from around the world that link to the Press Release and discuss the Abstract.

36. Upon information and belief, Defendants also encouraged the proliferation of the Abstract on various websites and message boards.

37. A Google search of the address to the Abstract results in hundreds of separate websites from around the world that link to the Abstract and discuss the Abstract.

38. The Press Release and the Abstract have spread much further than the hundreds of separate websites mentioned above, considering the number of additional websites and message

All American Responds to Defendants' Statements Regarding Kre-Alkalyn

39. On August 24, 2007, counsel for All American sent a letter to Defendants demanding that they post a public retraction of the disparaging Abstract on the CR-Tech website and send a copy of the retraction to ISSN. All American has made clear that the Abstract and the information in the Press Release have negatively affected All American's business with respect to Kre-Alkalyn. (All American's correspondence with Defendants is attached here as Exhibit D).

40. Responding to All American's letter, Defendants refused to retract the Abstract and represented that they "retain [ed] substantive material for all the information" underlying the Abstract.

(*See* Defendant's September 18, 2007 Letter, attached here as part of Exhibit D).

41. Counsel for All American responded to the letter by requesting that Defendants send All American the substantive material Defendants assert they retain. Defendants refused to do so, committing instead to send All American a copy of a manuscript being prepared based on the presentation made at the 2007 ISSN conference once that manuscript had been accepted. (*See* Defendants' October 23, 2007 Letter, attached here as part of Exhibit D.

42. All American has received no published paper nor any of the substantive material requested of Defendants, nor has the requested retraction occurred despite the exchange of several other letters. (*See* Exhibit D.)

43. Upon information and belief, no full paper, based on the presentation at the 2007 ISSN conference, has been prepared or published.

Defendants' Statements Have Damaged All-American and the Kre-Alkalyn Mark

44. The Press Release and Abstract have caused All American significant damage, making it substantially more difficult for All American to market and sell Kre-Alkalyn.

45. Upon information and belief, all of the websites and message boards discussing the Press Release and the Abstract are viewed and used by potential customers of Kre-Alkalyn and CREASAFE.

46. Upon information and belief, a number of the persons who comment on and discuss the Press Release and/or the Abstract view the claimed research and other statements made by Defendants as peer-reviewed and backed by proven scientific data, and consequently conclude that Kre-Alkalyn is ineffectual.

47. Upon information and belief, Kre-Alkalyn customers have reduced or discontinued their orders for Kre-Alkalyn, and a significant number of potential customers decided against ordering Kre-Alkalyn, as a direct consequence of Defendants' statements.

48. Upon information and belief, Defendants have engaged in a calculated campaign to undermine the opinions of current and potential customers as to the benefits of Kre-Alkalyn, while at the same time asserting the efficacy of CM, in order to increase the demand for CREASAFE, a product in which Defendants have a financial interest. Defendants have attempted to do so by, among other things,

a. making false and/or misleading statements about Kre-Alkalyn;

b. "presenting" those statements as "research" at the ISSN Conference by way of the Poster Presentation, which consisted only of printing the Abstract on a poster and standing in front of that poster during the ISSN Conference;

c. reporting their actions at the ISSN Conference as if they had instead made substantive, "headlining" presentations at the ISSN Conference in an effort to add credibility to their claims;

d. proliferating and encouraging the proliferation of the contents of the Press Release and Abstract along with information about Defendants' product, CREASAFE, to customers and potential customers of Kre-Alkalyn and CREASAFE.

49. Defendants have taken these actions while contemporaneously marketing CREASAFE, which is a delivery system for CM, in an effort to increase the marketability of CREASAFE.

50. By their actions, Defendants have intentionally and maliciously disparaged Kre-Alkalyn and otherwise damaged All American.

FIRST CAUSE OF ACTION
(Commercial Disparagement under Section 43(a) of the Lanham Act)

51. All American re-alleges and incorporates by reference the preceding allegations of its Complaint as if they were fully set forth herein.

52. Defendants have made false and misleading statements about Kre-Alkalyn.

53. These statements have been material in that they deal with the fundamental effectiveness of Kre-Alkalyn, and thus clearly influence customers' views of Kre-Alkalyn.

54. These statements have been used extensively in interstate commerce, and have had a substantial effect on the same.

55. These statements were made in connection with CREASAFE, in which, upon information and belief, Defendants have a significant financial interest.

56. These statements were made by Tallon and Child as well as CR-Tech, which competes with All American, are designed to influence customers, and have been widely disseminated to the relevant purchasing public throughout the United States and elsewhere.

57. As a direct result of Defendants' disparagement of Kre-Alkalyn, All American has been damaged in an amount of not less than $1,000,000.

SECOND CAUSE OF ACTION
(Tortious Interference with Business Relations)

58. All American re-alleges and incorporates by reference the preceding allegations of its Complaint as if they were fully set forth herein.

59. Defendants have taken actions calculated to cause damage to All American's business.

60. Defendants have taken these actions with the unlawful purpose of causing damage or loss to All American, and have done so without right or justifiable cause.

61. All American has been damaged by Defendants' improper actions in an amount of not less than $1,000,000.

THIRD CAUSE OF ACTION
(Business Libel)

62. All American re-alleges and incorporates by reference the preceding allegations of its Complaint as if they were fully set forth herein

63. Defendants have published false statements about All American and Kre-Alkalyn, including, but not limited to, the statements found in the Abstract and the Press Release.

64. Defendants' statements have disparaged All-American and exposed it to ridicule and have injured All American's interests.

65. All American has been damaged by Defendants' improper actions in an amount of not less than $1,000,000.

REQUEST FOR RELIEF

WHEREFORE, All American respectfully requests that the Court enter judgment:

A. First Cause of Action:

1. Declaring Defendants to have violated Section 43(a) of the Lanham Act;

2. Ordering Defendants to publicly and conspicuously retract the false and misleading statements about Kre-Alkalyn it has made, and remove such statements it has published or caused to be published;

3. Enjoining Defendants, its agents, affiliate, and servants, during the pendency of the action and permanently, from making false and misleading statements about Kre-Alkalyn including, but not limited to, the statements made in the Abstract and the Press Release;

4. Ordering the destruction of all false and misleading publications, including the removal of all such publications from any websites, message board, or other locations where they have been posted;

5. Ordering that corrective advertising including, but not limited to, a retraction, be posted to the CR-Tech website, the Natural Products Industry Center website, and JISSN;

6. Awarding All American actual and consequential damages including, but not limited to, damages for lost income, lost opportunities, and lost profits, in an amount of not less than $1,000,000.

7. Disgorgement of any profits of Defendants attributable to Defendants' act of commercial disparagement;

8. Awarding punitive damages;

9. Awarding attorney fees and costs pursuant to 15 U.S.C. § 1117; and

10. Awarding All American such other and further relief that this Court deems just and proper.

B. Second Cause of Action:

1. Declaring that Defendants have tortiously interfered with All American's business relations;

2. Awarding All American damages in an amount of not less than $1,000,000; and

3. Awarding All American such other and further relief that this Court deems just and proper.

C. Third Cause of Action:

1. Declaring that Defendants have published false statements about All American and Kre-Alkalyn that have exposed All American to ridicule and have injured All American's interests;

2. Awarding All American damages in an amount of not less than $1,000,000; and

3. Awarding All American such other and further relief that this Court deems just and proper.

DATED this 2nd day of June, 2009.

/s/ Richard C. Conover
Richard C. Conover
LAW OFFICES OF RICHARD C. CONOVER

and

Barbara K. Polich
(motion for *pro hac vice* admission pending)
BALLARD SPAHR ANDREWS & INGERSOLL, LLP

Attorneys for Plaintiff All American Pharmaceutical and Natural Foods Corp.

Defendants' Address:

Robert Child
Mark J. Tallon
CR-Technologies, LLP
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West Sussex
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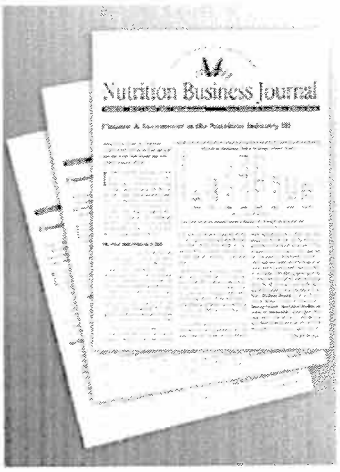
United Kingdom

EXHIBIT "A"



CR-Technologies launches CREASAFE®

CREASAFE® is the first ingredient application to use the controlled release system 'Liposphere' supported by CR-Technologies® clinical trials which provide evidence for increased retention and performance beyond that possible through traditional creatine supplementation. In a selection of studies scheduled for release in 2008, CR-Technologies® indicates that at last the sports industry finally has a delivery technology that can enhance nutrient uptake without the need for additional calories from carbohydrates.

"As a leader in the delivery and optimization of ingredients for the dietary supplement and food industry, we developed the Liposphere™ delivery system to maximize the bioavailability and stability of cutting-edge ingredients used by finished product manufacturers," says CR-Technologies® co-founder Dr Mark J Tallon. Liposphere™ is an enteric coating system that can be used on powdered ingredients. As an alternative to traditional capsule systems, which can limit product design flexibility, Liposphere™ gives manufacturers of finished products the ability to control the release of active ingredients without worrying about tablet and capsule size. This opens up the number of ingredients a finished product manufacturer can profit from.

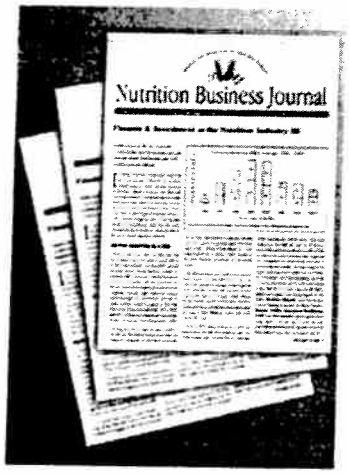
Given the current issues surrounding overages to support the labeling laws (NLEA) in the US and Maximum limits in Europe, CR-Technologies® is excited about the current development work underway to meet these challenges, and is even now utilizing a selection of ingredients beyond creatine in their Liposphere™ system.

CREASAFE® is the first product release which utilizes the novel application of this delivery technology and represents the result of two years of research and development into the enhancement and optimization of creatine monohydrate - sports nutrition's most efficacious ingredient. CR-Technologies®, a London based R&D and raw ingredient company with manufacturing facilities in Europe and North America, is currently in talks with three major multinationals positioning the release of CREASAFE® in late 2007.

Cr-Technologies, LLP., has also launched the industry's first medically animated micro-website in support of its patent pending controlled release enteric delivery system Liposphere™ which can be viewed at www.creatine.tv.

For additional information about Liposphere™ and CREASAFE®, please contact CR-Technologies today

EXHIBIT "B"



Kre-alkalyn® supplementation has no beneficial effect on creatine-to-creatinine conversion rates

Tallon MJ[1] and Child R[2]. Kre-alkalyn® supplementation has no beneficial effect on creatine-to-creatinine conversion rates. [1]University of Northumbria, Sport Sciences, Northumbria University, Northumberland Building, Newcastle upon Tyne, United Kingdom.[2]Department of Life Sciences, Kingston University, Penrhyn Rd, Kingston-upon-Thames, United Kingdom.

All American Pharmaceutical and Natural Foods Corp. (Billings, MT, USA) claim that Kre-alkalyn® (KA) is a "Buffered" creatine, is 100% stable in stomach acid and does not convert to creatinine. In contrast, they also claim that creatine monohydrate (CM) is highly pH labile with more than 90% of the creatine converting to the degradation product creatinine in stomach acids. To date, no independent or university laboratory has evaluated the stability of KA in stomach acids, assessed its possible conversion to creatinine, or made direct comparisons of acid stability with CM. This study examined whether KA supplementation reduced the rate of creatine conversion to creatinine, relative to commercially available CM (Creapure®). Creatine products were analyzed by an independent commercial laboratory using testing guidelines recommended by the United States Pharmacopeia (USP). Each product was incubated in 900ml of pH 1 HCL at 37± 1°C and samples where drawn at 5, 30 and 120 minutes and immediately analyzed by HPLC (UV) for creatine and creatinine. In contrast to the claims of All American Pharmaceutical and Natural Foods Corp., the rate of creatinine formation from CM was found to be less than 1% of the initial dose, demonstrating that CM is extremely stable under acidic conditions that replicate those of the stomach. This study also showed that KA supplementation actually resulted in 35% greater conversion of creatine to creatinine than CM. In conclusion the conversion of creatine to creatinine is not a limitation in the delivery of creatine from CM and KA is less stable than CM in the acid conditions of the stomach.

This research was presented at the 4th Annual International Society of Sports Nutrition Conference (Las Vegas, USA)

EXHIBIT "C"

Creatine Efficacy Headlines At Sports Nutrition Meeting

2007-06-18 - Cr-Technologies, LLP

The 4th International Society of Sports Nutrition (ISSN) annual meeting in Las Vegas showcased 2 novel creatinestudies by UK researchers. Category leaders Creatine Ethyl Ester and Kre-Alkalyn have been making waves within the sports market as 3rd generation products have been claimed to be more effective and safer than the original brand leader creatine monohydrate according to manufactures.

Many of the claims made by these products have not been substantial by a peer reviewed clinical trails but of greater concern to the authors of the studies where issues of consumer safety. Creatine monohydrate has been studied in over 2000 published trials and provides the sports nutrition sector a product of real efficacy and safety. Marketing by manufacturers have questioned the safety of creatine following its ingestion. One company goes, as far as to say, "Creatinine is a very dangerous bio-waste material produced by spent creatine.".

Dr Mark J Tallon a nutritional biochemist and author of one of the studies said "With the current climate of AER's and non-trade media looking out for any negative slant on natural products any claims of danger in relation the use of sport nutrition's gold standard product could threaten the whole market". Dr Robert Child co-author commented further "By allowing products which should be clearly classified as a Novel dietary ingredient for sale without approval should be a major concern. The use of non-natural products such as CEE pose a potential threat to consumer heath and without adequate safety data may lead to unwanted attention from regulatory agencies such as the FDA (US markets) or MHRA (UK markets)"....

The studies presented at the ISSN annual conference showed that both CEE and Kre-alkalyn do not confer any advantages beyond that of creatine monohydrate and where infact less stable when exposed to conditions similar to those found during during digestion. These studies should help increase consumer awareness of creatine products without safety data, which carry unsubstantiated marketing claims. More importantly these investigations further enhance the reputation of creatine monohydrtae as a safe and efficacious ingredient.

ISSN abstracts are listed below. For further information on these studies the ISSN can be contacted via their website:

http://www.sportsnutritionsociety.org/site/index.php

Kre-alkalyn® supplementation has no beneficial effect on creatine-to-creatinine conversion rates.

Tallon MJ[1] and Child R[2]

Discussions

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[1]University of Northumbria, Sport Sciences, Northumbria University, Northumberland Building, Newcastle upon Tyne, United Kingdom, [2]Department of Life Sciences, Kingston University, Penrhyn Rd, Kingston-upon-Thames, United Kingdom. DrTallon@CR-Technologies.net

All American Pharmaceutical and Natural Foods Corp. (Billings, MT, USA) claim that Kre-alkalyn® (KA) a "Buffered" creatine, is 100% stable in stomach acid and does not convert to creatinine. In contrast, they also claim that creatine monohydrate (CM) is highly pH labile with more than 90% of the creatine converting to the degradation product creatinine in stomach acids. To date, no independent or university laboratory has evaluated the stability of KA in stomach acids, assessed its possible conversion to creatinine, or made direct comparisons of acid stability with CM.

This study examined whether KA supplementation reduced the rate of creatine conversion to creatinine, relative to commercially available CM (Creapure®). Creatine products were analyzed by an independent commercial laboratory using testing guidelines recommended by the United States Pharmacopeia (USP). Each product was incubated in 900ml of pH 1 HCL at 37± 1°C and samples where drawn at 5, 30 and 120 minutes and immediately analyzed by HPLC (UV) for creatine and creatinine.

In contrast to the claims of All American Pharmaceutical and Natural Foods Corp., the rate of creatinine formation from CM was found to be less than 1% of the initial dose, demonstrating that CM is extremely stable under acidic conditions that replicate those of the stomach. This study also showed that KA supplementation actually resulted in 35% greater conversion of creatine to creatinine than CM. In conclusion the conversion of creatine to creatinine is not a limitation in the delivery of creatine from CM and KA is less stable than CM in the acid conditions of the stomach.

Creatine ethyl ester rapidly degrades to creatinine in stomach acid

Child R[1] and Tallon MJ[2]

[1]Department of Life Sciences, Kingston University, Penrhyn Rd, Kingston-upon-Thames, United Kingdom. [2]University of Northumbria, Sport Sciences, Northumbria University, Northumberland Building, Newcastle upon Tyne, United Kingdom, DrChild@CR-Technologies.net

Creatine ethyl ester (CEE) is a commercially available synthetic creatine that is now widely used in dietary supplements. It comprises of creatine with an ethyl group attached and this molecular configuration is reported to provide several advantages over creatine monohydrate (CM). The Medical Research Institute (CA, USA) claim that the CEE in their product (CE2) provides greater solubility in lipids, leading to improved absorption. Similarly San (San Corporation, CA, USA) claim that the CEE in their product (San CM2 Alpha) avoids the breakdown of creatine to creatinine in stomach acids. Ultimately it is claimed that CEE products provide greater absorption and efficacy than CM. To date, none of these claims have been evaluated by an independent, or university laboratory and no comparative data are available on CEE and CM.

This study assessed the availability of creatine from three commercial creatine products during degradation in acidic conditions similar to those that occur in the stomach. They comprised of two products containing CEE (San CM2 Alpha and CE2) and commercially available CM (Creapure®). An independent laboratory, using testing guidelines recommended by the United States Pharmacopeia (USP), performed the analysis. Each product was incubated in 900ml of pH 1 HCL at 37± 1°C and samples where drawn at 5, 30 and 120 minutes. Creatine availability was assessed by immediately assaying for free creatine, CEE and the creatine breakdown product creatinine, using HPLC (UV)

After 30 minutes incubation only 73% of the initial CEE present was available from CE2, while the amount of CEE available from San CM2 Alpha was even lower at only 62%. In contrast, more than 99% of the creatine remained available from the CM product. These reductions in CEE availability were accompanied by substantial creatinine formation, without the appearance of free creatine. After 120minutes incubation 72% of the CEE was available from CE2 with only 11% available from San CM2 Alpha, while more than 99% of the creatine remained available from CM.

CEE is claimed to provide several advantages over CM because of increased solubility and stability. In practice, the addition of the ethyl group to creatine actually reduces acid stability and accelerates its breakdown to creatinine. This substantially reduces creatine availability in its esterified form and as a consequence creatines such as San CM2 and CE2 are inferior to CM as a source of free creatine.

Supported by **Cr-Technologies, LLP**, London, England

EXHIBIT "D"

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August 24, 2007

Via Federal Express

Dr. Mark J. Tallon and Dr. Robert Child
CR-Technologies LLP
405 Kings Road
London
Great Britain
SW10 0BB

Re: All American Pharmaceutical & Natural Foods Corporation
Our Docket No. 567.52

Dear Dr. Tallon and Dr. Child

I am an intellectual property attorney in Bozeman, Montana, USA who has been retained by All American Pharmaceutical & Natural Foods Corporation with regard to intellectual property matters. It has come to our attention that you are publishing on your website a report entitled "Kre-Alkalyn® Supplementation Has No Beneficial Effect on Creatine-to-Creatinine Conversion Rates". A copy of this web page is enclosed for your easy reference.

My client strongly objects to the false statements set forth in this report and specifically that Kre-Alkalyn® supplementation has no beneficial effect on Creatine-to-Creatinine conversion rates. In this regard I am enclosing a copy of United States Patent No. 6,399,661 obtained by my client. In this patent the analysis results compiled by an independent laboratory is set forth showing that Kre-Alkalyn® is very effective in reducing creatine-to-creatinine conversion.

If we cannot obtain an immediate retraction of this publication, then my client has authorized me to proceed with all legal steps including filing a lawsuit for libel, slander and unfair

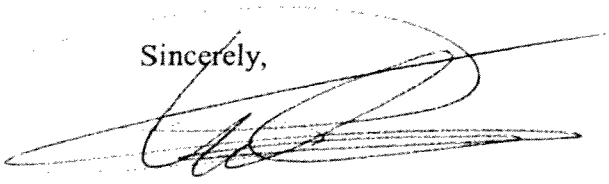
competition for publishing these false statements and making these false statements at the Fourth Annual International Society of Sports Nutrition Conference in Las Vegas, USA. We will be seeking monetary damages and injunctive relief.

We demand that you retract these false statements publicly in writing, which retraction shall be disseminated on your website and a copy sent to the International Society of Sports Nutrition. Further, you made representations that Dr. Tallon is associated with the University of Northumbria, Sport Sciences, Northumbria University, Northumberland Building, Newcastle. Please send information to us regarding Dr. Tallon's association with this University. Also, please send to us information regarding Dr. Child's association with the Department of Life Sciences, Kingston University, Penrhyn Road, Kingston-upon-Thames, United Kingdom.

Please advise within 15 days of your agreement to retract these false statements. If we cannot come to a resolution of this issue, we will be bringing legal proceeding against both of you for disseminating these false statements.

If you have questions, please let me know.

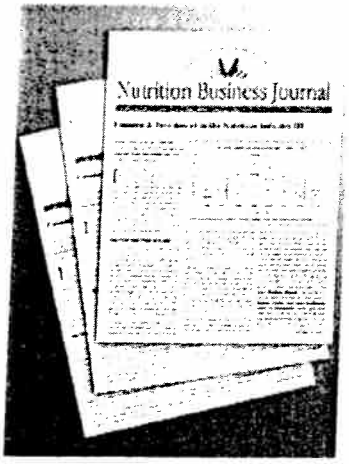
Sincerely,



Richard C. Conover

RCC/jh
Enclosures

cc: All American Pharmaceutical
& Natural Foods Corporation



Kre-alkalyn® supplementation has no beneficial effect on creatine-to-creatinine conversion rates

Tallon MJ[1] and Child R[2]. Kre-alkalyn® supplementation has no beneficial effect on creatine-to-creatinine conversion rates. [1]University of Northumbria, Sport Sciences, Northumbria University, Northumberland Building, Newcastle upon Tyne, United Kingdom.[2]Department of Life Sciences, Kingston University, Penrhyn Rd, Kingston-upon-Thames, United Kingdom.

All American Pharmaceutical and Natural Foods Corp. (Billings, MT, USA) claim that Kre-alkalyn® (KA) is a "Buffered" creatine, is 100% stable in stomach acid and does not convert to creatinine. In contrast, they also claim that creatine monohydrate (CM) is highly pH labile with more than 90% of the creatine converting to the degradation product creatinine in stomach acids. To date, no independent or university laboratory has evaluated the stability of KA in stomach acids, assessed its possible conversion to creatinine, or made direct comparisons of acid stability with CM. This study examined whether KA supplementation reduced the rate of creatine conversion to creatinine, relative to commercially available CM (Creapure®). Creatine products were analyzed by an independent commercial laboratory using testing guidelines recommended by the United States Pharmacopeia (USP). Each product was incubated in 900ml of pH 1 HCL at 37± 1°C and samples where drawn at 5, 30 and 120 minutes and immediately analyzed by HPLC (UV) for creatine and creatinine. In contrast to the claims of All American Pharmaceutical and Natural Foods Corp., the rate of creatinine formation from CM was found to be less than 1% of the initial dose, demonstrating that CM is extremely stable under acidic conditions that replicate those of the stomach. This study also showed that KA supplementation actually resulted in 35% greater conversion of creatine to creatinine than CM. In conclusion the conversion of creatine to creatinine is not a limitation in the delivery of creatine from CM and KA is less stable than CM in the acid conditions of the stomach.

This research was presented at the 4th Annual International Society of Sports Nutrition Conference (Las Vegas, USA)

US006399661B1

(12) **United States Patent**
Golini

(10) **Patent No.: US 6,399,661 B1**
(45) **Date of Patent: Jun. 4, 2002**

(54) **ORAL CREATINE SUPPLEMENT AND METHOD FOR MAKING SAME**

(76) Inventor: **Jeffrey M. Golini**, 1831 Main St., Billings, MT (US) 59105

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/892,890**

(22) Filed: **Jun. 26, 2001**

Related U.S. Application Data

(60) Provisional application No. 60/214,182, filed on Jun. 26, 2000.

(51) **Int. Cl.**[7] **A61K 31/195**
(52) **U.S. Cl.** **514/565**
(58) **Field of Search** 514/505

(56) **References Cited**

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* cited by examiner

Primary Examiner—James H. Reamer
(74) *Attorney, Agent, or Firm*—Richard C. Conover

(57) **ABSTRACT**

The present invention relates to an oral creatine supplement and the method of making this supplement which includes mixing an alkaline powder with a powdered creatine until the pH of the mixture is in the range between 7–14. A powdered additive is added to the mixture for improving sweetness and taste. Finally, a further alkaline powder is added to the mixture to adjust the pH of the mixture to a range between 7–14. This mixture is then mixed with water prior to ingestion.

21 Claims, 3 Drawing Sheets

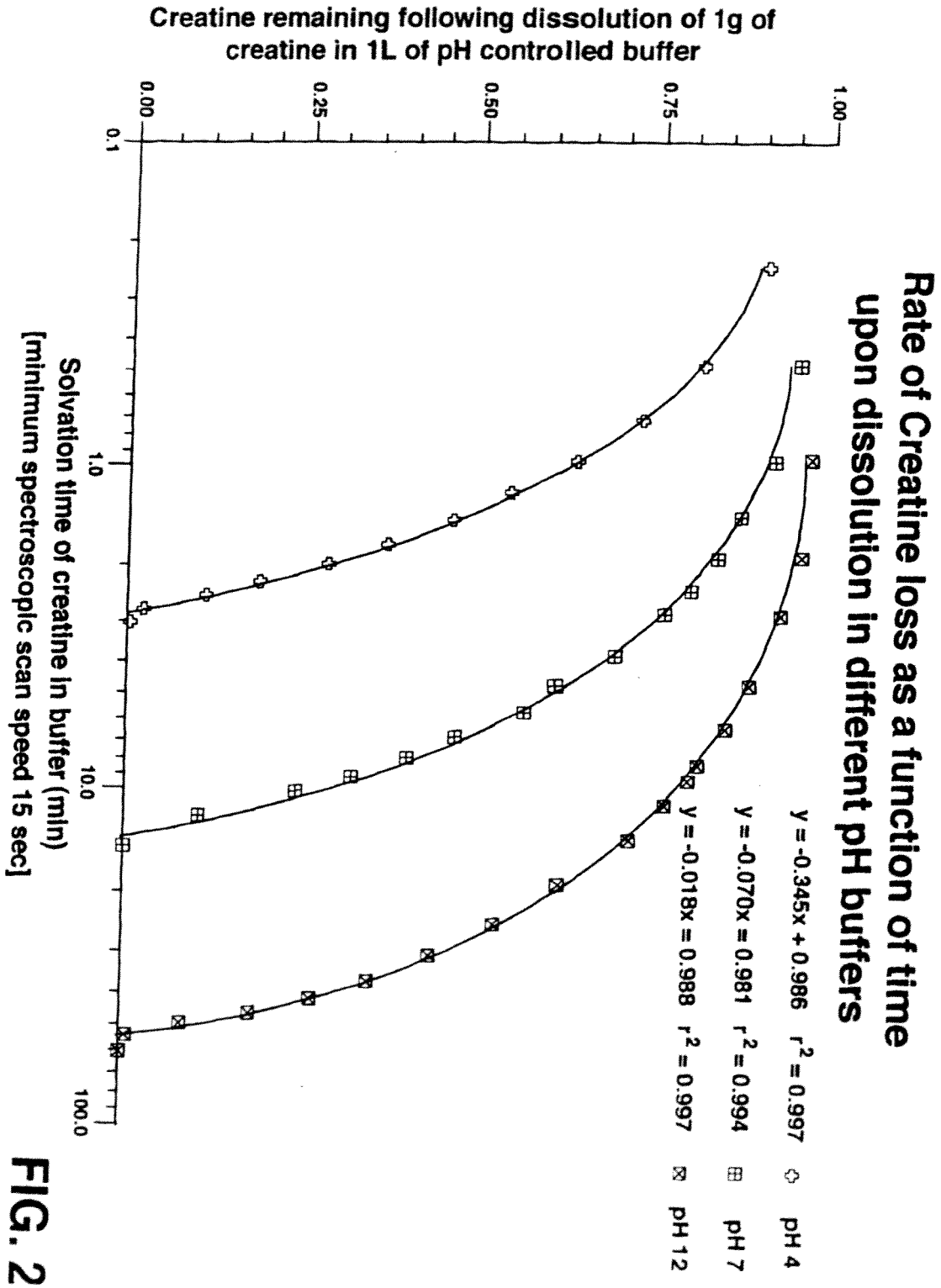
Creatine remaining following dissolution of 1g of creatine in 1L of pH controlled buffer
0.00
0.25
0.50
0.75
1.00
0.1
1.0
10.0
100.0
Solvation time of creatine in buffer (min)
[minimum spectroscopic scan speed 15 sec]
Rate of Creatine loss as a function of time upon dissolution in different pH buffers
y = -0.345x + 0.986 r2 = 0.997 pH 4
y = -0.070x = 0.981 r2 = 0.994 pH 7
y = -0.018x = 0.988 r2 = 0.997 pH 12

FIG. 2

ORAL CREATINE SUPPLEMENT AND METHOD FOR MAKING SAME

This application claims the benefit of provisional application 60/214,182 filed Jun. 26, 2000.

BACKGROUND OF INVENTION

The present invention relates to an oral creatine supplement, and the method for making this supplement.

Taking creatine orally has been used to increase creatine and creatine phosphate stores in the human body. This is important for athletes because creatine aids in the process of creating energy usable by muscles of the athlete.

When an athlete exercises or tenses a muscle, energy is required for the muscle to function properly. The energy it uses comes from several different sources, but primarily from nutrients obtained from food. These nutrients are broken down by natural processes occurring within the human body, and new compounds formed which are used to develop energy used by muscles. One of these compounds is adenosine triphosphate (ATP). When muscle energy is needed this ATP is broken down one step further into a chemical called adenosine diphosphate (ADP). This process releases energy which is then used by the contracting muscles. Without sufficient ATP, muscles do not perform properly.

Known energy increasers and stimulants have only superficially energized the body, and do not increase the body's ability to produce it's own ATP stores.

Muscle can store only limited amounts of ATP. As a result, it has been found that with about 5–10 seconds of muscle exertion, the amount of stored ATP is depleted. This results in muscle failure and fatigue. When this happens, the body tries to restore its immediate source of ATP by borrowing a high energy phosphate from a chemical called creatine phosphate (CP). Muscle cells store the chemical, CP, in the same way it stores ATP. If high intensity exercise goes beyond 10 seconds, the body will continue to try and restore its ATP levels by a process called glycolysis. This process is complicated and is a slow method of restoring ATP levels. This is a special problem for anaerobic athletes who require instant energy to maintain and sustain high powered muscle contractions.

By orally supplementing with creatine, an athlete can enhance his body's storage levels of CP. As the muscle runs out of ATP, it can recharge itself by borrowing this CP molecule. Research has shown that by supplementing with 5 grams of creatine, 4–6 times a day, for two or more days, the human body showed a significant increase in total creatine concentration.

ATP or CP cannot be ingested directly by athletes because these chemicals are destroyed by the digestive system of the athlete. However, it has been found that creatine can be ingested and converted by the body to CP. The resulting cellular concentrations of creatine after administration, is stable and is not prone to dissipation.

The most commonly used oral creatine supplement is creatine monohydrate. The most commonly used amounts have varied from 20 to 30 grams daily. It has been taken in powder, capsule, tablet hand liquid form. The creatine is mixed with or taken with water, fruit juice, acidic effervescent drink or acidic fruit flavored drinks.

Other that creatine monohydrate, other forms of creatine have also been used, such as creatine citrate and also creatine pyruvate. These other forms of creatine are administered similar to the method of administrating creatine monohydrate.

The main problem with all existing creatine supplementation is the ability to deliver creatine in a usable form by the human body. Research has shown that known creatine delivery systems actually have the human body ingesting creatinine, a poison and toxic byproduct. It is believed that the main reason for complaints resulting from creatine consumption, namely, stomach cramps, edema, bloodedness and dehydration, is caused by the body's defense to this toxic compound.

The known oral creatine supplements are dissolved in acidic solutions having a pH range of from 3–6. Research has shown that at these pH levels, the rate of conversion of creatine to creatinine is almost instantaneous.

From the above, it may be ascertained that a need exists for a method of enhancing the delivery of usable creatine to humans without substantial creatinine being formed. Further, a need exists for an oral creatine supplement that is in the form of a powder, capsule, tablet or liquid that is stable when mixed with water or taken premixed or in pill form.

SUMMARY OF INVENTION

The present invention relates to an oral creatine supplement and the method of making this supplement which includes mixing an alkaline powder with a powdered creatine until the pH of the mixture is in the range between 7–14. A powdered additive is added to the mixture for improving sweetness and taste. Finally, a further alkaline powder is added to the mixture to adjust the pH of the mixture to a range between 7–14. This mixture is then mixed with water prior to ingestion.

DESCRIPTION OF THE DRAWINGS

In order that the invention may be clearly understood and readily carried into effect, a preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings wherein:

FIG. 1 is a graph showing rate of creatinine formation from creatine as a function of pH;

FIG. 2 is a graph showing rate of creatine loss as a function of time upon dissolution in different pH buffers; and

FIG. 3 is a chart showing time in minutes for conversion of 1 g creatine to creatinine in 2 liter at given pH.

DESCRIPTION OF A PREFERRED EMBODIMENT

The rate of creatinine formation from creatine as a function of pH is shown in FIG. 1 in accordance with research conducted by the inventor. In FIG. 2, the rate of creatine loss as a function of time upon dissolution in different pH buffers is shown. Clearly the higher the pH, the higher the creatine remaining following dissolution in a pH buffer. FIG. 3 shows a summary of experiments showing the rate of conversion of one gram of creatine to creatinine in various pH solutions. This chart shows that the rate of conversion is substantially slowed by increasing the pH of the solution.

In accordance with the present invention, the inventor has created a buffered delivery system wherein creatine monohydrate is dissolved in a solution having a pH greater than 7. The inventor has developed five separate systems for delivery of creatine in an oral supplement.

The first is a powder mix having the following formulation:

overcomes the problems caused when creatine is converted to creatinine. The higher the pH, the more creatine a human will ingest.

While the fundamental novel features of the invention have been shown and described, it should be understood that various substitutions, modifications and variations may be made by those skilled in the art without departing from the spirit or scope of the invention. Accordingly, all such modifications or variations are included in the scope of the invention as defined by the following claims:

I claim:

1. A process for producing a creatine mixture for ingestion comprising the steps of:

mixing an alkaline powder with a powdered creatine to adjust the pH of the mixture to a range between 7–14;

adding a powdered additive to the mixture for improving sweetness and taste; and

adding a further alkaline powder to the mixture to adjust the pH of the mixture to a range between 7–14.

2. The method according to claim 1 wherein the alkaline powder is comprised of soda ash.

3. The method according to claim 1 wherein the alkaline powder is comprised of magnesium glycerol phosphate.

4. The method according to claim 1 wherein the alkaline powder is selected from a hydroxide, carbonate, bicarbonate, chloride, tree latex or a phosphate.

5. The method according to claim 1 wherein the creatine powder is comprised of creatine monohydrate.

6. The method according to claim 1 wherein the creatine powder is comprised of creatine phosphate.

7. The method according to claim 1 wherein the creatine powder is comprised of creatine pyruvate.

8. The method according to claim 1 wherein the creatine powder is comprised of creatine citrate.

9. The method according to claim 1 further including the step of mixing the mixed creatine powder with water prior to ingestion.

10. The method of claim 1 further including the steps of adding a flow agent and the step of encapsulating the mixture in a capsule.

11. The method according to claim 10 wherein the flow agent is comprised of magnesium stearate.

12. The method according to claim 1 further including the steps of adding a hardener material, a binder material, and a flow agent, and the further step of compressing the mixture into tablets.

13. The method according to claim 12 wherein the hardener material is comprised of sorbitol.

14. The method according to claim 12 wherein the binder material is comprised of microcrystalline cellulose.

15. The method according to claim 12 wherein the flow agent is comprised of magnesium stearate.

16. The method according to claim 1 further including the step of adding water to the mixture together with a base material and a stabilizer material for forming a creatine solution.

17. The method according to claim 16 wherein the base material is comprised of glycerine.

18. The method according to claim 16 wherein the stabilizer material is comprised of potassium sorbate.

19. The method according to claim 1 further including the step of adding a gel base material to the mixture for forming a soft gel.

20. The method according to claim 1 wherein the gel base material is comprised of soy bean oil.

21. A creatine mixture for ingestion which is produced by a process comprising the steps of:

mixing an alkaline powder with a powdered creatine to adjust the pH of the mixture to a range between 7–14;

adding a powdered additive to the mixture for improving sweetness and taste; and

adding a further alkaline powder to the mixture to adjust the pH of the mixture to a range between 7–14.

* * * * *

Dr Robert Child
Alimentarius Ltd.
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18th September 2007

Mr Richard C. Conover
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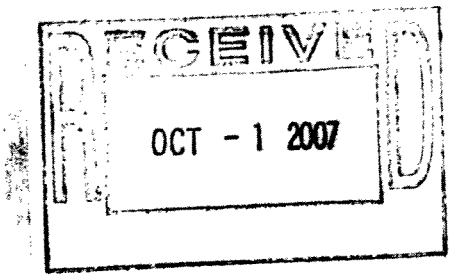
USA



Dear Mr Conover,

Thank you for your letter dated 24th August 2007, which I note was actually dispatched on 9th September 2007. Your letter makes reference to copy of the CR-Technologies web page related to a research trial entitled 'Kre-Alkalyn supplementation has no beneficial effect on creatine-to-creatinine conversion rates'. It is claimed that 'A copy of this web page is enclosed for your easy reference' yet this information has not been provided by you.

It is apparent that your client believes that a research trial performed by CR-Technologies and reported at the 4th Annual International Society of Sports Nutrition (ISSN) Conference in Las Vegas contains false claims. In particular your client claims that 'Kre-Alkalyn is very effective in reducing creatine to creatinine conversion', which is in direct conflict with our findings. As a consequence you have demanded an immediate retraction of the publication in the Journal of the ISSN and have threatened to proceed with all legal steps including filing a lawsuit for libel slander and unfair competition.

The study presented at the ISSN conference in Las Vegas was conducted to extremely rigorous standards and as such we have no concerns about the validity of the findings, or the manner in which they were reported. We would like to highlight to your client that the study presented at the ISSN underwent independent peer review by scientific experts prior to publication. Any issues with the publication and its presentation could have brought forth at the meeting, where we were able to fully defend the paper in person. If warranted, All American Pharmaceutical could have presented a scientific rationale to the ISSN editor for the paper not to be published in the journal. Alternatively, as with all scientific peer reviewed publications, All American could also have cited their own peer reviewed studies in defence of their data. For these reasons it is wholly inappropriate to retract the study and CR-Technologies will not entertain such a proposal.

We retain substantive material for all the information provided in the ISSN publication. Should your client wish to pursue legal action against us we will be more than happy to make the necessary disclosures of these materials at the appropriate time. At this point we feel it is appropriate to highlight that we do have additional data, which further corroborates our earlier findings. If All American Pharmaceuticals continues with legal action we will of course counter claims and seek monetary damages from your client.

Yours sincerely

Dr R. Child and pp Dr M. Tallon

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October 18, 2007

Via Federal Express

Dr. Robert Child and Dr. M. Tallon
Alimentarius Ltd.
5 East Row Mews
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United Kingdom

Re: CR-Technologies

Dear Dr. Child and Dr. Tallon,

Thank you for your letter of September 18, 2007. We apologize that the letter delivered to you did not enclose the CR-Technologies web page. I am enclosing a copy of this web page herewith for your easy reference. Our letter dated August 24, 2007 was sent to

CR-Technologies, LLP
405 Kings Road
Chelsea
SW10 0BB
United Kingdom

via Federal Express. We were led to believe this was your correct address. This letter was returned because CR-Technologies was not located at this address. My client was able to locate your individual address and sent our letter of August 24, 2007 to you directly, apparently omitting the copy of your web page.

As I previously advised, my client is very concerned about the statements made at the 4th Annual International Society of Sports Nutrition (ISSN) Conference in Las Vegas together with the statements set forth on your web page. We only became aware of these materials after your

conference in Las Vegas. We have now received several letters of concern from my client's customers regarding this report and if we cannot obtain resolution of this issue, we will be proceeding with a lawsuit.

Preliminarily, I would appreciate if you would send to me the "substantive material" to which you referred on the second page of your letter substantiating your claim that the "Kre-Alkalyn product is not effective in reducing creatine to creatinine conversion." We would like to see this material to determine what went wrong. We had an independent analysis conducted for our KRE-ALKALYN product as shown in United States Patent No. 6,399,661. This analysis confirmed that the KRE-ALKALYN product did have a beneficial effect on creatine to creatinine conversion rates. If you can prove to us that our analysis was incorrect, we will of course discontinue our claim. At this time, we continue to believe that the statements made by you and presented at this conference together with the statements made on your web page are false. Your continued publication of these materials is damaging my client's business and reputation.

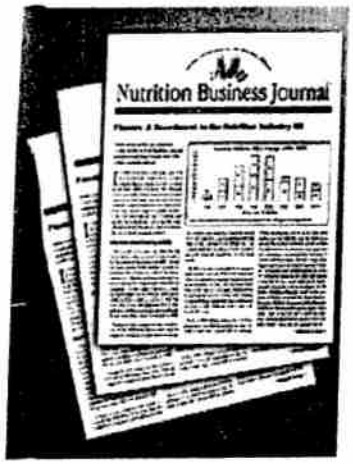
If we do not hear from you within 15 days, we will proceed with an action against CR-Technologies, the two of you individually, and the International Society of Sports Nutrition for false advertising and deceptive business practices under Section 43(a) of the Lanham Act, 15 U.S.C. Section 1125(a) seeking damages, injunctive relief and punitive damages.

Very truly yours,

Richard C. Conover

RCC/rh

Enc.



Kre-alkalyn® supplementation has no beneficial effect on creatine-to-creatinine conversion rates

Tallon MJ[1] and Child R[2]. Kre-alkalyn® supplementation has no beneficial effect on creatine-to-creatinine conversion rates. [1]University of Northumbria, Sport Sciences, Northumbria University, Northumberland Building, Newcastle upon Tyne, United Kingdom.[2]Department of Life Sciences, Kingston University, Penrhyn Rd, Kingston-upon-Thames, United Kingdom.

All American Pharmaceutical and Natural Foods Corp. (Billings, MT, USA) claim that Kre-alkalyn® (KA) is a "Buffered" creatine, is 100% stable in stomach acid and does not convert to creatinine. In contrast, they also claim that creatine monohydrate (CM) is highly pH labile with more than 90% of the creatine converting to the degradation product creatinine in stomach acids. To date, no independent or university laboratory has evaluated the stability of KA in stomach acids, assessed its possible conversion to creatinine, or made direct comparisons of acid stability with CM. This study examined whether KA supplementation reduced the rate of creatine conversion to creatinine, relative to commercially available CM (Creapure®). Creatine products were analyzed by an independent commercial laboratory using testing guidelines recommended by the United States Pharmacopeia (USP). Each product was incubated in 900ml of pH 1 HCL at 37± 1°C and samples where drawn at 5, 30 and 120 minutes and immediately analyzed by HPLC (UV) for creatine and creatinine. In contrast to the claims of All American Pharmaceutical and Natural Foods Corp., the rate of creatinine formation from CM was found to be less than 1% of the initial dose, demonstrating that CM is extremely stable under acidic conditions that replicate those of the stomach. This study also showed that KA supplementation actually resulted in 35% greater conversion of creatine to creatinine than CM. In conclusion the conversion of creatine to creatinine is not a limitation in the delivery of creatine from CM and KA is less stable than CM in the acid conditions of the stomach.

This research was presented at the 4th Annual International Society of Sports Nutrition Conference (Las Vegas, USA)

Dr Robert Child
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United Kingdom

23rd October 2007

Mr Richard C. Conover
104 East Main
Suite 404
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Montana 59771-1329
USA

Dear Mr Conover,

Thank you for your letter dated 18th October 2007 and copy of the abstract related to creatinine formation from Kre-Alkalyn and conventional creatine monohydrate, downloaded from the CR-Technologies website. We know our findings are correct and are consistent with those of many other laboratories. We would also highlight that it is your client who wishes to take legal action against CR-Technologies and as such your client should have complete confidence in the materials that he has assembled.

The abstract presented at the ISSN in Las Vegas 2007 is currently being prepared as a full paper for a peer reviewed scientific journal. Once accepted, will be happy to send your client a copy of the manuscript. This will of course provide your client the opportunity to write a response to the article in the form of a letter to the editor, which no doubt could also be published in the journal.

This would seem a more satisfactory than legal proceedings, however if your client wishes to take legal action against CR-Technologies we will be happy to fully substantiate the data in court. We will of course seek to recover all damages and costs incurred by such action from your client.

Yours sincerely

Dr R. Child and pp Dr M. Tallon

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January 10, 2008

Dr. Robert Child
Alimentarius Ltd.
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Chichester, West Sussex
PO191PR
United Kingdom

Re: Creatinine Formation from Kre-Alkalyn
Our Docket No. 567.52

Dear Dr. Child:

With regard to your letter of October 23, 2007 please send us a copy of the full paper published in a scientific journal with peer review.

This is to advise that we have also conducted further independent studies regarding the Kre-Alkalyn product and we will be writing you shortly regarding the results of these independent studies.

If you have questions, please let me know.

Very truly yours,

Richard C. Conover

RCC/rh
Enclosures

cc: All American Pharmaceutical
& Natural Foods Corporation

Dr Robert Child
74 Grosvenor Road
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30th January 2008

Mr Richard C. Conover
104 East Main
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Dear Mr Conover,

Thank you for your letter dated 10th January 2008. We are pleased to see that you have chosen the time-honoured tradition of pursuing a scientific response, rather than mounting a legal challenge against us. As yet preparation of our manuscript for publication as a full paper has not been completed, however we will be happy to send you a copy of the paper once it is in press.

We look forward to seeing your research published in a peer-reviewed journal. Undoubtedly this will contribute to the growing body of knowledge on dietary supplements, which can only be beneficial for the food industry. Please note that all future correspondence should be sent to the above address.

Yours sincerely

Dr R. Child and pp Dr M. Tallon

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September 18, 2008

Via Federal Express

Dr. Robert Child
Dr. M. Tallon
74 Grosvenor Road
Harborne
Birmingham
B17 9AN
United Kingdom

Re: Creatinine Formation from Kre-Alkalyn
Our Docket No. 567.52

Dear Dr. Child and Dr. Tallon:

In further regard to my letter of January 10, 2008, we now have obtained the results of an independent study regarding the Kre-Alkalyn product. I am sending to you a summary of this investigation prepared by Royal Knight, Inc. for your review.

You advised in your letter of October 23, 2007 that a full paper was being prepared for a peer reviewed scientific journal. I have heard nothing further from you regarding this full paper since your letter almost a year ago.

I urge you again to send to me a copy of this paper for our review. If we do not receive this paper from you within the next fifteen (15) days then we will presume that no such paper has been prepared.

As indicated of my letter of October 18, 2007 my client is very concerned about the statements made at the Fourth Annual International Society of Sports Nutrition (ISSN) Conference in Las Vegas together with the statements set forth in your web page. Your as of yet unsupported claims are causing damage to my client.

If we cannot resolve this situation, then we will proceed with an action against CR Technologies, the two of you individually and the International Society of Sports Nutrition for false advertising and deceptive business practices under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a) seeking damages, injunctive relief and punitive damages.

Please let me hear from you.

Very truly yours,,

Richard C. Conover

RCC/sf
Enclosures

cc: All American Pharmaceutical
& Natural Foods Corporation

Royal Knight Inc.

1204 Harbor Drive, SE • Suite 100 • Rochester, Minnesota 55904

(August 29th – originally sent as a fax on August 24th, 2008)

8/24/2008
Good Morning Jeff,

As per your instructions, I am summarizing the Kre-alkalyn stability data from the 8/20/08 fax and from our discussion for your legal people.

* * * *

Re: Kre-alkalyn stability data

Samples of Kre-alkalyn were tested at two independent laboratories: the Laboratory of Bio-inorganic and Bio-analytical Chemistry (Department of Analytical Chemistry) at Sofia University – St. Kliment Ohridsky, in Bulgaria; and Atlas Bioscience, Inc. in Tucson, Arizona. Both facilities used the Jaffe reaction for creatine-creatinine detection.

The Bulgarian laboratory used the Jaffe reaction quantitative, for the purpose of determining the amount of creatinine generated from any Kre-alkalyn degradation detectable at fixed time points (10 - 20 - 30 -, and 60 minute, respectively), under acetic pH conditions (1.2, 4.5, and 6.8, respectively). Multiple duplicated runs of Kre-alkalyn under these conditions generated data which indicated an average of approximately 12.5 micrograms (± 1.5 micrograms) of creatinine per every one-milligram* of creatine in the sample, irrespective of when the sample was assayed. This consistent finding suggests that any creatinine found was either, (a) co-existing in the Kre-alkalyn samples at the time of dissolution, or (b) was the result of self-limiting degradation which occurred rapidly, and before the first sampling (at 10 minutes), across the entire range of pHs tested. Given the static nature of the creatinine-data generated, the first explanation ('co-existing') would be the most logical assumption.

*(One milligram is equal to 1000 micrograms).

The Tucson laboratory used the Jaffe reaction to observe the reaction kinetics (the rate of any creatine-to-creatinine reaction). Creatine (buffered at pH 12) was subjected to degradation at physiological temperature, over the course of 120 minutes. Data indicated that the transformation proceeded very, very slowly with the first verifiable indication of creatinine's existence found at 3 minutes into the reaction. It is important to note that a kinetic study does not attempt to quantify the actual amount of creatine being converted.

Based upon the test results generated, Kre-alkalyn appears generally stable under physiological temperature, in a wide range of pHs.

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18th October 2008

Mr Richard C. Conover
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Bozeman,
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USA

Dear Mr Conover,

Firstly may I offer my sincere apologies for the delay in responding to you. I have just returned from several business trips and a vacation and only just received your letter dated 18th September and the summary of your client's research trial.

Dr Tallon and myself have been preparing data from several other research trials we are involved in. As a consequence, we have not had the opportunity to complete the full paper based on our presentations at the 2007 ISSN conference. I am sure you are aware the preparation of scientific papers to the standard required for publication in peer reviewed journals is a very time consuming process.

We wish to reassure your client that we do have the scientific data necessary to fully support the abstracts presented at the ISSN, which were subsequently published following peer review in JISSN. We will be giving preparation of this data our full attention in the coming months and will of course make the full paper available to you once it has been accepted for publication.

As we have highlighted previously, in cases of academic conflict a letter to the Journal editor is the appropriate route of recourse and resolution. Clearly this is considerably less costly than pursuing a legal case unnecessarily. We would advise that if you and your client are set on taking legal action against both Dr Tallon and myself, CR-Technologies we will of course counter claim and seek fiscal damages from your client. As you are also threatening to take legal action against the ISSN, we feel it is appropriate that they are made fully aware of the situation so that they can make preparations as they see fit. Therefore your letter dated 18th September and our response to it, have been forwarded to Dr Douglas Kalman (Executive Vice-President and Treasurer) and Dr Jose Antonio, (CEO) of Journal of ISSN.

Please note that all future correspondence should be sent to the above address.

Yours sincerely

Dr R. Child and pp Dr M. Tallon