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DISTRICT OF UTAH
BY: _____
DEPUTY CLERK

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IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF UTAH, NORTHERN DIVISION

| | |
|---|---|
| ALBION LABORATORIES, INC., d.b.a. ALBION ADVANCED NUTRITION, a Utah corporation,<br><br>Plaintiffs,<br><br>vs.<br><br>ALL AMERICAN PHARMACEUTICAL & NATURAL FOODS CORPORATION., a Montana corporation; and JEFFREY GOLINI, an individual residing in Montana;<br><br>Defendants. | **COMPLAINT**<br><br>**Judge Ted Stewart**<br>**DECK TYPE: Civil**<br>**DATE STAMP: 05/05/2006 @ 16:44:53**<br>**CASE NUMBER: 1:06CV00056 TS** |

Plaintiff Albion Laboratories, Inc., d.b.a. Albion Advanced Nutrition brings this action against Defendants All American Pharmaceutical & Natural Foods Corporation and Jeffrey Golini for declaratory and injunctive relief and damages as follows:

**Subject Matter Jurisdiction**

1. This Court has subject matter jurisdiction over the claims in this action pursuant to 28 U.S.C. §§ 1331, 1332, 1338(a) and 2201.

**Venue**

2. Venue is proper in this district and division pursuant to 28 U.S.C. §§ 1391(b) and 1400

**Parties and Personal Jurisdiction**

3. Plaintiff Albion Laboratories, Inc., d.b.a. Albion Advanced Nutrition ("Albion") is a Utah corporation, and a wholly-owned subsidiary of Albion International, Inc., with its principal place of business in Clearfield, Utah.

4. Defendant All American Pharmaceutical & Natural Foods Corporation ("AAP") is, upon information and belief, a Montana corporation with its principal place of business at 1845 Main St., Billings, Montana, 59105, and claims to be the owner of United States Patent No. 6,399,661 (the "'661 Patent"), a copy of which is attached hereto as Exhibit 1.

5. On information and belief, AAP does business in Utah, manufactures, licenses, and sells products, directly or indirectly, to residents of Utah, and/or has directed its activities at and injured Utah residents.

6. On information and belief Defendant Jeffrey Golini ("Golini") is a resident of Montana, and is the named sole inventor on the '661 Patent.

7. The wrongful acts alleged in this Complaint arose in the District of Utah, and APP is subject to personal jurisdiction of courts in the State of Utah.

**General Allegations**

8. Albion is one of the premier nutritional companies in the world, specializing in chelated minerals, manufactured and sold in bulk to other companies manufacturing finished human nutritional products.

9. One of Albion's products is a magnesium creatine chelate sold in bulk under the name Creatine MagnaPower®, which is the subject of United States Patent No. 6,114,379 ("'379 patent"), filed July 1999, issued September 2000, and owned by an Albion affiliate. A copy of the '379 Patent is attached hereto as Exhibit 2.

10. By letter dated January 4, 2006, a copy of which is attached hereto as Exhibit 3, Defendant APP accused Custom Nutrition Warehouse and Omega Sports of infringing the '661 Patent by the manufacture, use and sale of a "Magnesium Creatine Chelate," which upon information and belief contains Creatine MagnaPower® manufactured by and obtained from Albion.

11. By letter dated January 17, 2006, a copy of which is attached hereto as Exhibit 4, Custom Nutrition Warehouse and Omega Sports (located in Missouri) informed APP that it had, "[e]ffective immediately, . . . pulled the product from [its] site and ha[s] ceased all sales."

12. By letter dated January 24, 2006, a copy of which is attached hereto as Exhibit 5, Defendant APP accused Controlled Labs of infringing the '661 Patent by the manufacture, use and sale of a "Magnesium Creatine Chelate," which upon information and belief contains Creatine MagnaPower® manufactured by and purchased from Albion.

13. Upon information and belief, APP has made statements to others in the industry, including at trade shows, that Albion's formulation of Creatine MagaPower® has been changed in a way that obviously infringes the '661 patent.

14. APP's statements are made in an effort to damage the reputation of Albion and the sales of its products in the marketplace and are untruthful, false, and damaging to Albion.

15. When Albion learned of APP's false infringement assertions, Albion wrote to APP by letter dated February 2, 2006, a copy of which is attached hereto as Exhibit 6, and informed APP that it did not "see how any use of our product by our customers could infringe" the '661 Patent, and demanded that APP "cease [its] harassment of [Albion's] customers based on these ill founded patent infringement claims."

16. By letter dated April 11, 2006, a copy of which is attached hereto as Exhibit 7 and was sent to Albion's principal place of business in Utah, APP directly accused Albion of infringing the '661, repeated its assertion that Albion had changed its formulation, and threatened to take steps to protect its patent if Albion did not change its formulation back to its alleged original formulation with a pH under 7.

**First Claim for Relief**
**(Declaratory Judgment of Non-infringement and Invalidity of the '661 patent against APP and Golini)**

17. Albion realleges and incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

18. APP has alleged and, upon information and belief continues to allege, that Albion and its customers infringe the '661 Patent by using Albion's Creatine MagnaPower®, and Albion has a reasonable apprehension of enforcement of the '661 Patent against it by APP.

19. Albion does not infringe, directly or indirectly, the '661 Patent.

20. Upon information and belief, Albion's customers do not infringe, directly or indirectly, the '661 Patent.

21. If the manufacture, use or sale of Creatine MagnaPower® infringes the '661 patent, then the '661 Patent is invalid and/or unenforceable for failure to satisfy the requirements of 35 U.S.C. §§ 102, 103, and 112, including, but not limited to, anticipation under 35 U.S.C. § 102 by the '379 patent and the conception, reduction to practice, and sale of Albion's various products.

22. Pursuant to 28 U.S.C. § 2201, Albion hereby seeks a declaratory judgment from the Court that neither Albion nor its customers infringe, directly or indirectly, the '661 Patent by use of Albion's Creatine MagnaPower® or other products and/or that the '661 Patent is invalid or unenforceable.

23. This case is exceptional in that APP's allegations of infringement are baseless, recklessly made and/or known to be false, thereby entitling Albion to an award of attorneys fees under 35 U.S.C. §285.

**Second Claim for Relief**
**(Tortious Interference with Prospective Economic Relations and Commercial Disparagement against APP)**

24. Albion realleges and incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

25. Albion has existing contractual and prospective economic relations with companies purchasing its products, including Creatine MagnaPower®.

26. APP has accused Albion and its customers that the use of Albion's Creatine MagnaPower® or other magnesium creatine chelated products infringes the '661 Patent, which assertion is not true.

27. Albion has demanded that APP cease its baseless allegations of infringement, but, upon information and belief, APP has refused to do so.

28. Upon information and belief, APP knows or should have known that its allegations of infringement are untrue and without basis in fact or law.

29. APP's untrue and baseless allegations of infringement constitute commercial disparagement, and an improper means, which interferes with Albion's economic relations with its customers.

30. Upon information and belief, APP's commercial disparagement and wrongful interference with Albion's economic relations has harmed and will continue to harm Albion's reputation and has otherwise damaged, and will continue to damage Albion.

31. As a result, Albion has been damaged in an amount to be proven at trial.

32. Such damage is, in whole or in part, irreparable, thereby entitling Albion to preliminary and permanent injunctive relief against APP.

**Prayer**

WHEREFORE, Albion respectfully requests judgment for the following:

(1) A declaration that neither Albion nor its customers infringe the '661 Patent by their use of Albion's magnesium creatine chelates.

(2) A declaration that the claims of the '661 Patent are invalid or unenforceable.

(3) An award of damages from APP in an amount to be proved at trial, but not less than $100,000.

(4) An award against APP of Albion's attorneys' fees and costs in responding to APP's baseless allegations of infringement, including all those fees and costs incurred in this action.

(5) Such further relief as the Court deems just and proper.

DATED this 5th day of May, 2006.

RAY, QUINNEY & NEBEKER

Mark M. Bettilyon
Rick B Hoggard

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Plaintiffs' Address:

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Clearfield, Utah 84015

870526

# EXHIBIT 1

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

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*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**

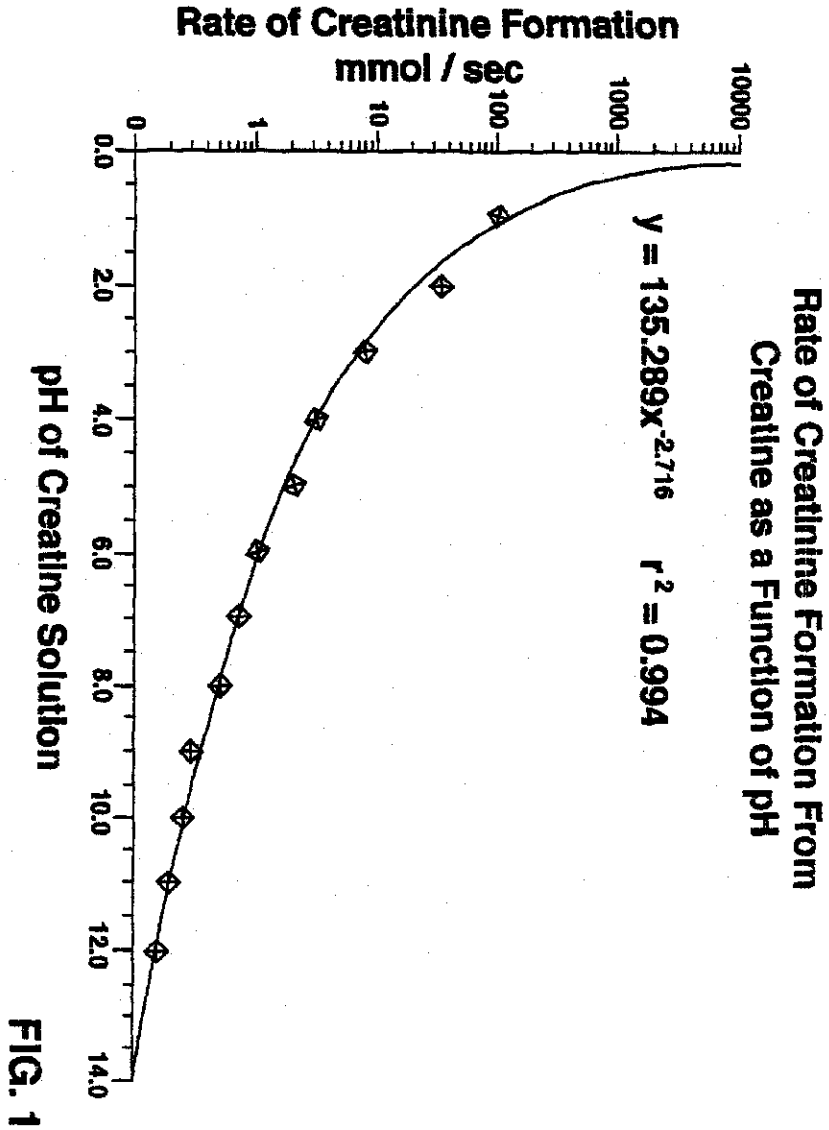
Rate of Creatinine Formation
mmol / sec
0
1
10
100
1000
10000
0.0
2.0
4.0
6.0
8.0
10.0
12.0
14.0
pH of Creatine Solution
y = 135.289x-2.716
r2 = 0.994
Rate of Creatinine Formation From
Creatine as a Function of pH

FIG. 1

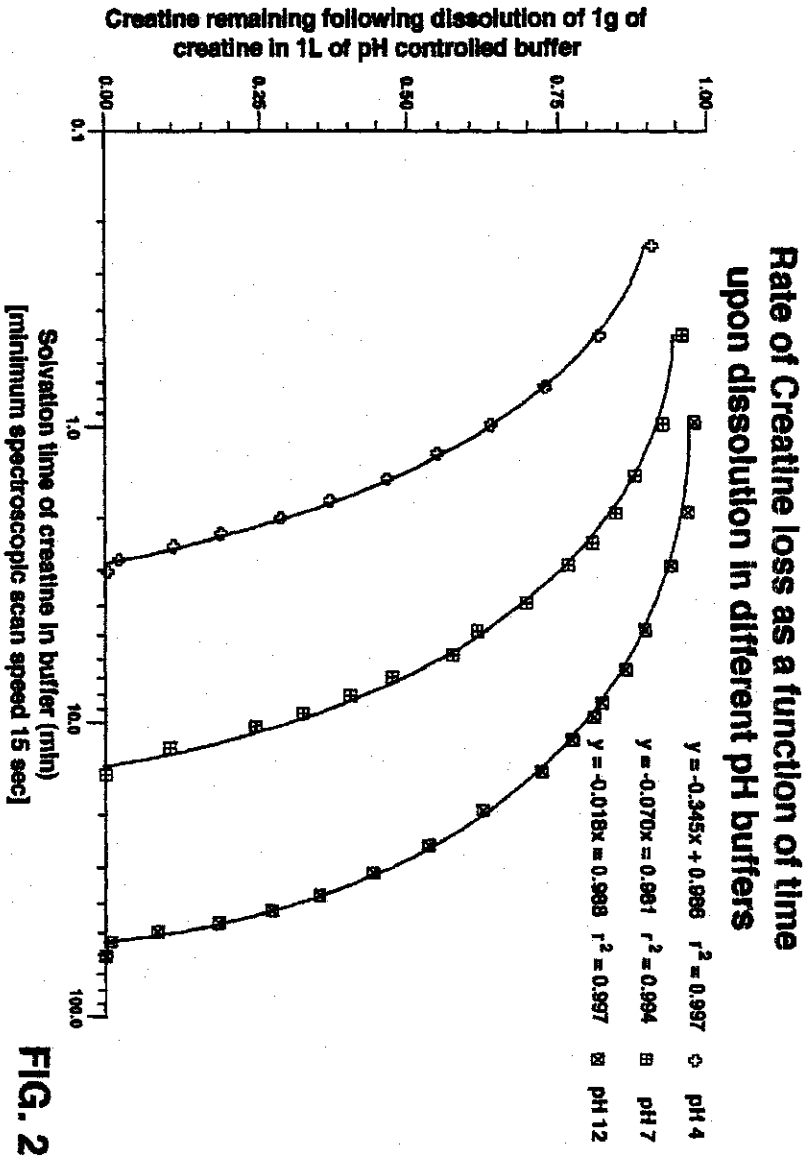
Creatine remaining following dissolution of 1g of creatine in 1L of pH controlled buffer
0.00
0.25
0.50
0.75
1.00
0.1
1.0
10.0
100.0
Solvation time of creatine in buffer (min)
[minimum spectroscopic scan speed 15 sec]
Rate of Creatine loss as a function of time upon dissolution in different pH buffers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

| PH | Time for conversion of 1g creatine to creatinine in 1 liter at given ph (min) |
|---|---|
| 2 | 0.4274 |
| 4 | 2.8081 |
| 6 | 8.4465 |
| 8 | 18.4507 |
| 10 | 33.8236 |
| 12 | 55.4979 |
| 14 | Never |

FIG. 3

# 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:

| | |
|---|---|
| Creatine Monohydrate | 5000 mg |
| Sugar (from dextrose, fructose, sucrose, or a type of sugar) | 10–15 g |
| Maltodextrin (from corn and/or rice) | 5–10 g |
| Soda Ash | 50 mg–1.5 g |
| Natural and/or Artificial Flavors | 2 g |
| Magnesium Glycerol Phosphate | 500 mg |
| Aspartame, Acesulfame K, Sucralose and/or Stevia Extract (Powder mix can be with/without flavors, sugars or sweeteners) | 200 mg |

The method for preparing the powder mix includes placing the 5000 mg of creatine monohydrate in a mixing vessel. The soda ash is then added to adjust the pH of the mixture from 7–14. After the pH has been adjusted, the sugar, natural and/or artificial flavors, and the aspartame, acesulfame K, sucralose and/or stevia extract are added to adjust the mixture for desired taste and desired sweetness. The pH of the mixture is again checked and magnesium glycerol phosphate is added to adjust the pH to be between 7 and 14. The powder is then bottled for distribution.

In capsule form, the capsule includes the following formulation:

| | |
|---|---|
| Creatine Monohydrate | 1000 mg |
| Maltodextrin | 200 mg |
| Magnesium Stearate | 5 mg |
| Magnesium Glycerol Phosphate | 25 mg |
| Soda Ash | 5–1000 mg |
| Natural and/or Artificial Flavors | 20 mg |

The method for making capsules is to place 1000 mg of creatine monohydrate in a mixing vessel. The pH is adjusted to be between 7 and 14 by adding soda ash. The maltodextrin, magnesium stearate (a flow agent) and natural and/or artificial flavors are added to desired taste and sweetness. The pH is again checked, and magnesium glycerol phosphate is added to adjust the pH to be between 7 and 14. The mixed powder is then processed by a conventional encapsulation machine which prepares capsules of the powder.

A capsule with this formulation is swallowed by a user and dissolves in the solution present in the stomach.

In tablet form, the formulation is as follows:

| | |
|---|---|
| Creatine Monohydrate | 250 mg |
| Sorbitol | 400 mg |
| Microcrystalline Cellulose | 50 mg |
| Magnesium Stearate | 5 mg |
| Magnesium Glycerol Phosphate | 25 mg |
| Soda Ash | 5–500 mg |

In preparing the tablets, creatine monohydrate is placed in a mixing vessel and soda ash is added to adjust the pH from between 7 and 14. Sorbitol, which is a hardener, and microcrystalline cellulose, which is a binder, is added to the mixture, as well as magnesium stearate, which is a stabilizer, in preparation for forming tablets. The pH of the mixture is then checked and magnesium glycerol phosphate is then added to adjust the pH to be between 7 and 14. The powder is then processed by a conventional machine which compresses the powder into tablets.



A tablet with this formulation is swallowed by a user and dissolves in the solution present in the stomach.

In liquid form, the formulation is as follows:

| | |
|---|---|
| Creatine Monohydrate | 3 grams |
| Water | 1–30 ml |
| Glycerine | 1–30 ml |
| Magnesium Glycerol Phosphate | 25 mg |
| Natural and/or Artificial Flavors | 5 ml |
| Soda Ash | 50–1000 mg |
| Potassium Sorbate | 200 mcg |

In preparing the liquid form, water and creatine monohydrate are mixed together in a mixing vessel. Soda ash is added to adjust the pH to be between 7 and 14. The glycerine, which acts as a base and preservative, together with potassium sorbate, which acts as a stabilizer and preservative, are added to the admixture. Further, natural and/or artificial flavors are added to adjust the mixture for desired taste and sweetness. The pH is again checked, and magnesium glycerol phosphate is then added to adjust the pH to be between 7 and 14. The resulting liquid is then bottled for distribution.

With this liquid form, the product is ingested directly.

In a softgel form, the formulation is as follows:

| | |
|---|---|
| Creatine Monohydrate | 100 mg |
| Sugar | 300 mg |
| Chocolate | 50 mg |
| Soy Bean Oil | 500 mg |
| Magnesium Glycerol Phosphate | 25 mg |
| Soda Ash | 5–1000 mg |

The method for making the softgel includes placing the creatine monohydrate in a mixing vessel. Soda ash is then added to adjust the pH to be between 7 and 14. Next, the sugar, chocolate and soy bean oil, which acts as a base for the gel, is added to the mixture. Again, the pH is checked, and magnesium glycerol phosphate is added to adjust the pH to be between 7 and 14. The resulting gel is then placed in bottles for distribution.

With these formulations, the pH of the solution is above 7, and the beneficial results shown in FIGS. 1–3 are thereby obtained.

It should be understood that organic or inorganic substances could be used with equally beneficial results to raise the pH of the solution. For example, hydroxides, carbonates, bicarbonates, chlorides, tree latex or phosphates could be used.

Further, the creatine used could be creatine monohydrate as described in the above formulations, or could be creatine phosphate, creatine pyruvate or creatine citrate.

The types, combination and amounts of buffers can vary with various delivery forms, flavors, and combination type products.

The method for enhancing a stable concentration of creatine in a human includes dissolving the creatine powder into water or any other type of fluid. Once the mixture has been mixed, the solution is ingested immediately and an effective amount of creatine is absorbed. The capsule, tablet and liquid form can be ingested as is.

This buffered delivery system enhances the delivery of usable creatine to the person taking the supplement, and

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.

* * * * *

# EXHIBIT 2

US006114379A

# United States Patent [19]

**Wheelwright et al.**

[11] **Patent Number: 6,114,379**

[45] **Date of Patent: Sep. 5, 2000**

[54] **BIOAVAILABLE CHELATES OF CREATINE AND ESSENTIAL METALS**

[75] Inventors: **David C. Wheelwright; Stephen D. Ashmead**, both of Clearfield, Utah

[73] Assignee: **Albion Laboratories, Inc.**, Clearfield, Utah

[21] Appl. No.: **09/348,359**

[22] Filed: **Jul. 7, 1999**

[51] **Int. Cl.**[7] ..... **A61K 31/28**; C07F 13/00; C07F 11/00; C07F 15/00; C07F 1/00

[52] **U.S. Cl.** ..... **514/492**; 514/499; 514/501; 514/502; 514/505; 556/50; 556/63; 556/116; 556/134; 556/148; 562/899

[58] **Field of Search** ..... 556/50, 63, 116, 556/134, 148; 562/899; 514/492, 499, 501, 502, 505

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*Primary Examiner*—Porfirio Nazario-Gonzalez
*Attorney, Agent, or Firm*—Thorpe, North & Western, LLP

[57] **ABSTRACT**

A chelate comprised of creatine bonded to an essential mineral selected from the group consisting of Mg, Ca, Cu, Zn, Fe, Cr, Co, Mo, Se and Mn to form a heterocyclic ring. Preferably, the metal is Mg, but Ca, Zn, Fe, Cr and Mn are also preferred. The creatine chelates of the present invention are capable of being absorbed in the stomach or intestines via active transport without substantial metabolism of the chelate. In other words, the creatine ligand is protected by the metal from undergoing cyclization in the acidic environment of the stomach and the metal is made more bioavailable due to the presence of the creatine ligand.

54 Claims, No Drawings

# BIOAVAILABLE CHELATES OF CREATINE AND ESSENTIAL METALS

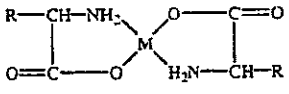
## FIELD OF THE INVENTION

The present invention relates to a chelate comprised of creatine and various essential metals selected from the group consisting of Mg, Ca, Cu, Zn, Fe, Cr, Co, Mo, Se and Mn, preferably Mg. These chelates are absorbed into biological tissue and subsequently migrate to specific tissue sites where the various chelates are utilized by corresponding tissue. The respective tissue sites may have use for the chelates intact as delivered or as dissociated chelates in the form of a mineral cation and/or creatine.

## BACKGROUND OF THE INVENTION

When a metal combines with an electron donor ligand, a complex or coordination compound is formed. Further, when an electron donor contains two or more donor groups tied together in some way, the ligand is referred to as a polydentate ligand, e.g., a bidentate ligand has two donor groups. The commonality found in all chelates is the formation of a heterocyclic ring comprised of a ligand and a metal atom. For ring formation to occur, several conditions must be present. First, the electron donor molecule must contain two or more groups that can each combine with a particular metal atom. Second, groups and/or atoms must be present that can simultaneously coordinate with the metal atom through their electron pairs. Finally, these donor groups must be separated from each other by sufficient atoms so that sterically permissible heterocyclic rings may be formed. An example of a chelate involving two organic ligands, each ligand containing a carboxyl functional group and an α-amine functional group, may be depicted by the following graphic:

FORMULA 1



In the above depiction, M represents the metal atom that acts as the closing member for the organic ligands.

The structure, chemistry and bioavailability of amino acid chelates are well documented, e.g. Ashmead et al., *Chelated Mineral Nutrition*, (1982), Chas. C. Thomas Publishers, Springfield, Ill.; Ashmead et al., *Intestinal Absorption of Metal Ions*, (1985), Chas. C. Thomas Publishers, Springfield, Illinois; Ashmead et al., *Foliar Feeding of Plants with Amino Acid Chelates*, (1986), Noyes Publications, Park Ridge, N.J.; U.S. Pat. Nos. 4,020,158; 4,167,564; 4,216,143; 4,216,144; 4,599,152; 4,774,089; 4,830,716; 4,863,898 among others.

Additionally, flavored effervescent mixtures of vitamins and amino acid chelates in the form of a beverage have also been disclosed in U.S. Pat. No. 4,725,427.

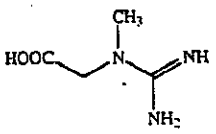
In the field of mineral nutrition, amino acid chelates have increasingly been recognized as providing certain advantages over inorganic mineral salts. One advantage is attributed to the fact that these chelates are readily absorbed in the intestines via mucosal cells by means of active transport as though they were small peptides. In other words, the minerals are absorbed along with the amino acids as a single unit by utilizing the amino acids as carrier molecules. This method of metal absorption is beneficial because it enables absorption of specific metals into the body without utilizing standard absorption sites for free metal ions. Therefore, the



problems associated with the competition of ions for active sites and the suppression of specific nutritive mineral elements by others are avoided. Other advantages of amino acid chelates include stimulation of gonadotropic hormones as is disclosed in U.S. Pat. No. 4,774,089, delivery of metal ions to targeted tissue sites disclosed in U.S. Pat. No. 4,863,898 and enhancement of the immune system disclosed in U.S. Pat. No. 5,162,369.

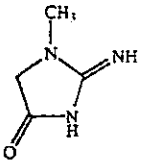
Creatine, also known as N-(Aminoiminomethyl)-N-methylglycine, methylglycoamine or N-methyl-guanido acetic acid is a well known substance. In fact, creatine is listed in *The Merck Index*, Twelfth Edition, No. 2637, and may be represented as follows:

FORMULA 2



It is important to note that creatine is susceptible to cyclization. Perhaps, because of the positioning of the $NH_2$ gamma to the carboxylic acid, creatine is labile to acid hydrolysis. Regardless of any purported rational, under acidic conditions, creatine has the propensity to form creatinine, which may be represented by the following formula:

FORMULA 3



In fact, in acidic aqueous solutions, the formation of creatinine from creatine is nearly quantitative and irreversible. Cannan, Shore, *Biochem. J.* 22, 924 (1928). With this in mind, it is apparent that the exposure of creatine to the acidic environment of the stomach will cause an irreversible formation of creatinine. Once creatinine is formed, any further biological use of ingested creatine will be precluded.

Muscle contraction and relaxation are fueled by energy liberated during the dephosphorylation of adenosinetriphosphate (ATP). The ATP stored within a cell is rapidly depleted during even normal activity. For normal tissue function to continue, ATP must be rapidly resynthesized from its breakdown products, one of which is adenosinediphosphate (ADP). During maximal exercise of a short duration, this resynthesis is accomplished almost exclusively by the anaerobic degradation of phosphocreatine (PCR) and glycogen. Hultman E. et al., *Energy metabolism and fatigue*; Taylor A. et al., eds. *Biochemistry of exercise VII*, Champaign, Ill., Human Kinetic Publishers, 1990: vol. 21, 73–92. It has also been proposed that the observed decline in force production during intense muscle contraction may be related to the availability of muscle PCR stores. Greenhaff P. L. et al., *Influence of oral creatine supplementation of muscle torque during repeated bouts of maximal voluntary exercise in man, Clinical Science* (1993) 84, 565–571. The depletion of these PCR stores limits the rephosphorylation of ADP, thereby limiting the ATP available for energy production. Greenhaff further proposed that any mechanism capable of increasing the total intramuscular creatine store might arrest PCR depletion during intense muscular con-

traction and offset, or even prevent, the decline in the rate of ADP rephosphorylation during exercise. However, no efforts were made to explain the increase of creatine within the muscle cells. Greenhaff merely relied upon work previously published that demonstrated that the creatine content of skeletal muscles could be increased by 20%–50% through standard oral pathways. However, in that study, in order to achieve this marginal increase in the creatine content of muscle cells, the subjects of the study were required to ingest 20 grams of creatine hydrochloride. Harris R. C. et al., *Elevation of creatine in resting and exercised muscle of normal subjects by creatine supplementation. Clin. Sci.*, 1992; 83: 367–74.

Creatine can be found biologically in diverse portions of the body. However, some reports indicate that creatine is found primarily in the nerves and muscle. Walker J. B., *Creatine: Biosynthesis, regulation, and function; Adv. Enzymology and Related Areas of Molecular Biology* (1979) 50: 177–242. Essentially, creatine is used biologically for the regeneration of ATP from ADP. However, in the process of regenerating ATP, creatine is irreversibly transformed to creatinine which in turn, is eliminated from the body through the urine. Because creatine is irreversibly used, i.e., from creatine to creatinine, the body must either produce creatine biochemically or secure an outside source to supply the body with needed creatine.

Biochemically, the human liver and pancreas use various amino acids such as glycine, serine, arginine and methionine to synthesize creatine. However, when sufficient in one's diet, creatine may be made bioavailable through ingestion. Although animal muscle contains approximately 0.5% creatine by weight, most of the creatine which is bioavailable for ingestion is degraded by the cooking process. Therefore, cooked meat is a poor source of ingestible creatine. Moreover, plants and/or vegetables are also a poor source of creatine.

The securing of creatine from an outside source has also been discussed in several recent U.S. patents. U.S. Pat. No. 5,397,786 entitled, REHYDRATION DRINK, discloses a drink for the treatment and prevention of the loss of essential electrolytes due to fluid loss. This patent teaches that creatine, B vitamins, pantothenic acid and choline are energy enhancers. Additionally, this invention provides for the addition of numerous salts such as $MgCO_3$, $CaCO_3$ and magnesium aspartate as supplements containing essential nutrients. Although the necessity of these elements in a healthy metabolism was recognized, the use of ionic salts is largely ineffective because most of the ingested elements are lost in the acidic environment of the stomach.

U.S. Pat. No. 5,576,316 entitled METHOD FOR INHIBITING TUMOR GROWTH RATE USING CREATINE OR CREATINE ANALOGS discloses the use of creatine and creatine analogs for the treatment of tumors. Specifically, this invention teaches that the administration of creatine in the form of a salt can reduce a tumor's growth rate. The patent further teaches that significant portions of orally administered creatine are lost through the urine without having been used by the body at all.

Finally, U.S. Pat. No. 5,888,553 entitled NON-STEROIDAL ANABOLIC COMPOSITION discloses a composition used to build and sustain muscle mass. The complex is comprised of effective amounts of chromium salt and a magnesium glycyl glutaminate chelate as core ingredients. Optional ingredients include a magnesium amino acid chelate, an α-glutaric acid salt of ornithine, creatine (or a salt thereof) and a branched chain amino acid (leucine, isoleucine and/or valine).



Based upon what is known about the prior art, there is a need to provide a composition and method of making a compound that enables creatine and essential metals to be introduced to the body in such a manner so that more creatine than previously known in the art may be used by the body prior to undergoing cyclization. In other words, it would be desirable to provide a creatine chelate for oral consumption comprised in such a way that the creatine ligand is protected by the metal from undergoing cyclization in the acidic environment of the stomach, thus making the creatine more readily available to the body in a useful form. Further, it would be desirable to provide a creatine chelate so that the metal is made more bioavailable due to the presence of the creatine ligand.

## OBJECTS AND SUMMARY OF THE INVENTION

It is an object of the present invention to provide a creatine chelate composition which, when ingested into a living organism, will be transported to one or more sites within the organism such as muscle, nerve, brain tissue, enzyme system, immune system, blood cells or tumors.

It is another object of the present invention to provide a nutrient formulation which enhances fatigue resistance and recovery time during high intensity, short-term exercise by providing a nutrient formulation which is comprised of the anabolic nutrients phosphorus and creatine, which are precursors for the bodies formation of phosphocreatine.

It is another object of the present invention to complement creatine and phosphorus with chelated magnesium as an activator of the enzymes that hydrolyze and transfer phosphate groups, e.g. the phosphatases and those concerned in the reactions involving adenosine triphosphate (ATP).

It is another object of the present invention is to provide a creatine chelate for oral consumption such that the chelate remains intact in the acidic conditions of the stomach, thereby providing a mechanism to prevent creatine from undergoing cyclization before it reaches the target tissue.

It is yet another object of the present invention is to provide a metal selected from the group consisting of Mg, Ca, Cu, Zn, Fe, Cr, Co, Mo, Se and Mn in a form that has enhanced bioavailability over inorganic salts.

These and other objects may be accomplished by providing a creatine chelate composition and method for making and using the same. Creatine chelates may be absorbed through the intestinal tract as intact molecules, and subsequently, may then be transported to various tissues for use as intact chelates, creatine and/or metal ions. This is possible because these chelates are protected from dipeptidase activity due to the presence of metal. Further, they are also protected from acid hydrolysis because the hydrolysis reaction of a creatine chelate is energetically disfavored.

## DETAILED DESCRIPTION OF THE INVENTION

Before the present invention comprising a creatine chelate and method of making the same is disclosed and described, it is to be understood that this invention is not limited to the particular process steps and materials disclosed herein as such process steps and materials may vary to some degree. It is also to be understood that the terminology used herein is used for the purpose of describing particular embodiments only and is not intended to be limiting as the scope of the present invention will be limited only by the appended claims and equivalents thereof.

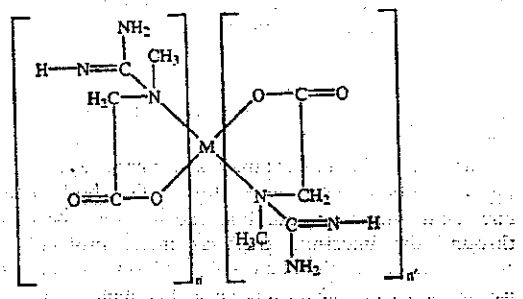
It must be noted that, as used in this specification and the appended claims, singular forms of "a," "an," and "the" include plural referents unless the content clearly dictates otherwise.

"Bioavailable" means, for purposes of this invention, that the creatine chelate, creatine and/or the metal is available to the body. In the case of creatine, the metal provides a mechanism of protecting the creatine from undergoing cyclization in the acidic environment of the stomach.

"Chelate" means, for purposes of this invention, that the creatine ligand forms a heterocyclic ring with the metal as the closing member. Coordinate covalent bonds may exist at both the carboxyl oxygen group and amine groups may exist. However, coordinate covalent bonds are not required as long as there is at least one bidentate ligand and a metal which interact to form a ring, i.e. coordination with the amine groups and coulombic attraction to the negatively charged carboxyl group.

With this in mind, the present invention is essentially a metal chelate comprising a creatine ligand bonded to a metal selected from the group consisting of Mg, Ca, Cu, Zn, Fe, Cr, Co, Mo, Se and Mn to form a chelate ring and having a ligand to metal molar ratio from about 1:1 to 3:1. The chelate is formed by reacting creatine with a metal under reaction conditions that are conductive to chelate formation. The creatine may be provided by a member selected from the group consisting of creatine, creatine salts, creatine esters, creatine amides and creatine hydrates. The metal may be provided by a member selected from the group consisting of magnesium (Mg), calcium (Ca), copper (Cu), zinc (Zn), iron (Fe), chromium (Cr), cobalt (Co), molybdenum (Mo), selenium (Se) and manganese (Mn) in elemental form or in the form of chlorides, sulfates, oxides, hydroxides, carbonates and/or bicarbonates. A preferred basic structure of a creatine chelate may be depicted as follows:

FORMULA 4



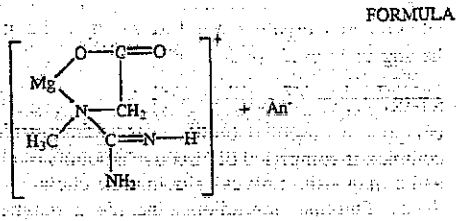
In the above depiction, M is a metal, n is 1 and n' is 0, 1, or 2. However, it is most preferred that n' is 0 providing a ligand to metal molar ratio of 1:1. To illustrate this aspect of the invention, magnesium creatine may have a ligand to metal molar ratio of 2:1 (n'=1), but 1:1 (n'=0) is preferred. Additionally, other preferred ligand to metal molar ratios include creatine to calcium at 1:1 (n'=0); creatine to zinc at 1:1 (n'=0); creatine to chromium at 1:1 (n'=0), 2:1 (n'=1) and/or 3:1 (n'=2); creatine to manganese at 1:1 (n'=0); and creatine to iron a 1:1 (n'=0); 2:1 (n'=1) and/or 3:1 (n'=2). When n'=0, there may be one or more anions present in the solution (see Formula 5 below). It is important to note that the bonds depicted between the metal (M) and the amine group and between the metal (M) and carboxyl oxygen group as shown and described should not necessarily be strictly construed to represent coordinate covalent bonds. For example, in one embodiment, a covalent bond may exists between the metal (M) and the amine group whereas an ionic or coulombic bond exists between the metal (M) and the carboxyl oxygen group (see Formula 6 below). However, for optimal absorption through the intestinal tract, the net electrical charge at the metal ion is preferably zero. In other words any positive charge on the metal ion is neutralized by electrons contributed by the ligand in formation of the heterocyclic chelate ring.

Generally, the method of preparing the creatine chelates of the present invention is as follows. First, a soluble metal salt or an insoluble metal compound is dissolved in water or solubilized in an acidic solution respectively. If an acidic solution is required to disassociate the metal ions, acids such as acetic, citric, lactic, malic, hydrochloric, phosphoric, sulfuric, tartaric, maleic and naturally occurring amino acids such as aminobutyric, aspartic and glutamic acids, etc., may be used. If a metal salt is used that is soluble in water, it may not be required to use an acidic solution, though it may be desired. To illustrate, if magnesium is the metal to be chelated, magnesium sulfate, magnesium citrate, magnesium chloride, magnesium phosphate monobasic, magnesium nitrate, magnesium oxide, etc., may be used as the metal source which will either be dissolved in water or acidified in an acidic solution. To this solution, a creatine ligand is then added. If the pH level is not around neutral, i.e., if it is between about 7.5 and 10, a pH adjuster may be added. pH adjusters may include o-phosphoric acid, citric acid, malic acid, acetic acid, hydrochloric acid, tartaric acid, lactic acid, nitric acid, sulfuric acid and naturally occurring amino acids such as aminobutyric acid, aspartic acid and glutamic acid among others, though o-phosphoric acid is preferred. For example if a creatine chelate is prepared by reacting a creatine ligand with a metal oxide in the presence of citric acid, o-phosphoric acid or another acidifying agent may be added to lower the pH from more basic levels (about 7.5 to 10) to a more neutral pH (about 7).

It is important to note that the order that one mixes the ingredients is not central to the invention. The creatine ligand may be added to the aqueous acidic solution first followed by the addition of the metal, or even simultaneously. However, these embodiments are not preferred because the creatine ligand may undergo hydrolysis, i.e., cyclization to creatinine, if exposed to the acidic environment for an extended period of time prior to the addition of the metal.

The product magnesium creatine, a preferred embodiment, may be prepared by reacting magnesium oxide, creatine, o-phosphoric acid and citric acid in an aqueous environment. The formulation is stoichiometrically balanced so that no unreacted magnesium oxide remains in the product. The product is believed to involve the interaction between the magnesium ion and the ligand creatine by coulombic attraction to the negatively charged carboxyl group and coordination with the amine group. Of the possible combinations and permutations, one possible structure is as follows:

FORMULA 5



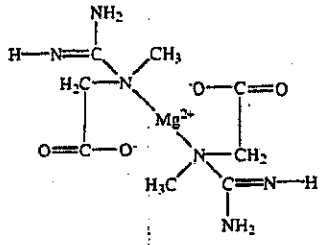
In the above depiction, the ligand to metal molar ratio is 1:1 and $An^-$ may be any of a number of possible corresponding

anions such as chloride ($Cl^-$), iodide ($I^-$), bisulfate ($HSO_4^-$), bicarbonate ($HCO_3^-$), dihydrogen phosphate ($H_2PO_4^-$), phosphate ($PO_4^-$), sulfate ($SO_4^{2-}$), citrate, acetate ($C_2H_3O_2^-$), lactate, malate, aminobutyrate, aspartate and glutamate or anions from other soluble salts. If the ligand to metal molar ratio is more than 1:1, then another creatinate anion may be present.

Specifically, magnesium creatine having a 1:1 molar ratio may be prepared by admixing equal moles of creatine and magnesium oxide in a citric acid solution. This produces a magnesium creatine chelate having a pH of about 8 to 9. To this, phosphoric acid is added to lower the pH level to about 7.

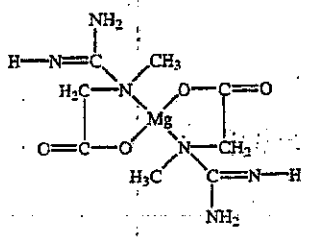
As discussed above, 2:1 structures of creatine chelates may also be formed. As such, another possible structure for magnesium creatine may be as follows:

FORMULA 6



In the above depiction, the ligand to metal molar ratio is 2:1. However, this molecule is not fully coordinated as the carboxyl oxygen groups have not formed coordinate covalent bonds with the magnesium center. In fact, 2 coordination sites remain available, as represented by $Mg^{2+}$, at the center. However, the available electrons of the carboxylate ion essentially neutralize the positive charge of the $Mg^{2+}$ ion effectively resulting in a neutralized Mg ion. Full coordination is not required in the context of the present invention. The present invention contemplates chelates having a ligand to metal molar ratio from about 1:1 to 3:1 comprised of a heterocyclic creatine ring having a metal ion acting as the closing member. Therefore, the present invention is intended to cover chelates having coordinate covalent bonds at both the amine group and the carboxyl group and chelates having a coordinate covalent bond at the amine group and an ionic bond or other attraction at the carboxyl group. As such, under the right conditions, a fully coordinated magnesium creatine chelates may also be formed as depicted below:

FORMULA 7



The present invention is also drawn toward a method of administering a creatine chelate to a warm-blooded mammal. The steps include 1) formulating an effective amount of creatine chelate into a nutritional supplement suitable for oral consumption; and 2) administering the nutritional supplement containing the creatine chelate to a warm blooded mammal. The nutritional supplement may be in the form of tablets, food bars, drinks, dry drink mixes or other substances acceptable for oral consumption. Tablets may be chewable or non-chewable. Food bars may be in the form of energy bars, weight loss bars, snack bars, granola bars or combinations thereof. Drinks may be in the form of energy drinks, sports drinks, fruit drinks, citrus drinks, carbonated drinks, other suitable drink mediums or combinations thereof. Finally, the dry drink mixes may be in the form of a fruit mix and/or citrus mix or other particulate drink mixes.

The following examples illustrate compositions and methods of preparing creatine chelates as well as various applications for which creatine chelates may be used. The following examples should not be considered as limitations of the present invention, but should merely teach how to make the best known creatine chelates based upon current experimental data.

## EXAMPLES

### Example 1

Preparation of Magnesium Creatine

Magnesium creatine chelate having a 1:1 ligand to metal molar ratio is prepared, first, by combining the following ingredients: 136.00 ml of water at 50 to 55° C.; 50.78 g of creatine monohydrate; 14.26 g of magnesium oxide; 7.63 g of 85% o-phosphoric acid; and 35.97 g of citric acid. The reaction mixture is heated to about 50 to 55° C. and spray dried. The expected yield of the dried product is 100.00 g when adjustments are made to account for evaporation of the water formed from the acid base reaction with magnesium oxide, waters of hydration associated with creatine monohydrate and 15% water associated with phosphoric acid. The assumption is made that 5.00 ml of water from the starting material is retained in the spray drying process.

The citric acid is used in the formulation as a source of acidic $H^+$ ions so as to react with $OH^-$ ions forming water and shifting the equilibrium $Mg(OH)_2 <--> Mg^{2+} + 2OH^-$ to the right. This presents the magnesium to the creatine ligand as soluble $Mg^{2+}$ ions so that reaction can occur between the creatine and magnesium. The advantage of avoiding undesirable anions such as sulfate or chloride is realized by this process. Additionally, the soluble magnesium citrate initially formed has the advantage of having a higher overall pH than magnesium chloride or sulfate. This is of importance because hydrogen ions compete with metal ions for the lone pair of electrons on the amine groups. Phosphoric acid is used to bring the overall product pH down to a range that is desirable for greater food compatibility while not significantly adding to the overall weight of the finished product, and thus lowering the overall weight percent of magnesium and creatine in the product. Additionally, it has nutritive benefits and lacks the undesirable qualities associated chlorides and sulfates.

### Example 2

Magnesium Creatine Fortified Energy Bars

The following formulations for three different energy bars show products with 200 mg of magnesium and 1.3 grams of creatine per 50 g using magnesium creatine prepared as discussed herein.

Ingredients for Milk Chocolate Peanut Butter Bar

8% Mg creatine chelate
13% soy protein isolate
8% whey powder
5% 10 D.E. maltodextrin
12% crystalline fructose
10% sucrose
2% nonfat dry milk

13% corn syrup 42 D.E.
2% peanut flour
6% peanut butter
4% partially hydrogenated soybean oil
2% honey
5% densified crisp rice #110
0.1% salt
0.5% lecithin
0.6% vitamin & mineral blend
0.4% butter vanilla flavor
0.4% natural flavor blend
8% water

Ingredients for Black & White Chocolate Bar

8% Mg creatine chelate
13% soy protein isolate
8% whey powder
8% 10 D.E. maltodextrin
13% crystalline fructose
10% sucrose
3% nonfat dry milk
13% corn syrup 42 D.E.
5% dark cocoa
4% partially hydrogenated soybean oil
2% honey
5% densified crisp rice
0.1% salt
0.5% lecithin
0.6% vitamin & mineral blend
0.4% butter vanilla flavor
0.4% natural flavor blend
6% water

Ingredients for DBL Dark Chocolate Crunch Bar

8% Mg creatine chelate
13% soy protein isolate
8% whey powder
6% 10 D.E. maltodextrin
15% crystalline fructose
10% sucrose
3% nonfat dry milk
13% corn syrup 42 D.E.
5% dark cocoa
4% partially hydrogenated soybean oil
2% honey
5% densified crisp rice
0.1% salt
0.5% lecithin
0.6% vitamin & mineral blend
0.4% butter vanilla flavor
0.4% natural flavor blend
6% water

The general procedure for preparing these energy bars is as follows: First, in a blend tank, a slurry of water, corn syrup, sucrose, fructose, soybean oil and honey is formed. To this slurry, either peanut butter (milk chocolate peanut butter bar) or dark cocoa (black and white chocolate bar or DBL dark chocolate bar) is added. The slurry is then heated up to 120° F. and placed in a dough mixer. Other dry ingredients are then added to the slurry and the batch is mixed until homogenous. Next, flavors and crisp rice are added and mixed until dispersed.

The resulting mass is then loaded into an extruder and extruded to a predetermined size. The extruded bars are then run under refrigerated air blast to cool. Once cooled, the bars are coated with milk chocolate (milk chocolate peanut butter bar), white chocolate (black and white chocolate bar) or dark chocolate containing crisp rice (DBL dark chocolate crunch bar). The weight ratio of chocolate coating to extruded center is 1:2 (or 50 pounds of chocolate coating to 100 pounds of extruded center).

Example 3

Magnesium Creatine Fortified Energy Drink

This model formulation for an energy drink will provide a product with 200 mg of magnesium and 1.3 g of creatine per 8-fl oz. using magnesium creatine as disclosed herein.

Ingredients for Vanilla Flavored Drink

1.1% Mg creatine chelate
4% 10 D.E. maltodextrin
9% sucrose
8% nonfat dry milk
0.25% sodium citrate
0.02% carrageenan
0.6% vitamin & mineral blend
0.55% vanilla flavor
76.3% filtered water

A liquid drink is prepared as sucrose, nonfat dry milk, maltodextrin, sodium citrate, carrageenan, vitamins and minerals and magnesium creatine are blended into water under good agitation. To this liquid, vanilla flavor is added and the complete mixture is heat treated to 165° F. and homogenized. The product is cooled to 40° F. and packaged.

A powdered drink is prepared as all dry ingredients are blended together as a premix for mixing with water or milk.

Example 4

Magnesium Creatine Fortified Sports Drink

This formulation for a sports drink will provide a product with 300 mg of magnesium and 1.9 g of creatine per 8-fl oz. using magnesium creatine as disclosed herein.

Ingredients for Fruit Punch Flavored Sports Drink

1.65% Mg creatine chelate
2.7% 42 D.E. corn syrup
3.5% sucrose
0.3% citric acid
0.1% salt
0.5% fruit punch flavor
91.25% filtered water

A liquid drink is prepared as sugar, corn syrup citric acid, salt and magnesium creatine is blended into water under good agitation. To this liquid, a fruit punch flavoring is added.

The complete batch is heat treated to 150° F., allowed to cool to 40° F. and packaged.

Example 5

Preparation of Calcium Creatine

Calcium creatine chelate having a 1:1 ligand to metal molar ratio is prepared, first, by combining the following ingredients: 540.00 ml of water at 50 to 55° C.; 150.00 g of creatine monohydrate; 59.98 g of calcium oxide; and 23.43 g of 85% o-phosphoric acid. The reaction mixture is heated to about 50 to 55° C. and spray dried. The expected yield of the dried product is 314.49 g when adjustments are made to account for evaporation of the water formed from the acid base reaction with calcium oxide, waters of hydration associated with creatine monohydrate and 15% water associated with phosphoric acid. The assumption is made that 15.72 ml of water from the starting material is retained in the spray drying process.

Example 6

Calcium Creatine Fortified Energy Bar

The following formulation for a black and white chocolate energy bar provides a product with 500 mg of calcium and 2 grams of creatine per 50 g using calcium creatine prepared as discussed herein.

Ingredients for Black & White Chocolate Bar
12% Ca creatine chelate
13% soy protein isolate
8% whey powder
6% 10 D.E. maltodextrin
11% crystalline fructose
10% sucrose
3% nonfat dry milk
13% corn syrup 42 D.E.
5% dark cocoa
4% partially hydrogenated soybean oil
2% honey
5% densified crisp rice
0.1% salt
0.5% lecithin
0.6% vitamin & mineral blend
0.4% vanilla flavor
0.4% natural flavor blend
6% water

The procedure for preparing the black and white energy bar is as follows: First, in a blend tank, a slurry of water, corn syrup, sucrose, fructose, soybean oil and honey is formed. The slurry is heated up to 120° F. and placed in a dough mixer where the other ingredients are added and mixed until homogenous. Next, flavors and crisp rice are added and mixed until dispersed. The resulting mass is then loaded into an extruder and extruded to a predetermined size. The extruded bars are then run under refrigerated air blast to cool. Once cooled, the bars are coated with white chocolate. The weight ratio of chocolate coating to extruded center is 1:2 (or 50 pounds of chocolate coating to 100 pounds of extruded center). Once tempered, the finished bar may be packaged.

Example 7

Preparation of Zinc Creatine

Zinc creatine chelate having a 1:1 ligand to metal molar ratio is prepared, first, by combining the following ingredients: 620.48 ml of water at 50 to 55° C.; 150.00 g of creatine monohydrate; 83.85 g of zinc oxide; 17.80 g of 85% o-phosphoric acid; and 106.26 g of citric acid. The reaction mixture is heated to about 50 to 55° C. and spray dried. The expected yield of the dried product is 335.32 g when adjustments are made to account for evaporation of the water formed from the acid base reaction with zinc oxide, waters of hydration associated with creatine monohydrate and 15% water associated with phosphoric acid. The assumption is made that 18.12 ml of water from the starting material is retained in the spray drying process.

Example 8

Zinc Creatine Fortified Sports Drink

This formulation for a sports drink will provide a product with 5 mg of zinc and 1.9 g of creatine per 8-fl oz. using zinc creatine as disclosed herein.

Ingredients for Fruit Punch Flavored Sports Drink
0.12% Zn creatine chelate
5% 42 D.E. corn syrup
0.85% creatine monohydrate
8% sucrose
0.5% citric acid
0.1% salt
0.5% fruit punch flavor
84.93% filtered water

A liquid drink is prepared as sugar, corn syrup, citric acid, salt, zinc monohydrate and zinc creatine is blended into water under good agitation. To this liquid, a fruit punch flavoring is added. The complete batch is heat treated to 150° F., allowed to cool to 40° F. and packaged.



While the invention has been described with reference to certain preferred embodiments, those skilled in the art will appreciate that various modifications, changes, omissions, and substitutions can be made without departing from the spirit of the invention. For example, the creatine chelates of the present invention may be used to fortify other foods and/or drinks such as weight loss bars, chewable tablets, etc. Further, creatine chelates having other chelated metals than those in Examples 1, 5 and 7 may be prepared by following similar procedures as would be apparent to those skilled in the art. It is intended, therefore, that the invention be limited only by the scope of the following claims.

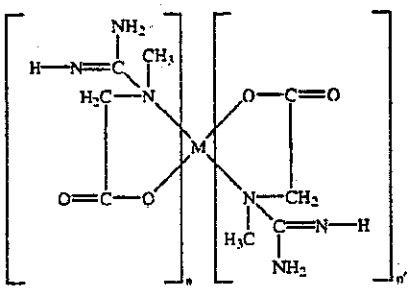
We claim:

1. A creatine chelate comprised of a creatine ligand bonded to a metal selected from the group consisting of Mg, Ca, Cu, Zn, Fe, Cr, Co, Mo, Se and Mn to form a chelate ring, and wherein said ligand to metal molar ratio is from 1:1 to 3:1.

2. A creatine chelate as in claim 1 wherein said creatine ligand is provided by a member selected from the group consisting of creatine, creatine salts, creatine esters, creatine amides, creatine hydrates and combinations thereof.

3. A creatine chelate as in claim 2 wherein said metal is provided by a member selected from the group consisting of ions, elemental, oxides, hydroxides, carbonates, bicarbonates, sulfates, nitrates, chlorides, phosphates, citrates, lactates, amino acid salts and combinations thereof.

4. A creatine chelate as in claim 1 wherein said creatine chelate is defined by the formula:



wherein M is a metal selected from the group consisting of Mg, Ca, Cu, Zn, Fe, Cr, Co, Mo, Se and Mn, and wherein n is 1 and n' is 0, 1, or 2.

5. A creatine chelate as in claim 4 wherein M is Mg.
6. A creatine chelate as in claim 5 wherein n' is 0.
7. A creatine chelate as in claim 5 wherein n' is 1.
8. A creatine chelate as in claim 4 wherein M is Ca.
9. A creatine chelate as in claim 8 wherein n' is 0.
10. A creatine chelate as in claim 4 wherein M is Zn.
11. A creatine chelate as in claim 10 wherein n' is 0.
12. A creatine chelate as in claim 4 wherein M is Cr.
13. A creatine chelate as in claim 12 wherein n' is 0.
14. A creatine chelate as in claim 12 wherein n' is 1.
15. A creatine chelate as in claim 12 wherein n' is 2.
16. A creatine chelate as in claim 4 wherein M is Mn.
17. A creatine chelate as in claim 16 wherein n' is 0.
18. A creatine chelate as in claim 4 wherein M is Fe.
19. A creatine chelate as in claim 18 wherein n' is 0.
20. A creatine chelate as in claim 18 wherein n' is 1.
21. A creatine chelate as in claim 18 wherein n' is 2.

22. A method of preparing a creatine chelate comprising reacting creatine with a metal selected from the group consisting of Mg, Ca, Cu, Zn, Fe, Cr, Co, Mo, Se and Mn in an aqueous solution, and wherein said creatine to metal molar ratio is from about 1:1 to 3:1.

23. A method according to claim 22 wherein said creatine is provided by the group consisting of creatine, creatine salts, creatine esters, creatine amides, creatine hydrates and combinations thereof.

24. A method according to claim 23 wherein said metal is provided by the group consisting of ions, elemental, oxides, hydroxides, carbonates, bicarbonates, sulfates, nitrates, chlorides, phosphates, citrates, lactates, amino acid salts and combinations thereof.

25. A method according to claim 24 wherein said aqueous solution is water or an acidified aqueous solution selected from the group consisting of citric, phosphoric, sulfuric, hydrochloric, aminobutyric, malic, acetic, tartaric, maleic, lactic and naturally occurring amino acids.

26. A method according to claim 22 wherein said metal is Mg.

27. A method according to claim 26 wherein said creatine to Mg molar ratio is 1:1.

28. A method according to claim 26 wherein said creatine to Mg molar ratio is 2:1.

29. A method according to claim 22 wherein said metal is Ca.

30. A method according to claim 29 wherein said creatine to Ca molar ratio is 1:1.

31. A method according to claim 22 wherein said metal is Zn.

32. A method according to claim 31 wherein said creatine to Zn molar ratio is 1:1.

33. A method according to claim 22 wherein said metal is Cr.

34. A method according to claim 33 wherein said creatine to Cr molar ratio is 1:1.

35. A method according to claim 33 wherein said creatine to Cr molar ratio is 2:1.

36. A method according to claim 33 wherein said creatine to Cr molar ratio is 3:1.

37. A method according to claim 22 wherein said metal is Mn.

38. A method according to claim 37 wherein said creatine to Mn molar ratio is 1:1.

39. A method according to claim 22 wherein said metal is Fe.

40. A method according to claim 39 wherein said creatine to Fe molar ratio is 1:1.

41. A method according to claim 39 wherein said creatine to Fe molar ratio is 2:1.

42. A method according to claim 39 wherein said creatine to Fe molar ratio is 3:1.

43. A method according to claim 26 wherein said Mg is provided by magnesium oxide.

44. A method according to claim 23 wherein said creatine is provided by creatine monohydrate.

45. A method according to claim 25 wherein said aqueous solution is citric acid.

46. A method according to claim 22 wherein subsequent to said admixing step, a pH adjuster is added selected from the group consisting of o-phosphoric acid, citric, malic, acetic, hydrochloric, tartaric, lactic, nitric, sulfuric and naturally occurring amino acids.

47. A method according to claim 46 wherein said pH adjuster is o-phosphoric acid.

48. A method according to claim 46 wherein said pH adjuster is added to reduce the pH from about 7.5–10 to about 7.

49. A method of administering a creatine chelate to a warm-blooded mammal comprising the steps of:

formulating an effective amount of said creatine chelate into a nutritional supplement suitable for oral consumption; and

administering said nutritional supplement containing said creatine chelate to a warm blooded mammal.

50. A method as in claim 49 wherein said nutritional supplement is selected from the group consisting of tablets, food bars, drinks and dry drink mixes.

51. A method as in claim 50 wherein said nutritional supplement is a chewable or non-chewable tablet.

52. A method as in claim 50 wherein said nutritional supplement is a food bar selected from the group consisting of energy bars, weight loss bars, snack bars, granola bars and combinations thereof.

53. A method as in claim 50 wherein said nutritional supplement is a drink selected from the group consisting of energy drinks, sports drinks, citrus drinks, fruit drinks, carbonated drinks and combinations thereof.

54. A method as in claim 50 wherein said nutritional supplement is a dry drink mix selected from the group consisting of fruit mix, citrus mix and combinations thereof.

* * * * *

# EXHIBIT 3

LAW OFFICES OF
RICHARD C. CONOVER
104 EAST MAIN
SUITE 404
P. O. BOX 1328
BOZEMAN, MONTANA 59771-1328
TELEPHONE (406) 587-4840
FACSIMILE (406) 587-4530

January 4, 2006

**CERTIFIED MAIL/RETURN**
**RECEIPT REQUESTED**

Nutrition Warehouse
P.O. Box 128
Wentziville, MO 63385

Re: Infringement of:
U.S. Patent No. 6,399,661
Our Docket No. 567.28

Dear Sir:

I am a patent attorney located in Bozeman, Montana, and I have been retained by All American Pharmaceutical & Natural Foods Corporation with regard to patent and trademark matters.

It has been brought to our attention that Nutrition Warehouse is marketing a product "Magnesium Creatine Chelate" which appears to be covered by United States Patent No. 6,399,661 which issued to my client on June 4, 2002. I am enclosing a copy of this patent for your review.

By making, using or selling this product without permission, you are violating my client's patent rights. In this regard, we demand that you immediately cease and desist from manufacturing or having made or selling any products embodying my client's patented invention. Further, we demand that you collect and turn over to my client the inventory of such products in your possession, custody or control, and that you identify all retail or distributor customers selling these infringing products and that you provide my client with a full accounting of your sales of such unauthorized goods.

We request that you advise us in writing within ten (10) days of your receipt of this letter that you have ceased selling your "Magnesium Creatine Chelate" product or other products embodying my client's patented invention. We further demand that you provide us with the information identified above. Upon your failure to comply, my client will immediately seek all remedies available under the patent statutes for infringement of a validly issued United States patent.

My client may be willing to discuss with you a license agreement regarding your manufacture and selling of these infringing products provided that a reasonable royalty is paid to my client for sale of products covered by this patent. Please call me if you have an interest in such an agreement.

Very truly yours,

Richard C. Conover

RCC/kh

Enclosures

cc: All American Pharmaceutical & Natural Foods Corporation (w/o enc.)

# EXHIBIT 4

**Custom Nutrition Warehouse**
**Omega Sports**

January 17, 2006

Richard C. Conover
104 East Main St
Suite 404
PO Box 1329
Bozeman, MT 59771

RE: Your Docket No. 567.28 / Magnesium Creatine Chelate

Mr. Conover:

I have received your letter indicating that you believe I have infringed on your client's patent rights regarding Magnesium Creatine Chelate.

Effective immediately, I have pulled the product from my site and have ceased all sales. I will further comply in the proper manner to resolve this situation as quickly and as friendly as possible.

However, I would like to speak with you at your earliest possible convienence regarding this case as I believe there is some confusion on your part as to which product is actually being sold on my site.

I look forward to speaking with you and getting this situation resolved in a timely manner. Please reference my contact information below.

Best regards,

Matt Palada

1951 Briarfield Drive
O'Fallon, MO 63366
Ph 636-578-2102 Fx: 636-561-3350
info@customnutritionwarehouse.com

01/19/2006 12:25 6366613358 MATT PALADA PAGE 04

# EXHIBIT 5

LAW OFFICES OF
RICHARD C. CONOVER
104 EAST MAIN
SUITE 404
P. O. BOX 1929
BOZEMAN, MONTANA 59771-1929
TELEPHONE (406) 587-4240
FACSIMILE (406) 587-4330

January 24, 2006

Controlled Labs Fax
(201) 735
0244

**CERTIFIED MAIL/RETURN RECEIPT REQUESTED**

Controlled Labs
1333A North Ave. #423
New Rochelle, NY 10804

Re: Infringement of:
U.S. Patent No. 6,399,661
Our Docket No. 567.29

Dear Sir:

I am a patent attorney located in Bozeman, Montana, and I have been retained by All American Pharmaceutical & Natural Foods Corporation with regard to patent and trademark matters.

It has been brought to our attention that Controlled Labs is marketing a product "Green Bulge" which appears to be covered by United States Patent No. 6,399,661 which issued to my client June 4, 2002. I am enclosing a copy of this patent for your review.

By making, using or selling this product without permission, you are violating my client's patent rights. In this regard, we demand that you immediately cease and desist from manufacturing or having made or selling any products embodying my client's patented invention. Further, we demand that you collect and turn over to my client the inventory of such products in your possession, custody or control, and that you identify all retail or distributor customers selling these infringing products and that you provide my client with a full accounting of your sales of such unauthorized goods.

We request that you advise us in writing within ten (10) days of your receipt of this letter that you have ceased selling your "Green Bulge" product or other products embodying my client's patented invention. We further demand that you provide us with the information identified above. Upon your failure to comply, my client will immediately seek all remedies available under the patent statutes for infringement of a validly issued United States patent.

This fax was received by GFI FAXmaker fax server. For more information, visit: http://www.gfi.com

My client may be willing to discuss with you a license agreement regarding your manufacture and selling of these infringing products provided that a reasonable royalty is paid to my client for sale of products covered by this patent. Please call me if you have an interest in such an agreement.

Very truly yours,

Richard C. Conover

RCC/kh

Enclosures

cc: All American Pharmaceutical & Natural Foods Corporation (w/o enc.)

This fax was received by GFI FAXmaker fax server. For more information, visit: http://www.gfi.com

# EXHIBIT 6

Albion
Advanced Nutrition

February 2, 2006

Richard C. Conover
104 East Main, Suite 404
P.O. Box 1329
Bozeman, Montana 59771-1329

Subject: Allegations that Users of Albion Magnesium Creatine Chelate Products Infringe U.S. Patent 6,399,661

Dear Mr. Conover:

I am General Counsel for Albion Laboratories, Inc. d.b.a. Albion Advanced Nutrition, and a registered patent attorney. I have received copies of two letters you have sent to companies that use Albion's Magnesium Creatine Chelate, complaining that such use is a violation of U.S. Patent 6,399,661 issued to your client All American Pharmaceuticals. I feel compelled to respond to these letters on behalf of Albion, due to its interest as the supplier of these companies and possibly others you may have notified but of whom we are not aware. Specifically, I hereby request that you cease your harassment of our customers based on these ill founded patent infringement claims.

I have reviewed your client's patent and our outside patent counsel has also reviewed it. We fail to see how any use of our product by our customers could infringe upon your client's patented invention. On the contrary, I observe in the list of references cited in your patent that Albion's U.S. Patent 6,114,379 titled "Bioavailable Chelates of Creatine and Essential Metals" is listed among them. This Albion patent, which predates your client's patent by nearly two years, is the patent upon which our products are based. The fact that you listed it, and the examiner considered it in evaluating the patentability of your client's invention, tends to show that the two patents have different and distinctly patentable subject matter. However, if you persist, I may be forced to take steps to invalidate your client's patent.

Very Truly Yours,

ALBION ADVANCED NUTRITION

Brent M. Burningham
General Counsel

cc: Max Motyka

101 North Main Street • Clearfield, Utah 84015 / P.O. Box 750 • Clearfield, Utah 84089
(801) 773-4631 • (800) 453-2406 • Fax (801) 773-4633 • www.albion-an.com • E-mail: info@albion-an.com

**SENDER: COMPLETE THIS SECTION**

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Richard C. Conover
104 East Main, Suite 404
P.O. Box 1329
Bozeman, MT 59771-1329

**COMPLETE THIS SECTION ON DELIVERY**

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) Richard C. Conover
C. Date of Delivery 2/14/06

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☑ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service) 7003 1010 0005 1691 1760

PS Form 3811, August 2001 Domestic Return Receipt 102595-02-M-103

**U.S. Postal Service™**
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| | |
|---|---|
| Postage | $ 0.39 |
| Certified Fee | 2.40 |
| Return Receipt Fee (Endorsement Required) | 1.85 |
| Restricted Delivery Fee (Endorsement Required) | |
| Total Postage & Fees | $ 4.64 |

Postmark Here

4.64
- .39
4.25

7003 1010 0005 1691 1760

Sent To: Richard Conover
Street, Apt. No.; or PO Box No. 104 East Main, Suite 404
City, State, ZIP+4 Bozeman MT 59771-1329

PS Form 3800, June 2002 See Reverse for Instructions

# EXHIBIT 7

LAW OFFICES OF
RICHARD C. CONOVER
104 EAST MAIN
SUITE 404
P. O. BOX 1329
BOZEMAN, MONTANA 59771-1329
TELEPHONE (406) 587-4240
FACSIMILE (406) 587-4330

RECEIVED 4/12/06

April 11, 2006

Mr. Brent M. Burningham
Albion Advanced Nutrition
101 North Main Street
Clearfield, Utah 84015

Re: Alleged infringement of:
U.S. Patent No. 6,399,661
Our Docket No. 567.30

Dear Mr. Burningham:

I have received your letter of February 2, 2006 wherein you stated your belief that the Albion Magnesium Creatine Chelate product does not infringe United States Patent No. 6,399,661 (the '661 Patent) owned by All American Pharmaceutical & Natural Foods Corporation.

We had previously sent cease and desist letters to Nutrition Warehouse of Winsfield, Missouri, who was selling a magnesium creatine chelate product purchased from Albion and also Controlled Labs of Somerset, New Jersey, who was selling a product under the trade name "Green Bulge", also purchased from Albion. We sent these letters to these two companies, because my client had performed a pH analysis of these products and found that the magnesium creatine chelate product sold by Nutrition Warehouse was 9.45 and the Green Bulge product sold by Controlled Labs was 8.0. If you read the claims of the '661 Patent relating to a buffered creatine product, it is clear that these two products come within the scope of these claims.

We understand that these two companies purchased the creatine product from Albion and if these two companies do infringe the claims of the '661 Patent, then Albion would also infringe.

My client had also conducted a pH analysis of an earlier Albion product manufactured under your United States Patent No. 6,114,379 (the '379 Patent). The pH of this product was below 7.0 and below the claimed range set forth in the '661 patent. See for example claim 48 of your '379 Patent. It is believed that Albion has changed the composition of the magnesium creatine chelate product, raising the pH to a level within the claims of the '661 Patent.

If Albion were to agree to return to their original formulation, we do not believe there would be infringement problems. However, if the formulation is not changed, it is believed that Albion does infringe the '661 Patent and we need to take steps to resolve this issue.

After you have had a chance to review this letter with personnel of your company, I would appreciate it if you would call me so that we may discuss how to amicably and reasonably resolve this issue. I know that you are well aware that if there is infringement of the '661 Patent that we must take steps to protect our patent. Similarly, I would assume that if others were infringing your '379 Patent, that you would take steps to stop such infringement.

I look forward to hearing from you.

Very truly yours,

Richard C. Conover

RCC/jh

cc: All American Pharmaceutical & Natural Food Corp.

# CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

**I. (a) PLAINTIFF(s)**
ALBION LABORATORIES, INC., dba, ALBION ADVANCED NUTRITION

**(b)** County Of Residence of First Listed Plaintiff: Salt Lake County
(EXCEPT ON U.S. PLAINTIFF CASES)

**(c)** Attorney's (Firm Name, Address, and Telephone Number)

Mark M. Bettilyon (4798)
Rick B. Hoggard (5088)
**RAY QUINNEY & NEBEKER**
36 South State Street
Post Office Box 45385
Salt Lake City, Utah 84145-0385
Tel: (801) 532-1500

**DEFENDANT(s)**
ALL AMERICAN PHARMACEUTICAL & NATURAL FOODS CORPORATION and JEFFREY GOLINI

FILED
U.S. DISTRICT COURT
2006 MAY -5 P 4:44
DISTRICT OF UTAH
BY: _____
DEPUTY CLERK

County Of Residence Of First Listed Defendant: _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)
unknown at this time

**II. BASIS OF JURISDICTION** (PLACE AN "X" IN ONE BOX ONLY)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2. U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place An "X" in One Box for Plaintiff and One Box for Defendant) (For Diversity Cases Only)

| | PTF | DEF | | PTF | DEF |
|---|---|---|---|---|---|
| Citizen of This State | ☐1 | ☐1 | Incorporated or Principal Place of Business in this State | ☒4 | ☐4 |
| Citizen of Another State | ☐2 | ☐2 | Incorporated and Principal Place of Business in Another State | ☐5 | ☒5 |
| Citizen or Subject of a Foreign Country | ☐3 | ☐3 | Foreign Nation | ☐6 | ☐6 |

**IV. NATURE OF SUIT** (PLACE AN "X" IN ONE BOX ONLY)

**CONTRACT**
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ **190 Other Contract**
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

**REAL PROPERTY**
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

**TORTS**

**PERSONAL INJURY**
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

**CIVIL RIGHTS**
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities – Employment
- ☐ 446 Amer. w/Disabilities – Other
- ☐ 440 Other Civil Rights

**PERSONAL INJURY**
- ☐ 362 Personal Injury -Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

**PERSONAL PROPERTY**
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

**PRISONER PETITIONS**
- ☐ 510 Motions to Vacate Sentence

**HABEAS CORPUS:**
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

**FORFEITURE/PENALTY**
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

**LABOR**
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

**BANKRUPTCY**
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

**PROPERTY RIGHTS**
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

**SOCIAL SECURITY**
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

**FEDERAL TAX SUITS**
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS – Third Party 26 USC 7609

**OTHER STATUTES**
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt
- ☐ 480 Consumer
- ☐ 490 Cable/Sat T
- ☐ 810 Selective S
- ☐ 850 Securities/C Exchange
- ☐ 875 Customer C 12 USC 341
- ☐ 890 Other Statut
- ☐ 891 Agricultural
- ☐ 892 Economic S
- ☐ 893 Environment
- ☐ 894 Energy Allo
- ☐ 895 Freedom of
- ☐ 900 Appeal of F Determinati Equal Acce
- ☐ 950 Constitution State Statut

**V. ORIGIN** (Place An "X" In One Box Only)

☒ 1 Original Proceeding | ☐ 2 Removed from State Court | ☐ 3 Remanded from Appellate Court | ☐ 4 Reinstated or Reopened | ☐ 5 Transferred from another district (specify) _____ | ☐ 6 Multidistrict Litigation | ☐ 7 Appeal to District Judge from Magistrate Judgment

Judge Ted Stewart
DECK TYPE: Civil
DATE STAMP: 05/05/2006 @ 16:44:53
CASE NUMBER: 1:06CV00056 TS

**VI. CAUSE OF ACTION** Cite The U.S. Civil Statute Under Which You Are Filing. **(Do Not Cite Jurisdictional Statutes Unless Diversity.)**

Brief Description Of Cause: Defendant All American Pharmaceutical & Natural Foods Corporation has wrongfully accused Albion and Albion's customers of infringing U.S. Patent No. 6,399,661 through the use of Albion's Creatine MagnaPower®. Albion seeks a declaratory judgment that is Creatine MagnaPower® does not infringe the '661 patent, that the '661 patent is invalid and unenforceable, money damages for the Defendant's tortious interference with Albion's existing and prospective economic relations with its customers and for commercial disparagement, and injunctive relief against future allegations of infringement.

**VII. REQUESTED IN COMPLAINT:** CHECK IF THIS IS A CLASS ACTION ☐ UNDER F.R.C.P. 23

**DEMAND** $100,000 plus

CHECK YES only if demanded in complaint:

**JURY DEMAND:** ☐ YES ☒ NO

**VIII. RELATED CASE(S) IF ANY** (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE: May 5, 2006 SIGNATURE OF ATTORNEY OF RECORD: R. B. Hoggard