

JUDGE ENGELMAYER

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

GEORGE D. PETITO, ANITA M. PETITO AND
CONNECTIVE LICENSING, LLC,

Plaintiffs, **13** Case No. **CV 8040**

v.

JURY TRIAL DEMANDED

PURITAN'S PRIDE, INC.,

Defendants.

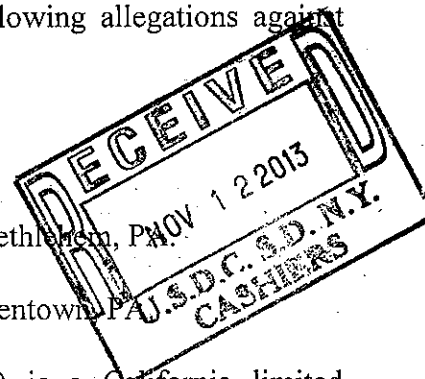
COMPLAINT FOR PATENT INFRINGEMENT

This is an action for patent infringement in which George D. Petito, Anita M. Petito and Connective Licensing, LLC (collectively "Plaintiffs") make the following allegations against Puritan's Pride, Inc. ("Puritan's" or "Defendant").

PARTIES

1. Plaintiff George D. Petito is an individual residing in Bethlehem, PA.
2. Plaintiff Anita M. Petito is an individual residing in Allentown, PA.
3. Plaintiff Connective Licensing, LLC ("Connective") is a California limited liability corporation with its principal place of business at 547 South Marengo Avenue, Pasadena, CA 91101.

4. On information and belief, Defendant Puritan's is a North Dakota corporation, with its principal place of business at 2100 Smithtown Ave, Ronkonkoma, NY 11779. On information and belief, Puritan's may be served through its registered agent Corporation Service Company at 80 State St, Albany, NY 12207.



JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. Venue is proper in this district under 28 U.S.C. §§ 1391(c) and 1400(b). On information and belief, Defendant resides and has transacted business in this district, and has committed and/or induced acts of patent infringement in this district.

COUNT I INFRINGEMENT OF U.S. PATENT NO. 6,645,948

7. Plaintiffs George D. Petito and Anita M. Petito (“the Petitos”) are the listed inventors and owners of United States Patent No. 6,645,948 (“the ‘948 Patent”) entitled “Nutritional Composition for the Treatment of Connective Tissue.” Plaintiff Connective has an exclusive license from the Petitos, which includes all rights to recover for past and future acts of infringement. The ‘948 Patent issued on November 11, 2003. A true and correct copy of the ‘948 Patent is attached as Exhibit A.

8. The Petitos own and operate The Hymed Group Corporation (See <http://hymed.com/>), which is a manufacturer and marketer of natural, innovative products that utilize collagen and glycosaminoglycan chemistry for the human and veterinary markets with applications in wound care, arthritis/tissue support, eye care, dental and cosmetics.

9. On information and belief, Puritan’s has been and now is infringing the ‘948 Patent in this judicial district, and elsewhere in the United States. Acts of infringement by Puritan’s include, without limitation, making, using, offering for sale, and/or selling within the United States, and/or importing into the United States, at least its supplement products

containing a glucosamine salt, chondroitin sulfate, collagen and sodium hyaluronate. Puritan's is thus liable for infringement of the '948 Patent under 35 U.S.C. § 271.

10. Puritan's infringing products include, but are not limited to its Hyaluronic Acid, Collagen, Glucosamine, Chondroitin & MSM Joint Soother® ("Accused Product") (See <http://www.puritan.com/msm-products-031/hyaluonic-joint-complex-001316>, a true and correct screenshot of which is attached as Exhibit B).

11. Puritan's infringes at least Claim 1 of the '948 Patent, by way of example only, and without limitation on Plaintiffs' assertion of infringement by Puritan's of other claims of the '948 Patent. Claim 1 of the '948 Patent reads as follows:

1. A nutritional composition for the treatment of connective tissue in mammals comprising: a therapeutically effective amount of a glucosamine salt, chondroitin sulfate, collagen and sodium hyaluronate.

On information and belief, Puritan's Accused Product contains each and every component of at least Claim 1 of the '948 Patent.

12. Puritan's Accused Product contains the first recited component, a glucosamine salt, as indicated on its product label. The exemplary product label attached hereto as Exhibit B lists 1500 mg of Glucosamine HCl among the ingredients.

13. Puritan's Accused Product also contains the next recited component chondroitin sulfate. The exemplary product label attached hereto as Exhibit B lists 1200 mg of Chondroitin Sulfate among the ingredients.

14. Puritan's Accused Product also contains the next recited component collagen. The exemplary product label attached hereto as Exhibit B lists 300 mg of BioCell Collagen II among the ingredients.

15. Puritan's Accused Product also contains the next recited component sodium hyaluronate. The exemplary product label attached hereto as Exhibit B lists 30 mg of Hyaluronic

Acid among the ingredients. On information and belief, the hyaluronic acid listed among the ingredients of the Accused Product is added as sodium hyaluronate.

16. As a result of Defendant's infringement of the '948 Patent, Plaintiffs have suffered monetary damages and are entitled to a money judgment in an amount adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by Defendant, together with interest and costs as fixed by the court, and Plaintiffs will continue to suffer damages in the future unless Defendant's infringing activities are enjoined by this Court.

17. In addition, Plaintiffs are entitled to the issuance of permanent injunction enjoining Defendant from continuing its infringement. Plaintiffs have suffered irreparable harm as Defendant's infringement has diluted the value of Plaintiffs' patent rights, and has taken business away from Plaintiffs, resulting in lost profits, and a loss of market share and good will, in amounts that cannot be compensated by payment of money. Moreover, allowing Defendant to continue in its infringement would encourage other would-be infringers to attempt to gain access, resulting in significant litigation expenses and uncertainty about the value of Plaintiffs' patent, which is the foundation of their business. In addition, a remedy in equity is warranted because, considering the balance of hardship as between Defendant and Plaintiffs, Defendant would suffer far less hardship from the issuance of an injunction than Plaintiffs would suffer if an injunction is not issued. Finally, the public interest would not be disserved by the issuance of a permanent injunction, as the public does not have any substantial interest in the Defendant's continued unauthorized infringement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter a judgment:

1. In favor of Plaintiffs that Defendant has infringed the '948 Patent;
2. Requiring Defendant to pay Plaintiffs their damages, costs, expenses, and prejudgment and post-judgment interest for Defendant's infringement of the '948 Patent as provided under 35 U.S.C. § 284;
3. Enjoining Defendant from further infringement;
4. Finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees; and
5. Granting Plaintiffs any and all other relief to which Plaintiffs may show themselves to be entitled.

DEMAND FOR JURY TRIAL

Plaintiff, under Rule 38 of the Federal Rules of Civil Procedure, requests a trial by jury of any issues so triable by right.

November 11, 2013

OF COUNSEL:

Darrell G. Dotson (TX Bar No. 24002010)
THE DOTSON LAW FIRM
222 N. Fredonia St.
Longview, Texas 75601
Telephone: (903) 212-3113
Facsimile: (903) 757-2387
darrell@dotsonlawfirm.com



Steven M. Hayes
HANLY CONROY BIERSTEIN SHERIDAN
FISHER & HAYES LLP
112 Madison Ave.
New York, NY 10016
Telephone: (212)784-6400
Facsimile: (212)213-5949
shays@hanlyconroy.com

*Counsel for Plaintiffs George D. Petito,
Anita M. Petito and Connective Licensing,
LLC*

“EXHIBIT A”



US006645948B2

(12) **United States Patent**
Petito et al.

(10) **Patent No.:** **US 6,645,948 B2**
 (45) **Date of Patent:** ***Nov. 11, 2003**

(54) **NUTRITIONAL COMPOSITION FOR THE TREATMENT OF CONNECTIVE TISSUE**

(76) Inventors: **George D. Petito**, 1890 Bucknell Dr., Bethlehem, PA (US) 18015; **Anita M. Petito**, 1890 Bucknell Dr., Bethlehem, PA (US) 18015

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

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/287,590**

(22) Filed: **Nov. 5, 2002**

(65) **Prior Publication Data**

US 2003/0069171 A1 Apr. 10, 2003

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/360,169, filed on Jul. 26, 1999, now Pat. No. 6,476,005, which is a continuation-in-part of application No. 09/046,710, filed on Mar. 24, 1998, now abandoned.

(51) **Int. Cl.**⁷ **A61K 31/7008**; A61K 38/16; A61K 35/32

(52) **U.S. Cl.** **514/62**; 514/2; 514/54; 424/449

(58) **Field of Search** 514/62, 2, 54; 424/449

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,950,100 A 3/1934 Crandall, Jr.
 4,006,224 A 2/1977 Prudden
 4,216,204 A 8/1980 Robertson

4,455,302 A 6/1984 Robertson
 4,837,024 A 6/1989 Michaeli
 5,141,928 A 8/1992 Goldman
 5,252,339 A 10/1993 Cristofori et al.
 5,364,845 A 11/1994 Henderson
 5,442,053 A 8/1995 della Valle et al.
 5,498,606 A 3/1996 Soll et al.
 5,587,363 A 12/1996 Henderson
 5,840,715 A 11/1998 Florio
 5,929,050 A 7/1999 Petito
 6,476,005 B1 * 11/2002 Petito et al. 514/62

FOREIGN PATENT DOCUMENTS

DE 3445324 12/1986
 FR 2035781 12/1970
 GB 896940 5/1962

OTHER PUBLICATIONS

Body Ammo Nutraceuticals, "Product Alert", Oct. 27, 1997.
 Richardson Labs, Inc., "Lookout (Non Foods Edition)", (Sep. 9, 1997).

* cited by examiner

Primary Examiner—James O. Wilson

Assistant Examiner—Devesh Khare

(74) *Attorney, Agent, or Firm*—Richard C. Litman

(57) **ABSTRACT**

A nutritional composition for the treatment of connective tissue in mammals which includes a glucosamine salt, chondroitin sulfate, collagen and sodium hyaluronate which synergistically act as a chondroprotective agent. The composition can further include a detoxifying agent, an anti-inflammatory agent or an analgesic to demonstrate additional therapeutic and physiologic properties. The nutritional composition acts as a chondro-protective agent which provides foundational support for the creation of new body tissue and cartilage growth in humans and animals.

19 Claims, No Drawings

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NUTRITIONAL COMPOSITION FOR THE TREATMENT OF CONNECTIVE TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 09/360,169 filed Jul. 26, 1999, now U.S. Pat. No. 6,476,005, which is a continuation-in-part of application Ser. No. 09/046,710 filed Mar. 24, 1998, and now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to therapeutic compositions which provide for the treatment of connective tissue in mammals and, more particularly to nutritional compositions capable of acting as chondroprotective agents, as well as exhibiting added pharmacological properties.

2. Description of the Related Art

The related art of interest discloses numerous pharmaceutical compositions and methods for the treatment of connective tissue in humans and animals. For example, U.S. Pat. No. 4,837,024 issued on Jun. 6, 1989, to Dov Michaeli describes topical compositions for improving wound healing comprising a suspension of particles of collagen and a glycosaminoglycan. The composition is taught to be useful for treating surface wounds by applying the composition to a gauze, bandage or the like.

U.S. Pat. No. 4,216,204 issued on Aug. 5, 1980, and U.S. Pat. No. 4,455,302 issued on Jun. 19, 1984, to Harry J. Robertson both disclose a medical protein hydrolysate containing an acetic acid extract of polypeptides and amino acids in the form of powder or a gel and produced from poultry feet. An aqueous solution can also be injected into a wound area such as burned animal regions. The composition is described as being useful for regrowing muscle, skin and nerve tissue.

U.S. Pat. No. 5,141,928 issued on Aug. 25, 1992, to Lawrence Goldman describes ophthalmic medications containing glycosaminoglycan polysulfates (GAGPS) or mucopolysaccharides having a molecular weight in the range of 5,000 to 20,000 Daltons combined with antibiotics for treating eye infections and antimicrobial agents such as pilocarpine or epinephrine for glaucoma. GAGPS include chondroitin sulfate and hyaluronic acid that contain hexosamines.

U.S. Pat. No. 5,840,715 issued on Nov. 24, 1998 to Vito Florio teaches a dietary regimen of nutritional supplements for relief of symptoms of arthritis. The dietary regimen comprises gamma linolenic acid (GLA), a mixture of eicosapentaenoic acid and docosahexaenoic acid (EPA) and a mixture of chondroitin sulfate, glucosamine sulfate and manganese aspartate.

U.S. Pat. No. 5,442,053 issued on Aug. 15, 1995, to Francesco della Valle et al. describes a pharmaceutical composition and method for treating ophthalmic and dermatological conditions, diseases of the oral and nasal cavities or diseases of the outer ear by administering a salt of hyaluronic acid (alkali, alkali metal, magnesium, aluminum or ammonium) combined with a pharmacologically active substance such as erythromycin. The hyaluronic acid fraction has an average molecular weight of 30,000 to 730,000. The topical medicament can be applied as solids or in solution.

U.K. Patent Application No. 896,940 published on May 23, 1962, to Chas. Pfizer & Co. describes a healing agent for

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wounds of the body surface containing glucosamine and/or N-acetylglucosamine and glucosamine phosphate in a saline solution

It has further been suggested by various prior art disclosures to use exclusively "nutraceuticals" or compositions containing only naturally-occurring components for treating connective tissue afflictions. For example, U.S. Pat. Nos. 5,364,845 issued on Nov. 15, 1994 and 5,587,363 issued Dec. 24, 1996, both to Robert W. Henderson describe therapeutic compositions administered in capsules form for the protection, treatment and repair of connective tissue in mammals. The compositions contain 250–3000 mg glucosamine hydrochloride or sulfate, 50–1000 mg chondroitin sulfate, and can additionally comprise 15–950 mg manganese ascorbate.

In other related art, Body Ammo Nutraceuticals in a "Product Alert" article, published Oct. 27, 1997, discloses capsules containing curcumin, hyaluronic acid, chondroitin sulfate and glucosamine. This product is stated to provide nutritional support for connective tissue. Further, Richardson Labs, Inc. in a "Lookout (Non Foods Edition)" abstract, published Sep. 9, 1997, discloses a product described as a food supplement containing hydrolyzed collagen, glucosamine and chondroitin sulfate that is described as being capable of reconstructing bone cartilage.

U.S. Pat. No. 5,929,050 issued on Jul. 27, 1999 to George D. Petito discloses a method and composition for treating open wounds by applying to the wound an effective amount of an aqueous solution of chondroitin sulfate, which may optionally include collagen, sodium hyaluronate and/or glucosamine hydrochloride.

While all the above references have been describes as being effective for their intended use, there remains a need in the art for a therapeutic composition which demonstrates enhanced effectiveness in the treatment of connective tissues, exhibit other improved beneficial properties, and provide even wider applications in the modes of administration. The present invention meets these needs.

SUMMARY OF THE INVENTION

Accordingly, it is a principal object of the present invention to provide therapeutic compositions that are not only capable of effectively treating connective tissues in mammals, but demonstrate other beneficial physiological properties as well.

It is another object of the present invention to provide nutritional compositions for the treatment of connective tissues in humans and animals which can be formulated into various pharmaceutical dosage forms for oral, topical and parenteral administration.

It a further object of the present invention to provide nutritional compositions including chondroprotective agents which provides foundational support for the creation of new body tissue and cartilage growth in humans and animals.

Yet another object of the present invention is to provide nutritional compositions for promoting the healing of wounds in humans and animals, while reducing the associated pain and inflammation.

These and other objects are accomplished in accordance with the present invention by providing nutritional compositions comprising a therapeutically effective amount of a glucosamine salt, chondroitin sulfate, collagen and sodium hyaluronate which synergistically act as a chondroprotective agent. The nutritional compositions of the present invention are capable of being formulated into powder, capsule or

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tablet form for oral ingestion. The present compositions can also be prepared as a gel, paste or cream for topical application, or in a solution or suitable pharmaceutical carrier for oral or parenteral administration. Preferably, a detoxifying agent, an anti-inflammatory agent and/or an analgesic is incorporated into the formulations to provide added beneficial therapeutic and physiologic properties to the present compositions.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides an improvement over the compositions set forth in the aforementioned application Ser. No. 09/360,169 filed Jul. 26, 1999, the disclosure of which is incorporated herein by reference in its entirety. Thus, the present invention is directed to a nutritional composition comprising a therapeutically effective amount of a chondroprotective agent, preferably in combination with at least one other physiologically beneficial agent. The present nutritional composition comprises about 1–30 mg/kg of a glucosamine salt, about 1–15 mg/kg of chondroitin sulfate, about 1–30 mg/kg of collagen and about 1–15 mg/kg of sodium hyaluronate which synergistically act as the chondroprotective agent, wherein the dosage of each solid component present in the composition is expressed herein in terms of mg per kg bodyweight of the human to be treated. The unit dosages of the present compositions for animals may be substantially larger.

While the present compositions effectively provide foundational support for the creation of new body tissue and cartilage growth, facilitate chondrocyte synthesis, protect and maintain healthy muscle and tissue, increase hyaluronic acid concentrations, and reduce inflammation, other beneficial physiological properties of the compositions can be significantly enhanced by the incorporation of additional chemical agents. Preferably, a detoxifying agent, an anti-inflammatory agent and/or an analgesic is added to the present nutritional compositions for these intended purposes.

The glucosamine salt component of the present compositions is preferably the hydrochloride salt, but other salts of glucosamine such as the sulfate, nitrate or iodide obtained from either synthetic, bovine or porcine sources are also suitable. The chondroitin sulfate component may include Type A (chondroitin-4-sulfate), Type B (chondroitin-5-sulfate), and/or Type C (chondroitin-6-sulfate), obtained through fermentation or extraction of bovine trachea, other bovine or porcine sources. A molecular weight range of 2,000–50,000 can be used, with a preferred range of 25,000–35,000. The sodium hyaluronate component of the present compositions are obtained from either synthetic, bovine or avian sources with a molecular weight range from about 50,000 to about 3,500,000 Daltons. Both the chondroitin sulfate and sodium hyaluronate components are glycosaminoglycans, commonly known as mucopolysaccharides.

All types of collagen, including native as well as hydrolyzed collagen, obtained from synthetic, avian, bovine or porcine sources would be suitable as the collagen component of the present compositions. The hydrolyzed collagen component can include hydrolyzed Type 1 collagen, preferably natural hydrolyzed collagen powder having a pH of 5.5–6.5, an ash content of 2.5% maximum, an isotonic point of 5.0–6.5. The hydrolyzed Type 1 collagen can have a molecular weight average up to 10,000 Daltons.

Other chemical agents which enhance the chondroprotective properties of the present nutritional compositions

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include a manganese salt and L-malic acid. A preferred salt is manganese ascorbate because it provides ascorbic acid for collagen synthesis, but other manganese salts such as the sulfate, nitrate, and gluconate can be used. The L-malic acid acts as a detoxifying agent by ridding the body of unwanted lactic acid, often found in connective tissue. Both the L-malic acid and manganese salt are preferably of U.S.P. food grade, and are present in the nutritional compositions of the present invention in dosages ranging from about 0.05 to about 8 mg/kg.

Pharmacological agents may be incorporated into the nutritional compositions of the present invention to significantly enhance the physiological properties of the compositions. The anti-inflammatory agents methyl sulfonyl methane (MSM) and cetyl myristoleate may be added to reduce an inflammatory response. The MSM may be added in amounts of about 0.5–40 mg/kg, and cetyl myristoleate in amounts of 1–105 mg/kg. The present compositions may also be combined with aspirin, preferably in the range of about 0.1–35 mg/kg, and other commercially available analgesics to reduce pain. In addition, the incorporation of such vitamins as Vitamin C (ascorbic acid) and Vitamin B₁₂ in the present compositions provides added benefits to soft and hard tissues.

The nutritional compositions of the present invention are formulated into powder, capsule or tablet form for oral ingestion. Also, the present compositions are capable of being combined with a suitable pharmaceutical carrier and prepared as a gel, paste or cream for topical application. Alternatively, the compositions can be formulated in a solution or suitable pharmaceutical diluent for oral as well as parenteral administration.

For parenteral administration, the present compositions are preferably dissolved in sterilized water and buffered with such buffering agents as citric acid or sodium chloride to improve shelf life. The pH of the present solutions can be adjusted with conventional agents. Also, preservatives such as ethylene-diaminetetraacetic acid (EDTA), benzyl alcohol, and benzalkonium chloride can be added.

The nutritional compositions of the present invention provide an enhanced chondroprotective effect by providing foundational support for the creation of new body tissue and cartilage growth in mammals. The collagen component acts as a transporter or carrier for the larger molecules of sodium hyaluronate and/or chondroitin sulfate by aiding in the absorption process of these large molecules, thereby increasing the bio-availability of these therapeutic effective components.

It is to be understood that the present invention is not limited to the embodiments described above, but encompasses any and all embodiments within the scope of the following claims.

We claim:

1. A nutritional composition for the treatment of connective tissue in mammals comprising: a therapeutically effective amount of a glucosamine salt, chondroitin sulfate, collagen and sodium hyaluronate.

2. The nutritional composition according to claim 1, wherein the glucosamine salt is selected from the group consisting of glucosamine hydrochloride, glucosamine sulfate, glucosamine nitrate and glucosamine iodide.

3. The nutritional composition according to claim 1, wherein the collagen is hydrolyzed collagen.

4. The nutritional composition according to claim 3, wherein the hydrolyzed collagen is hydrolyzed Type 1 collagen having a molecular weight average up to 10,000 Daltons.

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- 5. The nutritional composition according to claim 1, further comprising a manganese salt.
- 6. The nutritional composition according to claim 5, wherein the manganese salt is manganese ascorbate.
- 7. The nutritional composition according to claim 1, 5 further comprising a detoxifying agent.
- 8. The nutritional composition according to claim 7, wherein the detoxifying agent is L-malic acid.
- 9. The nutritional composition according to claim 1, further comprising an anti-inflammatory agent.
- 10. The nutritional composition according to claim 9, wherein the an anti-inflammatory agent is selected from the group consisting of methy sulfonyl methane and cetyl myristoleate.
- 11. The nutritional composition according to claim 1, 15 further comprising an analgesic.
- 12. The nutritional composition according to claim 11, wherein the analgesic is aspirin.
- 13. The nutritional composition according to claim 1, further comprising a vitamin selected from the group consisting of Vitamin C and Vitamin B₁₂.
- 14. The nutritional composition according to claim 1, 20 wherein the composition is formulated into a unit dosage form for oral administration.

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- 15. The nutritional composition according to claim 1, wherein the composition is combined with a suitable pharmaceutical carrier and prepared as a gel, paste or cream for topical application.
- 16. The nutritional composition according to claim 1, wherein the composition is formulated in a solution or suitable pharmaceutical diluent for oral or parenteral administration.
- 17. The nutritional composition according to claim 1, 10 wherein the composition comprises, based on mg/kg of bodyweight:
 - about 1–30 mg/kg of a glucosamine salt;
 - about 1–15 mg/kg of chondroitin sulfate;
 - about 1–30 mg/kg of collagen; and
 - about 1–15 mg/kg of sodium hyaluronate.
- 18. The nutritional composition according to claim 17, further including a manganese salt ranging from about 0.05 to about 8 mg/kg.
- 19. The nutritional composition according to claim 17, further including L-malic acid ranging from about 0.05 to about 8 mg/kg.

* * * * *

“EXHIBIT B”

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Supplement Facts

| | |
|--|-----------------------|
| Serving Size 3 Caplets | |
| Servings Per Container 20 | |
| Amount Per Serving | % Daily Value |
| Calories 10 | |
| Total | Carbohydrate 2 g 1%** |
| Sodium | 20 mg 1% |
| Glucosamine HCl | 1,500 mg (1.5 g) *** |
| Chondroitin Sulfate | 1,200 mg (1.2 g) *** |
| MSM (as Methylsulfonylmethane) | 1,500 mg (1.5 g) *** |
| BioCell Collagen II® (Standardized to contain 10% Hyaluronic Acid, 30 mg) | 300 mg *** |
| **Percent Daily Values are based on a 2,000 calorie diet. | |
| ***Daily Value not established | |

Directions: For adults, take three (3) caplets daily, preferably with a meal.

Other Ingredients: Vegetable Cellulose, Vegetable Stearic Acid. Contains <2% of: Silica, Vegetable Magnesium Stearate.

WARNING: If you are pregnant, nursing, taking any medications, including blood thinners, or have any medical condition, consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur. Keep out of reach of children. Store at room temperature. Do not use if seal under cap is broken or missing.



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- | | | | |
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‡Recent media coverage has focused on the product generically.

†Individual results may vary.

Puritan's Pride, 1233 Montauk Highway, PO Box 9001, Oakdale, NY 11769-9001

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