

JUDGE CASTIL

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

13 CV 8074

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

Plaintiffs,

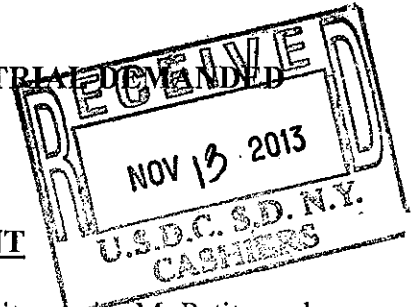
Case No.

v.

JURY TRIAL DEMAND

REXALL SUNDOWN, 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 Rexall Sundown, Inc. ("Rexall" 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 Rexall is a Florida corporation, with its principal place of business at 2100 Smithtown Avenue, Ronkonkoma, NY 11779. On information and belief, Rexall may be served at 2100 Smithtown Avenue, Ronkonkoma, NY 11779.

## 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, Rexall has been and now is infringing the ‘948 Patent in this judicial district, and elsewhere in the United States. Acts of infringement by Rexall 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 (“Accused Products”). Rexall is thus liable for infringement of the ‘948 Patent under 35 U.S.C. § 271.

10. Rexall’s Accused Products include, but are not limited to, the following products: Osteo Bi-Flex® with 5-Loxin® Advanced Joint Care MSM Formula (See [http://www.osteobiflex.com/Labels/products\\_044967\\_MSM.pdf](http://www.osteobiflex.com/Labels/products_044967_MSM.pdf), a true and correct screenshot of which is attached as Exhibit B); Osteo Bi-Flex® with 5-Loxin® Advanced Joint Care Triple Strength (See [http://www.osteobiflex.com/Labels/products\\_052272\\_triple.PDF](http://www.osteobiflex.com/Labels/products_052272_triple.PDF), a true and correct screenshot of which is attached as Exhibit C); Osteo Bi-Flex® with 5-Loxin® Advanced Joint & Energy (See [http://www.osteobiflex.com/Labels/products\\_052399\\_jointandenergy.pdf](http://www.osteobiflex.com/Labels/products_052399_jointandenergy.pdf), a true and correct screenshot of which is attached as Exhibit D); and Osteo Bi-Flex® w/ 5-Loxin® Advanced Joint Care Double Strength (See [http://www.osteobiflex.com/Labels/products\\_052526\\_Double.pdf](http://www.osteobiflex.com/Labels/products_052526_Double.pdf), a true and correct screenshot of which is attached as Exhibit E).

11. Rexall infringes at least Claim 1 of the ‘948 Patent, by way of example only, and without limitation on Plaintiffs’ assertion of infringement by Rexall 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, Rexall’s Accused Products contain each and every component of at least Claim 1 of the ‘948 Patent.

12. Each of Rexall’s Accused Products contains the first recited component, a glucosamine salt, as indicated on the respective product labels. The exemplary product labels attached hereto as Exhibits B-E each list 1500 mg of Glucosamine HCl among the ingredients.

13. Each of Rexall's Accused Products also contains the other three recited components chondroitin sulfate, collagen and hyaluronic acid, which are ingredients in Rexall's Joint Shield™ Proprietary Blend (*See Exhibits B-E*).

14. On information and belief, the hyaluronic acid listed among the ingredients of the labels of the Accused Products is added as sodium hyaluronate.

15. 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.

16. 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.

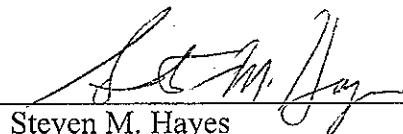
**DEMAND FOR JURY TRIAL**

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

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**“EXHIBIT A”**

(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.**<sup>7</sup> ..... **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**

US 6,645,948 B2

1

**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

2

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



US 6,645,948 B2

3

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

4

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 B<sub>12</sub> 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.

US 6,645,948 B2

5

- 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 B<sub>12</sub>.
- 14. The nutritional composition according to claim 1, 20 wherein the composition is formulated into a unit dosage form for oral administration.

6

- 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”**

**Osteo  
Bi-Flex**  
With 5-LOXIN<sup>®</sup> ADVANCED  
Joint Care<sup>®</sup>

**MSM Formula**  
GLUCOSAMINE CHONDROITIN  
PLUS JOINT SHIELD<sup>™</sup>

PROUD SPONSOR  
of the



Flexall Sundown, Inc., the maker of Osteo Bi-Flex<sup>®</sup>, is proud to support the Arthritis Foundation's efforts to help people take control of arthritis. For information about arthritis, contact the Foundation at 1-800-568-4045 or www.arthritis.org

#1 DOCTOR & PHARMACIST RECOMMENDED BRAND<sup>®</sup>

**DIRECTIONS FOR ADULT USE: TAKE FOUR (4) CAPLETS PER DAY PREFERABLY WITH FOOD.** As a reminder, discuss the supplements and medications you take with your health care providers.

Note: You have the option of taking four caplets together or spread throughout the day.

**Supplement Facts**

Serving Size 4 Caplets  
Servings Per Container 30

Amount Per Serving	%Daily Value
Vitamin C (as Ascorbic Acid)	60 mg 100%
Manganese (as Manganese Sulfate)	2 mg 100%
Sodium	40 mg 2%
Glucosamine HCl	1,500 mg (1.5 g) ***
Joint Shield <sup>™</sup> Proprietary Blend	1,998 mg ***
MSM/Chondroitin/5-LOXIN <sup>®</sup> Advanced Complex (Methylsulfonylmethane (MSM), Chondroitin Sulfate, Collagen (Hydrolyzed Gelatin), <i>Boswellia serrata</i> (resin), 5-LOXIN <sup>®</sup> Advanced AKBA <i>Boswellia serrata</i> Extract (resin), Hyaluronic Acid)	
Boron (as Sodium Tetraborate)	3 mg ***

\*\*\*Daily Value not established.

**Other Ingredients:** Cellulose (Plant Origin), Crospovidone. **Contains <2% of:** Caramel Color, Cellulose Coating, Silica, Titanium Dioxide Color, Vegetable Magnesium Stearate.

Contains shellfish (shrimp, crab, lobster, crayfish) ingredients.

Free of Gluten

5-LOXIN<sup>®</sup> ADVANCED is a registered trademark of P.L. Thomas - Lala Naira LLC and is used under license. International Patents Pending.

#1 DOCTOR & PHARMACIST RECOMMENDED BRAND<sup>®</sup>

Like calcium supplements can help your bones, Osteo Bi-Flex<sup>®</sup> can help your joints.\*

The natural aging process can add excessive stress on your joints. Annoying flare-ups can strike at any time. Add Osteo Bi-Flex<sup>®</sup> MSM Formula to your joint care regimen. It contains 1,500 mg of Glucosamine, a key building block of cartilage.\* With the addition of our Joint Shield<sup>™</sup> Proprietary Blend which contains Chondroitin, MSM and 5-LOXIN<sup>®</sup> Advanced, this revolutionary formula helps revitalize your joints to keep them jumpin'.\*

The only leading brand with 5-LOXIN<sup>®</sup> Advanced. Starts working to improve joint comfort within 7 days.\*<sup>1</sup>

5-LOXIN<sup>®</sup> Advanced contains high concentrations of AKBA, which is important for helping with joint flare-ups.\*



<sup>1</sup>Based on results of a GfK Healthcare 2011 survey among physicians who recommend a brand of Glucosamine and Chondroitin or Glucosamine supplements; and the results of a Pharmacy Times Survey among pharmacists who recommend a "bone/joint strengthener" dietary supplement, 2006-2012.

\*Based on two human studies with 5-LOXIN<sup>®</sup> Advanced where subjects rated their joint health over time, subjects' joint health improved within 7 days, and continued to improve throughout the duration of the studies.

\*\*52 week Nielsen ScanTrack data ending 8/25/12.

#1 DOCTOR & PHARMACIST RECOMMENDED BRAND<sup>®</sup>

Join the millions of people who choose Osteo Bi-Flex<sup>®</sup> for their joints every day, and have made it the #1 brand.\*\*

Osteo Bi-Flex<sup>®</sup> MSM Formula caplets are a potent combination of highly effective ingredients in Joint Care Science and the only leading brand containing Joint Shield<sup>™</sup> with 5-LOXIN<sup>®</sup> Advanced.

Osteo Bi-Flex<sup>®</sup> is manufactured under the highest standards for product quality, purity and potency.

To learn more about Osteo Bi-Flex<sup>®</sup> visit [WWW.OSTEOBIFLEX.COM](http://WWW.OSTEOBIFLEX.COM) or call us toll free at 1-888-VITAHHELP (848-2435).

See Bottom of Package for our **Ambassadors Club<sup>®</sup>** rewards points program.

KEEP OUT OF REACH OF CHILDREN. STORE AT ROOM TEMPERATURE AND AVOID EXCESSIVE HEAT. TAMPER RESISTANT: DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

CAUTION: If you are pregnant, nursing, taking any medications or have any medical condition, consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur. Not intended for use by persons under the age of 18.

MANUFACTURED BY: REXALL SUNDOWN, INC., BOCA RATON, FL 33487 USA

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



**Osteo  
Bi-Flex**  
With 5-LOXIN<sup>®</sup> ADVANCED  
Joint Care<sup>®</sup>

**MSM Formula**  
GLUCOSAMINE CHONDROITIN  
PLUS JOINT SHIELD<sup>™</sup>

HELP REVITALIZE YOUR JOINTS\*  
KEY BUILDING BLOCK OF  
CARTILAGE\*

4 PER DAY 120 COATED CAPLETS

DIETARY SUPPLEMENT

44967 07G B18617 LAB

60 POINTS **Osteo Bi-Flex** 60 POINTS

Ambassadors Club<sup>®</sup>

For more information visit [www.osteobiflex.com](http://www.osteobiflex.com)



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Part No. 22-67986

**“EXHIBIT C”**



#1 DOCTOR & PHARMACIST RECOMMENDED BRAND<sup>o</sup>

**DIRECTIONS FOR ADULT USE: TAKE TWO (2) CAPLETS PER DAY WITH FOOD.** As a reminder, discuss the supplements and medications you take with your health care providers.

**Note:** You have the option of taking two caplets together or spread throughout the day.

### Supplement Facts

Serving Size 2 Caplets  
Servings Per Container 40

Amount Per Serving		%Daily Value
Calories	10	
Total Carbohydrate	3 g	1%***
Vitamin C (as Ascorbic Acid)	60 mg	100%
Manganese (as Manganese Sulfate)	2 mg	100%
Sodium	40 mg	2%
Glucosamine HCl	1,500 mg (1.5 g)	****
Joint Shield™ Proprietary Blend Chondroitin/MSM Complex (Chondroitin Sulfate, Methylsulfonylmethane (MSM), Collagen (Hydrolyzed Gelatin), <i>Boswellia serrata</i> (resin), Hyaluronic Acid)	1,288 mg (1.28 g)	****
5-LOXIN® Advanced AKBA <i>Boswellia serrata</i> Extract (resin)		****
Boron (as Sodium Tetraborate)	3 mg	****

\*\*\*Percent Daily Values are based on a 2,000 calorie diet.  
\*\*\*\*Daily Value not established.

**Other Ingredients:** Crospovidone. Contains <2% of: Cellulose (Plant Origin), Cellulose Coating, Silica, Titanium Dioxide Color, Vegetable Magnesium Stearate.

Contains shellfish (shrimp, crab, lobster, crayfish) ingredients.

Free of Gluten

5-LOXIN® ADVANCED is a registered trademark of P.L. Thomas - Lala Nutr LLC and is used under license. International Patent Pending.

#1 DOCTOR & PHARMACIST RECOMMENDED BRAND<sup>o</sup>

**Like calcium supplements can help your bones, Osteo Bi-Flex® can help your joints.\***

The natural aging process can add excessive stress on your joints. Annoying flare-ups can strike at any time. Add Osteo Bi-Flex® Triple Strength to your joint care regimen. It contains 1,500 mg of Glucosamine, a key building block of cartilage.\* With the addition of our Joint Shield™ Proprietary Blend which contains Chondroitin, MSM and our 5-LOXIN® Advanced, this revolutionary formula helps revitalize your joints to keep them jumpin'.\*

**The only leading brand with 5-LOXIN® Advanced. Starts working to improve joint comfort within 7 days.\*<sup>1</sup>**

5-LOXIN® Advanced contains high concentrations of AKBA, which is important for helping with joint flare-ups.\*



<sup>o</sup>Based on results of a GfK Healthcare 2011 survey among physicians who recommend a brand of Glucosamine and Chondroitin or Glucosamine supplements; and the results of a Pharmacy Times Survey among pharmacists who recommend a "bone/joint strengthener" dietary supplement, 2006-2012.

<sup>1</sup>Based on two human studies with 5-LOXIN® Advanced where subjects rated their joint health over time, subjects' joint health improved within 7 days, and continued to improve throughout the duration of the studies.

\*52 week Nielsen ScanTrack data ending 8/25/12.

# Osteo Bi-Flex®

With 5-LOXIN® ADVANCED  
Joint Care®

**TRIPLE STRENGTH**  
GLUCOSAMINE CHONDROITIN  
PLUS JOINT SHIELD™

PROUD SPONSOR  
of the



Rexall Sundown, Inc. is proud to sponsor the Arthritis Foundation's efforts to help people take control of arthritis. For information about arthritis, contact the Foundation at 1-800-568-4045 or [www.arthritis.org](http://www.arthritis.org)

**NEW!** SMOOTH WHITE COATING  
SAME FORMULA

# Osteo Bi-Flex®

With 5-LOXIN® ADVANCED  
Joint Care®

**TRIPLE STRENGTH**  
GLUCOSAMINE CHONDROITIN  
PLUS JOINT SHIELD™

**HELPS REVITALIZE YOUR JOINTS\***  
**KEY BUILDING BLOCK OF  
CARTILAGE\***

**2 PER DAY 80 COATED CAPLETS**

DIETARY SUPPLEMENT

#1 DOCTOR & PHARMACIST RECOMMENDED BRAND<sup>o</sup>

**Join the millions of people who choose Osteo Bi-Flex® for their joints every day, and have made it the #1 brand.\*\***

Osteo Bi-Flex® Triple Strength caplets are a potent combination of highly effective ingredients in Joint Care Science and is the only leading brand containing Joint Shield™ with 5-LOXIN® Advanced.

Osteo Bi-Flex® is manufactured under the highest standards for product quality, purity and potency.

To learn more about Osteo Bi-Flex® visit [WWW.OSTEOBIFLEX.COM](http://WWW.OSTEOBIFLEX.COM) or call us toll free 1-888-VITAHHELP (848-2435)

See Bottom of Package for our **Ambassadors Club®** reward points program.

KEEP OUT OF REACH OF CHILDREN. STORE AT ROOM TEMPERATURE AND AVOID EXCESSIVE HEAT. TAMPER RESISTANT: DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

CAUTION: If you are pregnant, nursing, taking any medications or have any medical condition, consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur. Not intended for use by persons under the age of 18.

MANUFACTURED BY: REXALL SUNDOWN, INC., BOCA RATON, FL 33487 USA

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



Part No. 22-52272

52272 00B B52202 AAC

40 POINTS **Osteo Bi-Flex** 40 POINTS

Ambassadors Club®

For more information visit [www.osteobiflex.com](http://www.osteobiflex.com)



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**“EXHIBIT D”**

#1 DOCTOR & PHARMACIST RECOMMENDED BRAND<sup>o</sup>

**DIRECTIONS FOR ADULT USE: TAKE TWO (2) CAPLETS PER DAY PREFERABLY WITH FOOD.** As a reminder, discuss the supplements and medications you take with your health care providers.

### Supplement Facts

Serving Size 2 Caplets  
Servings Per Container 40

Amount Per Serving		%Daily Value
Calories	10	
Total Carbohydrate	2 g	1%***
Dietary Fiber	<1 g	1%***
Vitamin C (as Ascorbic Acid)	60 mg	100%
Vitamin D (as D3 Cholecalciferol)	200 IU	50%
Thiamin (Vitamin B-1) (as Thiamin Mononitrate)	1 mg	67%
Riboflavin (Vitamin B-2)	1 mg	59%
Vitamin B-6 (as Pyridoxine Hydrochloride)	2 mg	100%
Vitamin B-12 (as Cyanocobalamin)	25 mcg	417%
Manganese (as Manganese Sulfate)	2 mg	100%
Sodium	40 mg	2%
Glucosamine HCl	1,500 mg (1.5 g)	****
Joint Shield™ Proprietary Blend	1,104 mg (1.1 g)	****
Energy Blend		****
(Chondroitin Sulfate, Collagen (Hydrolyzed Gelatin), Methylsulfonylmethane (MSM), Citrus Bioflavonoids ( <i>Citrus limon</i> ) (fruit), Panax Ginseng Extract (root), Green Tea Extract ( <i>Camellia sinensis</i> ) (leaf), White Tea ( <i>Camellia sinensis</i> ) (leaf), Eleuthero ( <i>Eleutherococcus senticosus</i> ) (root), <i>Boswellia serrata</i> (resin), Hyaluronic Acid)		
5-LOXIN® Advanced AKBA		****
<i>Boswellia serrata</i> Extract (resin)		
Choline Bitartrate	50 mg	****
Inositol	50 mg	****
Boron (as Sodium Tetraborate)	3 mg	****

\*\*\*Percent Daily Values are based on a 2,000 calorie diet.  
\*\*\*\*Daily Value not established.

**Other Ingredients:** Cellulose (Plant Origin), Crospovidone. **Contains <2% of:** Cellulose Coating, Silica, Titanium Dioxide Color, Vegetable Magnesium Stearate.

Contains shellfish (shrimp, crab, lobster, crayfish) ingredients.

**Free of Gluten**

5-LOXIN® ADVANCED is a registered trademark of P.L. Thomas - Labo Nitro LLC and is used under license. International Patents Pending.

#1 DOCTOR & PHARMACIST RECOMMENDED BRAND<sup>o</sup>

Like calcium supplements can help your bones, Osteo Bi-Flex® can help your joints.\*

The natural aging process can add excessive stress on your joints. Annoying flare-ups can strike at any time. Add Osteo Bi-Flex® Joint & Energy to your joint care regimen. It contains 1,500 mg of Glucosamine, a key building block of cartilage.\* With the addition of our Joint Shield™ Proprietary Blend, which contains Chondroitin, MSM and 5-LOXIN® Advanced, this revolutionary Energy Formula helps support energy metabolism and revitalize your joints to keep them jumpin'.\*

The only leading brand with 5-LOXIN® Advanced. Starts working to improve joint comfort within 7 days.\*1



<sup>o</sup>Based on the results of a GfK Healthcare 2011 survey among physicians who recommend a brand of Glucosamine and Chondroitin or Glucosamine supplements; and the result of a Pharmacy Times Survey among pharmacists who recommend a "bone/joint strengthener" dietary supplement, 2006-2012.

<sup>1</sup>Based on two human studies with 5-LOXIN® Advanced where subjects rated their joint health over time, subjects' joint health improved within 7 days, and continued to improve throughout the duration of the studies.

<sup>o</sup>\*52 week Nielsen ScanTrack data ending 8/25/12.

# Osteo Bi-Flex®

With 5-LOXIN® ADVANCED

## JOINT & ENERGY

GLUCOSAMINE CHONDROITIN PLUS JOINT SHIELD™

PROUD SPONSOR of the



Rexall Sundown, Inc., the maker of Osteo Bi-Flex®, is proud to support the Arthritis Foundation's efforts to help people take control of arthritis. For information about arthritis, contact the Foundation at 1-800-568-4045 or www.arthritis.org

**NEW!** SMOOTH WHITE COATING  
SAME FORMULA

# Osteo Bi-Flex®

With 5-LOXIN® ADVANCED

## JOINT & ENERGY

GLUCOSAMINE CHONDROITIN PLUS JOINT SHIELD™

### SUPPORT ENERGY METABOLISM\*

HELPS REVITALIZE YOUR JOINTS\*  
KEY BUILDING BLOCK OF  
CARTILAGE\*

2 PER DAY 80 COATED CAPLETS

DIETARY SUPPLEMENT

#1 DOCTOR & PHARMACIST RECOMMENDED BRAND<sup>o</sup>

Join the millions of people who choose Osteo Bi-Flex® for their joints every day, and have made it the #1 brand.\*\*

Osteo Bi-Flex® Joint & Energy caplets are a potent combination of highly effective ingredients in Joint Care Science and is the only leading brand containing Joint Shield™ with 5-LOXIN® Advanced.

Osteo Bi-Flex® is manufactured under the highest standards for product quality, purity and potency.

To learn more about Osteo Bi-Flex® visit [WWW.OSTEOBIFLEX.COM](http://WWW.OSTEOBIFLEX.COM) or call us toll free 1-888-VITAHHELP (848-2435).

See Bottom of Package for our **Ambassadors Club®** reward points program.

KEEP OUT OF REACH OF CHILDREN. STORE AT ROOM TEMPERATURE AND AVOID EXCESSIVE HEAT. TAMPER RESISTANT: DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

**CAUTION:** Not intended for use by pregnant or nursing women. If you are taking any medications or have any medical condition, consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur. Not intended for use by persons under the age of 18.

MANUFACTURED BY: REXALL SUNDOWN, INC., BOCA RATON, FL 33487 USA

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Proud sponsor of the  
**ARTHRITIS FOUNDATION®**

52399 00A B52399 MAB

40 POINTS **Osteo Bi-Flex®** 40 POINTS

Ambassadors Club®  
For more information visit  
[www.osteobiflex.com](http://www.osteobiflex.com)



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Part No. 22-52399



**“EXHIBIT E”**

# Osteo Bi-Flex®

With 5-LOXIN® ADVANCED  
Joint Care™

**DOUBLE STRENGTH**   
GLUCOSAMINE CHONDROITIN  
PLUS JOINT SHIELD™

PROUD SPONSOR  
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Rexall Sundown, Inc., the maker of Osteo Bi-Flex®, is proud to support the Arthritis Foundation's efforts to help people take control of arthritis. For information about arthritis, contact the Foundation at 1-800-568-4045 or www.arthritis.org

**#1 DOCTOR & PHARMACIST RECOMMENDED BRAND®**

**DIRECTIONS FOR ADULT USE: TAKE THREE (3) CAPLETS PER DAY PREFERABLY WITH FOOD.** As a reminder, discuss the supplements and medications you take with your health care providers.

**Note:** You have the option of taking three caplets together or spread throughout the day.

### Supplement Facts

Serving Size 3 Caplets  
Servings Per Container 36

Amount Per Serving	%Daily Value
Calories	10
Total Carbohydrate	3 g 1%***
Vitamin C (as Ascorbic Acid)	60 mg 100%
Manganese (as Manganese Sulfate)	2 mg 100%
Sodium	45 mg 2%
Glucosamine HCl	1,500 mg (1.5 g) ****
Joint Shield™ Proprietary Blend	1,288 mg (1.28 g) ****
Chondroitin/MSM Complex (Chondroitin Sulfate, Methylsulfonylmethane (MSM), Collagen (Hydrolyzed Gelatin), <i>Boswellia serrata</i> (resin), Hyaluronic Acid)	
5-LOXIN® Advanced AKBA <i>Boswellia serrata</i> Extract (resin)	
Boron (as Sodium Tetraborate)	3 mg ****

\*\*\*Percent Daily Values are based on a 2,000 calorie diet.  
\*\*\*\*Daily Value not established.

**Other Ingredients:** Crospovidone. Contains <2% of: Cellulose (Plant Origin), Cellulose Coating, Silica, Titanium Dioxide Color, Vegetable Magnesium Stearate.

Contains shellfish (shrimp, crab, lobster, crayfish) ingredients.

**Free of Gluten**

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**#1 DOCTOR & PHARMACIST RECOMMENDED BRAND®**

**Like calcium supplements can help your bones, Osteo Bi-Flex® can help your joints.\***

The natural aging process can add excessive stress on your joints. Annoying flare-ups can strike at any time. Add Osteo Bi-Flex® Double Strength to your joint care regimen. It contains 1,500 mg of Glucosamine, a key building block of cartilage.\* With the addition of our Joint Shield™ Proprietary Blend, which contains Chondroitin, MSM and 5-LOXIN® Advanced, this revolutionary formula helps revitalize your joints to keep them jumpin'.\*

**The only leading brand with 5-LOXIN® Advanced. Starts working to improve joint comfort within 7 days.\*1**



\*Based on results of a GIK Healthcare 2011 survey among physicians who recommend a brand of Glucosamine and Chondroitin or Glucosamine supplements; and the results of a Pharmacy Times Survey among pharmacists who recommend a "bone/joint strengthener" dietary supplement, 2006-2012.

\*Based on two human studies with 5-LOXIN® Advanced where subjects rated their joint health over time, subjects' joint health improved within 7 days, and continued to improve throughout the duration of the studies.

\*\*52 week Nielsen ScanTrack data ending 8/25/12

**NEW! SMOOTH WHITE COATING**  
SAME FORMULA

# Osteo Bi-Flex®

With 5-LOXIN® ADVANCED  
Joint Care™

**DOUBLE STRENGTH**   
GLUCOSAMINE CHONDROITIN  
PLUS JOINT SHIELD™

**HELPS REVITALIZE YOUR JOINTS\***  
**KEY BUILDING BLOCK OF CARTILAGE\***

**3 PER DAY** **110 COATED CAPLETS**  
DIETARY SUPPLEMENT

**#1 DOCTOR & PHARMACIST RECOMMENDED BRAND®**

**Join the millions of people who choose Osteo Bi-Flex® for their joints every day, and have made it the #1 brand.\*\***

Osteo Bi-Flex® Double Strength caplets are a potent combination of highly effective ingredients in Joint Care Science and the only leading brand containing Joint Shield™ with 5-LOXIN® Advanced.

Osteo Bi-Flex® is manufactured under the highest standards for product quality, purity and potency.

To learn more about Osteo Bi-Flex® visit [WWW.OSTEOBIFLEX.COM](http://WWW.OSTEOBIFLEX.COM) or call us toll free 1-888-VITAHELP (848-2435).

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MANUFACTURED BY: REXALL SUNDOWN, INC., BOCA RATON, FL 33487 USA

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**ARTHRITIS FOUNDATION®**

52526 00A B52514 LAB

40 POINTS **Osteo Bi-Flex** 40 POINTS

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