

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
22 July 2010 (22.07.2010)

(10) International Publication Number
WO 2010/083409 A1

PCT

(51) International Patent Classification:

A23K 1/16 (2006.01) A23L 1/29 (2006.01)
A23K 1/18 (2006.01) A61P 3/04 (2006.01)

(21) International Application Number:

PCT/US2010/021189

(22) International Filing Date:

15 January 2010 (15.01.2010)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/145,125 16 January 2009 (16.01.2009) US
61/224,249 9 July 2009 (09.07.2009) US

(71) Applicant (for all designated States except US): **HILL'S PET NUTRITION, INC.** [US/US]; 400 Southwest 8th Avenue, Topeka, Kansas 66603 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **YAMKA, Ryan Michael** [US/US]; 1823 NW 49th Street, Topeka, Kansas 66618 (US). **FRANTZ, Nolan Zebulon** [US/US]; 3424 NW Fredith Road, Topeka, Kansas 66618 (US). **ZICKER, Steven C.** [US/US]; 3017 Oxford Rd., Lawrence, Kansas 66049 (US).

(74) Agent: **MCGARRAH, Shannon**; Colgate-Palmolive Company, 909 River Road, Piscataway, New Jersey 08855 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: COMPANION ANIMAL COMPOSITIONS INCLUDING PYRUVIC ACID AND SALTS THEREOF AND METHODS OF USE THEREOF

(57) Abstract: The invention encompasses pet food compositions and methods for the treatment and/or prevention of diseases or disorders in companion animals, for example, for the treatment or obesity, including administering a pet food composition including pyruvic acid or a salt thereof to a companion animal, or lipoic acid or salt thereof and pyruvic acid or a salt thereof to a companion animal. The invention encompasses pet food compositions and methods for managing weight including administering a pet food composition including pyruvic acid or a salt thereof, or lipoic acid or a salt thereof and pyruvic acid or a salt thereof to a companion animal to a companion animal.



WO 2010/083409 A1

**COMPANION ANIMAL COMPOSITIONS INCLUDING
PYRUVIC ACID AND SALTS THEREOF
AND METHODS OF USE THEREOF**

BACKGROUND OF THE INVENTION

[001] An important indicator of animal health is the body composition of the animal. An unhealthy diet and/or an unhealthy lifestyle can result in the animal having an unhealthy proportion of body fat, particularly in relation to lean muscle in the body. It is thought that a body fat amount in excess of 30% by weight indicates that the animal is unhealthy, particularly if the amount of body fat is in excess of 35% by weight.

[002] The invention encompasses pet food compositions for companion animals, which have increased therapeutic and prophylactic efficacy over currently marketed companion food products.

SUMMARY OF THE INVENTION

[003] The inventors have developed food compositions and methods of using the compositions for treating or preventing disorders in animals.

[004] Accordingly, the invention encompasses companion pet food compositions meeting ordinary nutritional requirements of a pet and including an effective amount of pyruvic acid or a salt thereof, or effective amounts of lipoic acid or a salt thereof and pyruvic acid or a salt thereof.

[005] In all of these methods, it is desirable to administer the antioxidant or mixture thereof in the diet of the animal.

[006] Another embodiment encompasses methods for maintaining or promoting a healthy body composition, for example, loss of weight or body fat, increased percentage of lean muscle mass in a companion animal, which includes feeding the animal a composition including pyruvic acid or a salt thereof, or lipoic acid or a salt thereof and pyruvic acid or a salt thereof in an amount effective to promote or maintain the healthy body composition.

DETAILED DESCRIPTION OF THE INVENTION

General Description

[007] The invention generally encompasses compositions comprising pyruvic acid or a salt thereof, or lipoic acid or a salt thereof and pyruvic acid or a salt thereof.

[008] In certain embodiments, the pyruvic acid or a salt thereof is present in the composition in an amount of 5 ppm to 20000 ppm.

[0009] In certain embodiments, the pyruvic acid or a salt thereof is present in the composition in an amount of 10 ppm to 10000 ppm.

[0010] In certain embodiments, the pyruvic acid or a salt thereof is present in the composition in an amount of 50 ppm to 5000 ppm.

[0011] In certain embodiments, the pyruvic acid or a salt thereof is present in the composition in an amount of 100 ppm to 2500 ppm.

[0012] In certain embodiments, the lipoic acid or a salt thereof is present in the composition in an amount of 5 ppm to 5000 ppm.

[0013] In certain embodiments, the lipoic acid or a salt thereof is present in the composition in an amount of 10 ppm to 4000 ppm.

[0014] In certain embodiments, the lipoic acid or a salt thereof is present in the composition in an amount of 50 ppm to 3000 ppm.

[0015] In certain embodiments, the lipoic acid or a salt thereof is present in the composition in an amount of 100 ppm to 2000 ppm.

[0016] In certain embodiments, the lipoic acid or a salt thereof is present in the composition in an amount of 500 ppm to 1000 ppm.

[0017] In certain embodiments, the composition further comprises a protein, fat, carbohydrate, fiber, and combinations thereof.

[0018] In certain embodiments, the composition is a dog food.

[0019] In certain embodiments, the composition is a cat food.

[0020] In certain embodiments, the composition is a food, a nutritional diet, a supplement, an animal treat, or a toy.

[0021] In certain embodiments, the composition is in the form of a moist food.

[0022] In certain embodiments, the composition is in the form of a dry food.

[0023] In another embodiment, the invention encompasses methods for managing weight in a companion animal, which comprises administering to the companion animal a composition comprising an effective amount of pyruvic acid or a salt thereof, or effective amounts of lipoic acid or a salt thereof and pyruvic acid or a salt thereof.

[0024] In certain embodiments, the administration is oral feeding.

[0025] Another embodiment of the invention encompasses methods for maintaining or promoting a healthy body composition in a companion animal, which includes feeding the animal a composition of the invention, which includes an effective amount of pyruvic acid or a salt thereof, or effective amounts of lipoic acid or a salt thereof and pyruvic acid or a salt thereof.

[0026] The term “companion animal” used in the present invention includes any non-human animal suitable for being kept as a pet by humans including a dog, a cat, and a rodent. All embodiments of the invention are preferably for the treatment of cats and/or dogs.

[0027] The term “dog” includes those dogs, which are companion animals such as *Canis familiaris*, working dogs and the like. The term dog is synonymous with the term canine.

[0028] The term “cat” includes those cats, which are, companion animals known as domestic cats or house cats.

[0029] The term “rodent” includes, but is not limited to, hamsters, mice, rats, guinea pigs, gerbils, rabbits, hedge hogs, ferrets, chinchillas etc.

[0030] All percentages expressed herein are by weight of the composition on dry matter basis unless specifically stated otherwise.

Compositions of the Invention

[0031] One embodiment of the invention encompasses compositions for companion animals including pyruvic acid or a salt thereof, or lipoic acid or a salt thereof and pyruvic acid or a salt thereof.

[0032] As used herein, the term “lipoic acid or a salt thereof” includes, but is not limited to, for example, alpha-lipoic acid, a racemic mixture of lipoic acids, a lipoate salt, ester, amide or derivative thereof, for example as described in U.S. patent number 5,621,117. In various embodiments, the lipoic acid can be administered in a composition comprising a wet or dry food composition, which may be in the form of a moist food, dry food, supplement or treat. The lipoic acid may be incorporated therein or on the surface of any food composition, such as, by spraying or precipitation thereon or may be added to the diet by way of snack, supplement, treat or in the liquid portion of the diet such as water or another fluid. The lipoic acid may be administered as a powder, solid or as a liquid including a gel. An important aspect is that the animal be provided an effective amount of the lipoic acid to provide a positive effect.

Typically, the source of lipoic acid is present in the composition in an amount of up to an amount which remains non-toxic to the animal. Typical maximum quantities can vary from 10 to 5000 ppm. In certain embodiments, the range is from 100 ppm to 2500 ppm.

[0033] As used herein, the term “pyruvic acid or a salt thereof” includes, but is not limited to, for example, pyruvic acid or carboxylate anion of pyruvic acid known as pyruvate. In various embodiments, the pyruvic acid or a salt thereof can be administered in a composition comprising a wet or dry food composition, which may be in the form of a moist food, dry food, supplement or treat. The pyruvic acid or a salt thereof may be incorporated therein or on the

surface of any food composition, such as, by spraying or precipitation thereon or may be added to the diet by way of snack, supplement, treat or in the liquid portion of the diet such as water or another fluid. The pyruvic acid or a salt thereof may be administered as a powder, solid or as a liquid including a gel. An important aspect is that the animal be provided an effective amount of the pyruvic acid or a salt thereof to provide a positive effect. Typically, the source of pyruvic acid or a salt thereof is present in the composition in an amount of up to an amount, which remains non-toxic to the animal. Typical maximum quantities can vary from 10 to 10000 ppm. In certain embodiments, the range is from 100 ppm to 5000 ppm.

[0034] As used herein, the term "salt" or "salt thereof" refers to acidic groups that may be present in compounds used in the present compositions. Lipoic acid and pyruvic acid are acidic in nature and are capable of forming base salts with various pharmacologically acceptable cations. Examples of such salts include alkali metal or alkaline earth metal salts and, particularly, calcium, magnesium, sodium, lithium, zinc, potassium, and iron salts.

[0035] In various embodiments, a food composition comprising lipoic acid provides a substantially nutritionally complete diet for the intended recipient animal. A "nutritionally complete diet" is a diet that includes sufficient nutrients for maintenance of normal health of a healthy animal on the diet.

[0036] The quantity of lipoic acid can vary from 5 ppm to 5000 ppm, 10 ppm to 4000 ppm, 50 ppm to 3000 ppm, 100 ppm to 2000 ppm, 500 ppm to 1000 ppm. In various embodiments, the range of lipoic acid that can be administered dogs is 150 ppm to 4500 ppm. In various embodiments, the range of lipoic acid that can be administered cats is 65 ppm to 2600 ppm. In certain illustrative embodiments, quantities can vary from 5 ppm to an amount which remains non-toxic to the pet. In other embodiments, a range is from 100 ppm to 200 ppm.

[0037] The compositions of the invention include pyruvic acid or salt thereof in an amount effective to treat or prevent a disorder in a companion animal. Generally, the amount effective in the composition includes a source of pyruvic acid or salt thereof in an amount of from 5 ppm to 20000 ppm, 10 ppm to 10000 ppm, 50 ppm to 5000 ppm, 100 ppm to 3000 ppm. In certain embodiments, the pyruvic acid or salt thereof is in an amount of 100 to 3000 ppm, and in other embodiments, the pyruvic acid or salt thereof is in an amount of approximately 2000 ppm.

[0038] The combination of lipoic acid or salt thereof and pyruvic acid or salt thereof is present at a concentration that is not deleterious to the intended animal's health. Thus, for example, the lipoic acid or salt thereof is present at a concentration that does not cause undesirable or toxic effects.

[0039] The invention is based upon the discovery that adding a combination of lipoic acid or salt thereof and pyruvic acid or salt thereof to a composition for consumption by a companion animal provides treatment for obesity. Adding a combination of lipoic acid or salt thereof and pyruvic acid or salt thereof to a composition for consumption also decreases body fat and increases lean muscle mass.

[0040] The composition can be a liquid or a solid food. When the composition is a liquid, the lipoic acid or salt thereof and pyruvic acid or salt thereof can be admixed with other components. Where the composition is solid, the lipoic acid or salt thereof and pyruvic acid or salt thereof may be coated on the composition, incorporated into the composition, or both.

[0041] In various embodiments, the lipoic acid or salt thereof and pyruvic acid or salt thereof may be added to the animal's food. In various embodiments, the lipoic acid or salt thereof and pyruvic acid or salt thereof may be added to the animal's food by a compounder or manufacturer at a site or by an animal's caregiver prior to feeding the animal. In various embodiments, the lipoic acid or salt thereof and pyruvic acid or salt thereof may be added during the processing of an animal's food, such as during and/or after mixing of other components of the composition that is then packaged and made available to consumers. Such processing may include extrusion, canning, baking, and the like or any other method or process of producing pet foods that is known in the art. In various embodiments, the lipoic acid or salt thereof and pyruvic acid or salt thereof may be contributed by a natural source like an animal or plant component, or the lipoic acid or salt thereof and pyruvic acid or salt thereof may be contributed by a synthetically derived source, or the lipoic acid or salt thereof and pyruvic acid or salt thereof may be contributed by a mixture of natural and synthetic sources.

[0042] The compositions in addition to the lipoic acid or salt thereof and pyruvic acid or salt thereof include at least one component suitable for consumption by a companion animal including, but not limited to, fats, carbohydrates, proteins, fibers, nutritional balancing agents such as vitamins, minerals, and trace elements, and mixtures thereof. One of ordinary skill in the art can select the amount and type of food ingredients for a typical food based upon the dietary requirements of the animal, for example, the animal's species, age, size, weight, health, and function.

[0043] The food ingredient part of the food composition can include up to about 100% of any particular food ingredient or can include a mixture of food ingredients in various proportions. In certain embodiments, the food composition includes a combination of food ingredients in amounts of about 0 wt. % to 50 wt. % fat, 0 wt. % to 75 wt. % carbohydrate, 0 wt. % to 95 wt.

% protein, 0 wt. % to 40 wt. % dietary fiber, and 0 wt. % to 15 wt. % of one or more nutritional balancing agents.

[0044] In certain embodiments, the fat and carbohydrate food ingredient is obtained from a variety of sources such as animal fat, fish oil, vegetable oil, meat, meat by-products, grains, other animal or plant sources, and mixtures thereof. Grains include wheat, corn, barley, and rice.

[0045] In certain embodiments, the protein food ingredient is obtained from a variety sources such as plants, animals, or both. Animal protein includes meat, meat by-products, dairy, and eggs. Meats include the flesh from poultry, fish, and animals such as cattle, swine, sheep, goats, and the like, meat by-products include lungs, kidneys, brain, livers, stomachs, and intestines. The protein food ingredient may also be free amino acids and/or peptides. Preferably, the protein food ingredient includes meat, a meat by-product, dairy products, or eggs.

[0046] In certain embodiments, the fiber food ingredient is obtained from a variety of sources such as vegetable fiber sources, for example, cellulose, beet pulp, peanut hulls, and soy fiber.

[0047] In certain embodiments, the nutritional balancing agents are obtained from a variety of sources known to skilled artisans, for example, vitamin and mineral supplements and food ingredients. Vitamins and minerals can be included in amounts required to avoid deficiency and maintain health. These amounts are readily available in the art. The National Research Council (NRC) provides recommended amounts of such nutrients for farm animals. See, e.g., Nutrient Requirements of Swine (10th Rev. Ed., Nat'l Academy Press, Wash. D.C., 1998), Nutrient Requirements of Poultry (9th Rev. Ed., Nat'l Academy Press, Wash. D.C., 1994), Nutrient Requirements of Horses (5th Rev. Ed., Nat'l Academy Press, Wash. D.C., 1989). The American Feed Control Officials (AAFCO) provides recommended amounts of such nutrients for dogs and cats. See American Feed Control Officials, Inc., Official publication, pp. 129-137 (2004). Vitamins generally useful as food additives include vitamin A, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin D, biotin, vitamin K, folic acid, inositol, niacin, and pantothenic acid. Minerals and trace elements useful as food additives include calcium, phosphorus, sodium, potassium, magnesium, copper, zinc, chloride, iron, selenium, iodine, and iron.

[0048] In certain embodiments, the food compositions may contain additional ingredients such as vitamins, minerals, fillers, palatability enhancers, binding agents, flavors, stabilizers, emulsifiers, sweeteners, colorants, buffers, salts, coatings, and the like known to skilled artisans. Stabilizers include substances that tend to increase the shelf life of the composition.

such as preservatives, synergists and sequestrants, packaging gases, stabilizers, emulsifiers, thickeners, gelling agents, and humectants. Examples of emulsifiers and/or thickening agents include gelatin, cellulose ethers, starch, starch esters, starch ethers, and modified starches. Specific amounts for each composition component, food ingredient, and other ingredients will depend on a variety of factors such as the particular components and ingredients included in the composition; the species of animal; the animal's age, body weight, general health, sex, and diet; the animal's consumption rate; the type of disease or condition being treated; and the like. Therefore, the component and ingredient amounts may vary widely and may deviate from the preferred proportions described herein.

[0049] In one illustrative embodiment, the composition may, for example, in addition to the lipoic acid or salt thereof and pyruvic acid or salt thereof also include at least one of the following:

- (a) 0% to 75% carbohydrate,
- (b) 2% to 50% fat,
- (c) 0% to 40% dietary fiber, and
- (d) 0% to 15% of one or more nutritional balancing agents.

[0050] The compositions can contain additional ingredients intended to maintain or improve the health of the animal, for example, supplements, medications, herbs, holistic drugs and compositions, and the like.

[0051] The composition of the invention may include one or more additional ingredients to prevent or treat one or more diseases or conditions. The component in the diet, which accomplishes this, is an antioxidant or mixture thereof. An antioxidant is a material that quenches a free radical. Examples of such materials include foods such as Ginkgo Biloba, citrus pulp, grape pomace, tomato pomace, carrot and spinach, all preferably dried as well as various other materials such as beta-carotene, selenium, coenzyme Q10 (ubiquinone), lutein, tocotrienols, soy isoflavones, S-adenosylmethionine, glutathione, taurine, N-acetylcysteine, Vitamin E, Vitamin C, alpha-lipoic acid, l-carnitine and the like. Vitamin E can be administered as a tocopherol or a mixture of tocopherols and various derivatives thereof such as esters like vitamin E acetate, succinate, palmitate, and the like. The alpha form is preferable but beta, gamma and delta forms can be included. The d form is preferable but racemic mixtures are acceptable. The forms and derivatives will function in a Vitamin E like activity after ingestion by the pet. Vitamin C can be administered in this diet as ascorbic acid and its various derivatives thereof such as calcium phosphate salts, cholesteryl salt, 2-monophosphate, and the like which will function in a vitamin C like activity after ingesting by the pet. They can

be in any form such as liquid, semisolid, solid and heat stable form. L-carnitine can be administered in the diet and various derivatives of carnitine such as the salts such as the hydrochloride, fumarate and succinates, as well as acetylated carnitine, and the like can be used.

[0052] The quantities administered in the diet, all as wt % (dry matter basis) of the diet, are calculated as the active material, per se, that is measured as free material. The maximum amounts employed should not bring about toxicity. At least about 100 ppm or at least about 150 ppm of Vitamin E can be used. A preferred range of 500 to 1,000 ppm can be employed. Although not necessary, a maximum of about 2000 ppm or about 1500 ppm is generally not exceeded. With respect to Vitamin C at least about 50 ppm is used, desirably at least about 75 ppm and more desirably at least about 100 ppm. A non-toxic maximum can be employed. The quantity of lipoic acid can vary from at least about 25, desirably at least about 50 ppm, more desirably about 100 ppm. Maximum quantities can vary from 100 ppm to 600 ppm or to an amount which remains non-toxic to the pet. A preferred range is from 100 ppm to 200 ppm. For l-carnitine about 50 ppm, desirably about 200 ppm, more desirably about 300 ppm for canines are a useful minimum. For felines, slightly higher minimums of l-carnitine can be employed such as about 100 ppm, 200 ppm, and 500 ppm. A non-toxic maximum quantity can be employed, for example, less than about 5,000 ppm. For canines, lower quantities can be employed, for example, less than about 5,000 ppm. For canines, a preferred range is 200 ppm to 400 ppm. For felines, a preferred range is 400 ppm to 600 ppm. Beta-carotene at 1-15 ppm can be employed. Selenium at 0.1 up to 5 ppm can be employed. Lutein at least about 5 ppm can be employed. Tocotrienols at least about 25 ppm can be employed. Coenzyme Q10 at least about 25 ppm can be employed. S-adenosylmethionine at least about 50 ppm can be employed. Taurine at least about 1000 ppm can be employed. Soy isoflavones at least about 25 ppm can be used. N-acetylcysteine at least about 50 ppm can be used. Glutathione at least about 50 ppm can be used. Ginkgo Biloba at least 50 ppm of extract can be used.

[0053] In certain embodiments, the compositions further include an effective amount of at least one substance selected from the group consisting of glucosamine, chondroitin, chondroitin sulfate, methylsulfonylmethane ("MSM"), creatine, antioxidants, *Perna canaliculata*, omega-3 fatty acids, omega-6 fatty acids and mixtures thereof.

[0054] In certain embodiments, the composition can be a treat. Treats include compositions that are given to an animal to entice the animal to eat during a non-meal time, for example, dog bones for canines. Treats may be nutritional wherein the composition includes one or more nutrients or and may have a food-like composition. Non-nutritional treats encompass any other

treats that are non-toxic. The composition or components are coated onto the treat, incorporated into the treat, or both. Treats of the invention can be prepared by an extrusion or baking process similar to those used for dry food. Other processes also may be used to either coat the composition on the exterior of existing treat forms or inject the composition into an existing treat form.

[0055] In certain embodiments, the composition can be a toy. Toys include chewable toys such as artificial bones. The lipoic acid or a salt thereof can form a coating on the surface of the toy or on the surface of a component of the toy, be incorporated partially or fully throughout the toy, or both. In one embodiment, the lipoic acid or a salt thereof is orally accessible by the intended user. There are a wide range of suitable toys currently marketed, for example, U.S. Pat. No. 5,339,771, U.S. Pat. No. 5,419,283, and references disclosed therein. This invention provides both partially consumable toys, for example, toys including plastic components, and fully consumable toys, for example, rawhides and various artificial bones. The invention preferably provides toys for use by a dog or a cat.

Preparation of the Compositions of the Invention

[0056] The compositions of the invention may be prepared in a canned or wet form using conventional food preparation processes known to skilled artisans. Typically, ground animal proteinaceous tissues are mixed with the other ingredients such as fish oils, cereal grains, balancing ingredients, special purpose additives (e.g. vitamin and mineral mixtures, inorganic salts, cellulose and beet pulp, bulking agents, and the like), the lipoic acid or salt thereof and pyruvic acid or salt thereof, and water in amounts sufficient for processing. These ingredients are mixed in a vessel suitable for heating while blending the components. Heating of the mixture is effected using any suitable manner, for example, direct steam injection or using a vessel fitted with a heat exchanger. Following the addition of the last ingredient, the mixture is heated to a temperature of about 50 °F to about 212 °F. Temperatures outside this range are acceptable but may be commercially impractical without use of other processing aids. When heated to the appropriate temperature, the material will typically be in the form of a thick liquid. The thick liquid is filled into cans. A lid is applied, and the container is hermetically sealed. The sealed can is then placed into conventional equipment designed to sterilize the contents. Sterilization is usually accomplished by heating to temperatures of greater than about 230 °F for an appropriate time depending on the temperature used, the composition, and similar factors. The compositions of the present invention can be added to the food compositions before, during, or after preparation.

[0057] Food compositions may be prepared in a dry form using conventional processes known to skilled artisans. Typically, dry ingredients such as animal protein, plant protein, grains, and the lipoic acid or salt thereof and pyruvic acid or salt thereof are ground and mixed together. Moist or liquid ingredients, including fats, oils, animal protein, water, and the like are then added to and mixed with the dry mix. The mixture is then processed into kibbles or similar dry pieces. Kibble is often formed using an extrusion process in which the mixture of dry and wet ingredients is subjected to mechanical work at a high pressure and temperature and forced through small openings and cut off into kibble by a rotating knife. The wet kibble is then dried and optionally coated with one or more topical coatings such as flavours, fats, oils, powders, and the like. Kibble also can be made from the dough using a baking process, rather than extrusion, wherein the dough is placed into a mold before dry-heat processing. The food compositions can be in the form of a treat using an extrusion or baking process similar to those described above for dry food or a toy such as those disclosed in U.S. Patent Nos. 5,339,771 and 5,419,283.

[0058] In certain embodiments, the lipoic acid or salt thereof and pyruvic acid or salt thereof can be added to the food compositions before, during, or after preparation.

Methods of Treating or Preventing Disorders with Compositions of the Invention...

[0059] The invention also encompasses methods of treating or preventing certain disorders by administering a therapeutically or prophylactically effective amount of a composition including pyruvic acid or a salt thereof, or lipoic acid or salt thereof and pyruvic acid or salt thereof to a companion animal in need thereof.

[0060] Another embodiment of the invention encompasses methods of treating or preventing an unhealthy body composition in a companion animal. In one embodiment, the method of treating or preventing an unhealthy body composition in a companion animal includes feeding the animal a composition including the pyruvic acid or salt thereof, or lipoic acid or salt thereof and pyruvic acid or salt thereof in an amount effective to treat or prevent the unhealthy body composition. The invention also encompasses the use of a composition including the pyruvic acid or salt thereof, or lipoic acid or salt thereof and pyruvic acid or salt thereof for the manufacture of a medicament for the treatment or prevention of an unhealthy body composition in a companion animal.

[0061] In another embodiment, an animal that is suffering from an unhealthy body composition is fed the composition of the invention for a period until the animal reaches the desired body composition. The period is preferably at least 4 weeks, more preferably at least 6

weeks, and most preferably at least 8 weeks. This period depends on the animal's original body composition and the desired optimal body composition trying to be achieved. As used herein, an animal that is suffering from an unhealthy body composition has a body fat amount in excess of 30% by weight indicates that the animal generally is unhealthy, particularly if that amount of body fat is in excess of 35% by weight. A useful measure of healthy body composition is given by the body fat:lean muscle ratio. In certain embodiments, an unhealthy body composition includes a body fat:lean muscle weight ratio greater than 30:60. In other words, the body fat amount is 30% by weight, there is 68% by weight of muscle and the remaining 2% is bone. On the other hand, a good, healthy body composition includes a body fat:lean muscle weight ratio of around 20:78, indicating 20% fat and 78% lean muscle by weight. These values can be determined using DEXA (dual-energy x-ray absorptiometry). Cats fed a food containing the pyruvic acid or salt thereof, or lipoic acid or salt thereof and pyruvic acid or salt thereof lost significantly more weight, body fat, and increased percentage lean and percent bone mineral content compared to a similar control food. Dogs fed a food containing pyruvic acid or salt thereof, or lipoic acid or salt thereof and pyruvic acid or salt thereof alone had a higher percentage lean and less percent body fat. In addition, dogs fed the pyruvic acid or salt thereof, or lipoic acid or salt thereof and pyruvic acid or salt thereof alone had greater bone mineral density compared to the other foods, and less total fat than the control food and fish oil. This data suggests pyruvic acid or salt thereof, or lipoic acid or salt thereof and pyruvic acid or salt thereof has the unique ability to increase fat loss and improve body composition in *ad libitum* fed dogs and cats.

[0062] In another aspect, the present invention provides a means for communicating information about or instructions for treating or preventing an unhealthy body composition in a companion animal. The communicating means includes a document, digital storage media, optical storage media, audio presentation, or visual display containing the information or instructions. Preferably, the communication is a displayed web site or a brochure, product label, package insert, advertisement, or visual display containing such information or instructions. Useful information includes one or more of (1) methods and techniques for administering the compositions and using the methods of the present invention, (2) details about the side effects, if any, caused by using the present invention, alone or in combination with other drugs, and (3) contact information for patients to use if they have a question about the invention and its use. Useful instructions include dosages, administration amounts and frequency, and administration routes. The communication means is useful for instructing on the

benefits of using the present invention and communicating the approved methods for using the invention.

[0063] The invention is not limited to the particular methodology, protocols, and reagents described herein because they may vary. Further, the terminology used herein is for the purpose of describing particular embodiments only and is not intended to limit the scope of the present invention. As used herein and in the appended claims, the singular forms “a,” “an,” and “the” include plural reference unless the context clearly dictates otherwise. Similarly, the words “include”, “includes”, and “including” are to be interpreted inclusively rather than exclusively. Unless defined otherwise, all technical and scientific terms and any acronyms used herein have the same meanings as commonly understood by one of ordinary skill in the art in the field of the invention. Although any compositions, methods, articles of manufacture, or other means or materials similar or equivalent to those described herein can be used in the practice of the present invention, the preferred compositions, methods, articles of manufacture, or other means or materials are described herein.

[0064] All patents, patent applications, publications, and other references cited or referred to herein are incorporated herein by reference to the extent allowed by law. The discussion of those references is intended merely to summarize the assertions made therein. No admission is made that any such patents, patent applications, publications or references, or any portion thereof, is relevant prior art for the present invention and the right to challenge the accuracy and pertinence of such patents, patent applications, publications, and other references is specifically reserved.

EXAMPLES

[0065] This invention can be further illustrated by the following examples of preferred embodiments thereof, although it will be understood that these examples are included merely for purposes of illustration and are not intended to limit the scope of the invention unless otherwise specifically indicated.

EXAMPLE 1

[0066] Thirty-two dogs were utilized in the weight loss study. All dogs began the study with % body fat (of total weight) greater than 34.8%. The dogs remained on the weight loss study for 4 months unless optimal body weight was achieved earlier (20% body fat). Dogs were allotted to one of four treatments (8 dogs per treatment; Tables 1, 2 and 3). Each food was kibbled and formulated in accordance with the Association of American Feed Control Officials

(2005) nutrient guide for dogs and balanced to meet adult maintenance requirements. During the weight loss study all dogs underwent dual energy x-ray absorptiometry (DEXA) at months 0, 1, 2, 3, and 4. Following weight loss the dogs remained on the same foods for a period of 4 months to determine if the food would prevent weight regain. During the maintenance portion of the study dogs underwent DEXA at months 0, 2 and 4. Blood chemistry screens were also analyzed at all DEXA timepoints.

Table 1: Formula # and Description of the Food

Formula #	Formula Description
1	Control
2	Control plus calcium pyruvate
3	Control plus lipoic acid
4	Control plus lipoic acid and calcium pyruvate

[0067] Table 2 illustrates four Pet Food Compositions used in the weight loss study. Formula 1 is a control that does not contain lipoic acid or pyruvate. Formula 2 is a Control plus calcium pyruvate. Formula 3 is a Control plus lipoic acid. Formula 4 is a Control plus lipoic acid and calcium pyruvate.

Table 2: Ingredient Composition of foods used

Ingredient (Wt. % of food)	Formula 1	Formula 2	Formula 3	Formula 4
Corn	29.4	27.8	29.1	27.5
Poultry Meal	19.4	19.5	19.4	19.5
Corn Gluten Meal	19.4	19.5	19.4	19.5
Cellulose	9.6	9.7	9.6	9.7
Soy Mill Run	9.6	9.5	9.6	9.5
Beet Pulp	4.3	4.3	4.3	4.3
Fat Enhancer	3.6	3.6	3.6	3.6
Soybean Oil	1.3	1.3	1.3	1.3
Calcium Pyruvate	---	1	---	1
Potassium Citrate	0.9	1	0.9	1
DL-Methionine	0.6	0.6	0.6	0.6
L-Lysine	0.5	0.5	0.5	0.5
Lipoic Acid	---	---	0.3	0.3
L-Carnitine	0.2	0.3	0.2	0.3
Vitamin E	0.1	0.1	0.1	0.1
Salt Iodized	0.1	0.1	0.1	0.1
Choline Chloride	0.1	0.1	0.1	0.1
Vitamin Premix	0.1	0.1	0.1	0.1

Ingredient (Wt. % of food)	Formula 1	Formula 2	Formula 3	Formula 4
Preservative	0.07	0.07	0.07	0.07
Taurine	0.07	0.07	0.07	0.07
Mineral Mix	0.07	0.07	0.07	0.07

[0068] Table 3 illustrates the nutrient values of each of the pet food compositions used in the study.

Table 3: Analyzed nutrient values of foods used in the study

Nutrient (100% dry matter basis)	Formula 1	Formula 2	Formula 3	Formula 4
Crude Protein, %	34.7	34.9	34.8	34.7
Crude Fat, %	8.7	9.1	8.6	8.8
Ash, %	5	5.3	5	5.3
Calcium, %	0.8	0.97	0.8	1
Phosphorus, %	0.67	0.67	0.65	0.69
Potassium, %	0.7	0.8	0.8	0.8
Sodium, %	0.26	0.23	0.23	0.24
Chloride, %	0.4	0.4	0.4	0.4
Crude Fiber, %	13.6	13.6	13.3	13.5
Total Dietary Fiber, %	25.8	26.6	26.5	27.5
Insoluble Fiber, %	24	24.9	23.4	24.5
Soluble Fiber, %	1.9	1.8	3.1	3
Lysine, %	1.8	1.8	1.8	1.9
Pyruvic Acid, %	0.0	0.22	0.0	0.23
Lipoic Acid, ppm	--	--	138	129

[0069] Table 4 illustrates predicted time to reach 20% body fat for dogs fed each of the pet food compositions.

Table 4: Predicted Time to Reach 20% Body Fat

	Formula 1	Formula 2	Formula 3	Formula 4
Months to Weight Loss Goal	5.07 +/- 2.72	5.48 +/- 2.12	7.58 +/- 2.77	4.79 +/- 1.78
Probability Associated with a Subject's Paired t-Test				
Formula 1	--	0.642	0.041	0.783
Formula 2	0.642	--	0.059	0.410
Formula 3	0.041	0.059	--	0.049
Formula 4	0.783	0.410	0.049	--

[0070] The rate of fat loss for all dogs in the current study was linear ($R^2 > 0.87$ for each dog).

As a result, the data was used to predict how long it would take for the dogs on average to achieve a weight loss goal of 20% body fat. The food containing both lipoic acid and pyruvate has the shortest time on average to reach the weight loss goal of 20% body fat. In addition, this food also has the smallest standard deviation indicating less variation amongst the dogs.

[0071] Tables 5 – 14 illustrate the average physical and chemical characteristics of dogs fed each of the pet food compositions.

[0072] Table 5 illustrates that illustrative pet food composition including lipoic acid and calcium pyruvate resulted in reduced lean body mass in dogs fed the illustrative pet food composition over a four month period.

DXA Analysis

Table 5: Lean Body Mass (grams)

Parameter Measured	Formula 1		Formula 2		Formula 3		Formula 4		Treatment Effect (Kruskal-Wallis)
—	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	—
- Observed Month 0	8	8505.95 $\pm$ 437	8	8764.70 $\pm$ 720	8	8873.39 $\pm$ 1032	8	8588.09 $\pm$ 1138	NS*
- Observed Month 1	8	8545.11 $\pm$ 450	8	8674.49 $\pm$ 648	8	8600.76 $\pm$ 1021	8	8379.35 $\pm$ 1104	NS*
- Observed Month 2	8	8482.50 $\pm$ 494	8	8674.95 $\pm$ 689	8	8626.30 $\pm$ 992	8	8422.71 $\pm$ 1105	NS*
-Observed Month 3	8	8534.54 $\pm$ 488	8	8727.70 $\pm$ 669	8	8541.00 $\pm$ 953	8	8518.20 $\pm$ 1087	NS*
-Observed Month 4	8	8672.64 $\pm$ 481	8	8848.52 $\pm$ 642	8	8636.60 $\pm$ 1001	8	8579.06 $\pm$ 1067	NS*
Change from Month 0 to 1	8	39.16 $\pm$ 115	8	-90.21 $\pm$ 113	8	-272.63 $\pm$ 66.1	8	-208.74 $\pm$ 122	NS*
Change from Month 0 to 2	8	-23.45 $\pm$ 143	8	-89.75 $\pm$ 84.1	8	-247.09 $\pm$ 119	8	-165.37 $\pm$ 136	NS*
Change from Month 0 to 3	8	28.59 $\pm$ 168	8	-37.00 $\pm$ 69.4	8	-332.39 $\pm$ 146	8	-69.89 $\pm$ 152	NS*
Change from Month 0 to 4	8	166.69 $\pm$ 151	8	83.82 $\pm$ 96.5	8	-236.79 $\pm$ 112	8	-9.03 $\pm$ 154	NS*
Month 0 vs		NS*		NS*		<0.0100		NS*	

1**				
Month 0 vs 2**	NS*	NS*	NS*	NS*
Month 0 vs 3**	NS*	NS*	NS*	NS*
Month 0 vs 4**	NS*	NS*	NS*	NS*
* NS = Not significant (i.e. p-values > 0.1)				
** Wilcoxin signed-rank test				

[0073] Table 6 illustrates that illustrative pet food composition including lipoic acid and calcium pyruvate resulted in reduced percent body fat in dogs fed the illustrative pet food composition over a four month period.

Table 6: Percent Body Fat

Parameter Measured	Formula 1		Formula 2		Formula 3		Formula 4		Treatment Effect (Kruskal-Wallis)
—	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	—
- Observed Month 0	8	40.43 ± 1.5	8	38.99 ± 1.01	8	40.59 ± 1.92	8	40.98 ± 1.11	NS*
- Observed Month 1	8	35.25 ± 2.3	8	35.36 ± 1.53	8	38.20 ± 2.18	8	36.71 ± 0.99	NS*
- Observed Month 2	8	31.05 ± 2.77	8	31.54 ± 1.85	8	34.84 ± 1.76	8	31.24 ± 1.18	NS*
- Observed Month 3	8	27.91 ± 2.14	8	28.45 ± 1.44	8	32.48 ± 2.06	8	26.25 ± 1.74	NS*
- Observed Month 4	8	25.11 ± 1.48	8	25.91 ± 1.5	8	30.58 ± 1.94	8	24.94 ± 1.33	NS*
Month 0 to 1		NS*		<0.0100		<0.46		-4.26 ± 0.72	
Month 0 to 2		NS*		<0.0100		<0.59		-9.74 ± 1.34	
Change from Month 0 to 3	8	-12.51 ± 1.31	8	-10.54 ± 1.04	8	-8.11 ± 0.79	8	-14.73 ± 2.21	0.226
Change from Month 0 to 4	8	-15.31 ± 1.18	8	-13.08 ± 1.45	8	-10.01 ± 0.62	8	-16.04 ± 1.9	0.0128
Month 0 vs		<0.0100		<0.0100		<0.0100		<0.0100	

1**									
Month 0 vs 2**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs 3**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs 4**		<0.0100		<0.0100		<0.0100		<0.0100	

* NS = Not significant (ie. p-values > 0.1)

** Wilcoxin signed-rank test

[0074] Table 7 illustrates that illustrative pet food composition including lipoic acid and calcium pyruvate resulted in reduced total body fat in dogs fed the illustrative pet food composition over a four month period.

Table 7: Total Body Fat (grams)

Parameter Measured		Formula 1		Formula 2		Formula 3		Formula 4	Treatment Effect (Kruskal-Wallis)
—	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	—
- Observed Month 0	8	6106.65 ± 341	8	5936.61 ± 540	8	6249.08 ± 679	8	6164.74 ± 696	NS*
- Observed Month 1	8	4954.41 ± 437	8	5065.91 ± 491	8	5454.59 ± 602	8	5070.16 ± 626	NS*
- Observed Month 2	8	4078.66 ± 442	8	4247.31 ± 424	8	4768.61 ± 529	8	4032.25 ± 572	NS*
- Observed Month 3	8	3515.89 ± 353	8	3671.10 ± 331	8	4269.15 ± 524	8	3259.35 ± 534	NS*
- Observed Month 4	8	3077.63 ± 264	8	3284.01 ± 324	8	3911.53 ± 454	8	3102.36 ± 525	NS*
Change from Month 0 to 1	8	-1152.2 ± 167	8	-870.70 ± 189	8	-794.49 ± 113	8	-1094.6 ± 134	NS*
Change from Month 0 to 2	8	-2028.0 ± 213	8	-1689.3 ± 288	8	-1480.5 ± 176	8	-2132.5 ± 248	NS*
Change from Month 0 to 3	8	-2590.8 ± 182	8	-2265.5 ± 328	8	-1979.9 ± 197	8	-2905.4 ± 351	NS*

Parameter Measured		Formula 1		Formula 2		Formula 3		Formula 4	Treatment Effect (Kruskal-Wallis)
—	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	—
Change from Month 0 to 4	8	-3029.0 ± 196	8	-2652.6 ± 385	8	-2337.8 ± 254	8	-3062.4 ± 291	NS*
Month 0 vs 1**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs 2**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs 3**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs 4**		<0.0100		<0.0100		<0.0100		<0.0100	

* NS = Not significant (i.e. p-values > 0.1)

** Wilcoxin signed-rank test

[0075] Table 8 illustrates that an illustrative pet food composition including lipoic acid and calcium pyruvate resulted in reduced total body weight in dogs fed the illustrative pet food composition over a four month period.

Table 8: Total Body Weight (grams)

Parameter Measured		Formula 1		Formula 2		Formula 3		Formula 4	Treatment Effect (Kruskal-Wallis)
—	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	—
- Observed Month 0	8	15094.8 ± 666	8	15172.3 ± 1240	8	15580.1 ± 1665	8	15207.2 ± 1858	NS*
- Observed Month 1	8	13964.5 ± 678	8	14204.2 ± 1099	8	14503.7 ± 1555	8	13886.5 ± 1747	NS*
- Observed Month 2	8	13027.8 ± 681	8	13379.1 ± 1039	8	13839.2 ± 1481	8	12883.6 ± 1686	NS*
- Observed Month 3	8	12506.4 ± 687	8	12852.2 ± 946	8	13253.2 ± 1402	8	12199.9 ± 1612	NS*
- Observed	8	12202.9 ±	8	12582.5 ±	8	12986.4 ±	8	12100.8 ±	NS*

Month 4		681		916		1401		1611	
Change from Month 0 to 1	8	-1130.4 ± 125	8	-968.06 ± 185	8	-1076.4 ± 124	8	-1320.7 ± 202	NS*
Change from Month 0 to 2	8	-2067.0 ± 135	8	-1793.2 ± 287	8	-1740.9 ± 198	8	-2323.6 ± 293	NS*
Change from Month 0 to 3	8	-2588.4 ± 103	8	-2320.1 ± 358	8	-2326.8 ± 280	8	-3007.3 ± 383	NS*
Change from Month 0 to 4	8	-2891.9 ± 137	8	-2589.8 ± 412	8	-2593.6 ± 288	8	-3106.4 ± 364	NS*
Month 0 vs 1**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs 2**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs 3**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs 4**		<0.0100		<0.0100		<0.0100		<0.0100	

* NS = Not significant (ie. p-values > 0.1)

** Wilcoxin signed-rank test

Chemistry Screens

[0076] Table 9 illustrates that an illustrative pet food composition including lipoic acid and calcium pyruvate resulted in reduced serum alanine aminotransferase levels in dogs fed the illustrative pet food composition over a four month period.

Table 9: Serum Alanine Aminotransferase

Parameter Measured		Formula 1		Formula 2		Formula 3		Formula 4	Treatment Effect (Kruskal-Wallis)
—	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	—
- Observed Month 0	8	48.25 ± 11.4	8	43.75 ± 6.43	8	44.44 ± 8.52	8	54.63 ± 10.7	NS*
- Observed Month 1	8	40.88 ± 9.5	8	33.88 ± 3.94	8	35.50 ± 6.42	8	51.38 ± 17.5	NS*
- Observed Month 2	8	42.50 ± 13.2	8	34.50 ± 3.67	8	34.63 ± 6.11	8	44.88 ± 12.8	NS*

Parameter Measured		Formula 1		Formula 2		Formula 3		Formula 4	Treatment Effect (Kruskal-Wallis)
—	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	—
- Observed Month 3	8	43.63 $\pm$ 10.4	8	37.63 $\pm$ 5.28	8	34.00 $\pm$ 6.39	8	54.63 $\pm$ 13.8	NS*
- Observed Month 4	8	51.38 $\pm$ 12.7	8	40.38 $\pm$ 4.73	8	56.25 $\pm$ 16.9	8	41.50 $\pm$ 8.48	NS*
Change from Month 0 to 1	8	-7.38 $\pm$ 10.6	8	-9.88 $\pm$ 7.57	8	-11.00 $\pm$ 7.08	8	-3.25 $\pm$ 8.33	NS*
Change from Month 0 to 2	8	-5.75 $\pm$ 14.2	8	-9.13 $\pm$ 7.2	8	-11.88 $\pm$ 7.34	8	-9.75 $\pm$ 5.85	NS*
Change from Month 0 to 3	8	-4.63 $\pm$ 7.58	8	-6.13 $\pm$ 8.4	8	-12.50 $\pm$ 7.09	8	0.00 $\pm$ 13.6	NS*
Change from Month 0 to 4	8	3.13 $\pm$ 11	8	-3.38 $\pm$ 8.16	8	9.75 $\pm$ 17.4	8	-13.13 $\pm$ 4.83	NS*
Month 0 vs 1**		NS*		NS*		NS*		NS*	
Month 0 vs 2**		NS*		NS*		NS*		NS*	
Month 0 vs 3**		NS*		NS*		0.0156		NS*	
Month 0 vs 4**		NS*		NS*		NS*		0.0469	

* NS = Not significant (ie. p-values > 0.1)

** Wilcoxin signed-rank test

[0077] Table 10 illustrates that an illustrative pet food composition including lipoic acid and calcium pyruvate resulted in reduced serum alkaline phosphatase levels in dogs fed the illustrative pet food composition over a four month period.

Table 10: Serum Alkaline Phosphatase

Parameter Measured		Formula 1		Formula 2		Formula 3		Formula 4	Treatment Effect (Kruskal-Wallis)
—	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	—
- Observed Month 0	8	243.38 $\pm$ 85.6	8	171.13 $\pm$ 72.3	8	124.56 $\pm$ 34.8	8	158.00 $\pm$ 64.1	NS*
- Observed Month 1	8	125.63 $\pm$ 47.4	8	83.38 $\pm$ 28.6	8	57.63 $\pm$ 7.38	8	72.63 $\pm$ 28.4	NS*
- Observed Month 2	8	111.50 $\pm$ 42.6	8	67.88 $\pm$ 17.9	8	52.25 $\pm$ 5.16	8	75.63 $\pm$ 28	NS*
- Observed Month 3	8	122.13 $\pm$ 41.3	8	68.63 $\pm$ 16.3	8	56.88 $\pm$ 3.98	8	75.00 $\pm$ 20.8	NS*
- Observed Month 4	8	111.00 $\pm$ 37.4	8	57.63 $\pm$ 11.7	8	51.25 $\pm$ 3.87	8	66.00 $\pm$ 17.2	NS*
Change from Month 0 to 1	8	-117.75 $\pm$ 39.3	8	-87.75 $\pm$ 44.4	8	-68.88 $\pm$ 33.6	8	-85.38 $\pm$ 36.4	NS*
Change from Month 0 to 2	8	-128.38 $\pm$ 43.6	8	-103.25 $\pm$ 55.3	8	-74.25 $\pm$ 36.5	8	-79.38 $\pm$ 41	NS*
Change from Month 0 to 3	8	-121.25 $\pm$ 44.8	8	-102.50 $\pm$ 57.9	8	-69.63 $\pm$ 38.9	8	-83.00 $\pm$ 46.5	NS*
Change from Month 0 to 4	8	-132.38 $\pm$ 49.7	8	-113.50 $\pm$ 63.7	8	-75.25 $\pm$ 38.9	8	-92.00 $\pm$ 50.8	NS*
Month 0 vs 1**		<0.0100		<0.0100		0.0156		<0.0100	
Month 0 vs 2**		<0.0100		0.0156		0.0156		0.0234	
Month 0 vs 3*		<0.0100		0.0234		0.0391		0.0234	
Month 0 vs 4*		<0.0100		<0.0100		0.0156		0.0234	

* NS = Not significant (ie, p-values > 0.1)

** Wilcoxin signed-rank test

[0078] Table 11 illustrates that an illustrative pet food composition including lipoic acid and calcium pyruvate resulted in reduced serum cholesterol levels in dogs fed the illustrative pet food composition over a four month period.

Table 11: Serum Cholesterol

Parameter Measured		Formula 1		Formula 2		Formula 3		Formula 4	Treatment Effect (Kruskal-Wallis)
—	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	—
- Observed Month 0	8	218.38 $\pm$ 14	8	191.25 $\pm$ 12.8	8	203.33 $\pm$ 12.7	8	238.75 $\pm$ 16.1	NS*
- Observed Month 1	8	158.25 $\pm$ 8.69	8	144.13 $\pm$ 12.6	8	146.00 $\pm$ 8.24	8	158.13 $\pm$ 12.2	NS*
- Observed Month 2	8	153.63 $\pm$ 6.76	8	146.00 $\pm$ 11.8	8	144.75 $\pm$ 8.3	8	159.88 $\pm$ 7.83	NS*
- Observed Month 3	8	154.75 $\pm$ 5.78	8	151.38 $\pm$ 11.4	8	145.25 $\pm$ 8.83	8	152.00 $\pm$ 8.04	NS*
- Observed Month 4	8	149.38 $\pm$ 5.37	8	144.63 $\pm$ 11.2	8	139.00 $\pm$ 9.22	8	149.75 $\pm$ 10	NS*
Change from Month 0 to 1	8	-60.13 $\pm$ 10.7	8	-47.13 $\pm$ 8.29	8	-58.50 $\pm$ 12	8	-80.63 $\pm$ 10.7	NS*
Change from Month 0 to 2	8	-64.78 $\pm$ 12.3	8	-45.25 $\pm$ 6.74	8	-59.75 $\pm$ 9.67	8	-78.88 $\pm$ 11.7	NS*
Change from Month 0 to 3	8	-63.63 $\pm$ 10.3	8	-39.88 $\pm$ 7.02	8	-59.25 $\pm$ 9.73	8	-86.75 $\pm$ 10.4	0.0256
Change from Month 0 to 4	8	-69.00 $\pm$ 11	8	-46.63 $\pm$ 6.38	8	-65.50 $\pm$ 10.9	8	-89.00 $\pm$ 9.64	0.0601
Month 0 vs 1**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs 2**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs 3**		<0.0100		<0.0100		<0.0100		<0.0100	
Month 0 vs		<0.0100		<0.0100		<0.0100		<0.0100	

4**									
-----	--	--	--	--	--	--	--	--	--

* NS = Not significant (ie. p-values > 0.1)

** Wilcoxin signed-rank test

[0079] Table 12 illustrates that illustrative pet food composition including lipoic acid and calcium pyruvate resulted in reduced serum creatinine levels in dogs fed the illustrative pet food composition over a four month period.

Table 12: Serum Creatinine

Parameter Measured	Formula 1		Formula 2		Formula 3		Formula 4		Treatment Effect (Kruskal-Wallis)
—	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	—
- Observed Month 0	8	0.61 ± 0.04	8	0.62 ± 0.04	8	0.70 ± 0.09	8	0.61 ± 0.04	NS*
- Observed Month 1	8	0.58 ± 0.03	8	0.50 ± 0.02	8	0.62 ± 0.04	8	0.54 ± 0.03	NS*
- Observed Month 2	8	0.59 ± 0.03	8	0.51 ± 0.02	8	0.60 ± 0.04	8	0.53 ± 0.03	NS*
- Observed Month 3	8	0.56 ± 0.04	8	0.46 ± 0.02	8	0.55 ± 0.03	8	0.48 ± 0.03	0.0774
- Observed Month 4	8	0.57 ± 0.03	8	0.45 ± 0.02	8	0.57 ± 0.03	8	0.49 ± 0.03	0.0135
Change from Month 0 to 1	8	-0.02 ± 0.02	8	-0.12 ± 0.03	8	-0.11 ± 0.08	8	-0.08 ± 0.02	0.0530
Change from Month 0 to 2	8	-0.01 ± 0.02	8	-0.11 ± 0.03	8	-0.13 ± 0.09	8	-0.08 ± 0.02	0.0388
Change from Month 0 to 3	8	-0.05 ± 0.01	8	-0.16 ± 0.03	8	-0.17 ± 0.09	8	-0.13 ± 0.02	0.0221
Change from Month 0 to 4	8	-0.03 ± 0.02	8	-0.17 ± 0.03	8	-0.15 ± 0.09	8	-0.13 ± 0.02	0.0244
Month 0 vs		NS*		<0.0100		NS*		0.0156	

1**								
Month 0 vs 2**		NS*		<0.0100		0.0781		0.0156
Month 0 vs 3**		<0.0100		<0.0100		0.01560		<0.0100
Month 0 vs 4**		NS*		<0.0100		0.04690		<0.0100

* NS = Not significant (ie. p-values > 0.1)

** Wilcoxin signed-rank test

[0080] Table 13 illustrates that illustrative pet food composition including lipoic acid and calcium pyruvate resulted in reduced serum triglyceride levels in dogs fed the illustrative pet food composition over a four month period.

Table 13: Serum Triglycerides

Parameter Measured		Formula 1		Formula 2		Formula 3		Formula 4	Treatment Effect (Kruskal-Wallis)
—	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	N	Mean ± SEM	—
- Observed Month 0	8	189.38 ± 17	8	185.50 ± 21.3	8	218.78 ± 15.8	8	235.25 ± 17.2	NS*
- Observed Month 1	8	154.50 ± 12	8	170.63 ± 13.9	8	176.00 ± 10.1	8	152.75 ± 13.1	NS*
- Observed Month 2	8	125.63 ± 8.9	8	144.38 ± 8.44	8	148.88 ± 6.47	8	147.00 ± 19.7	NS*
- Observed Month 3	8	112.75 ± 9.1	8	127.50 ± 11.3	8	137.50 ± 6.98	8	123.38 ± 19.1	NS*
- Observed Month 4	8	126.63 ± 9.81	8	137.38 ± 11.2	8	122.25 ± 13.9	8	113.38 ± 14	NS*
Change from Month 0 to 1	8	-34.88 ± 21.6	8	-14.88 ± 20.3	8	-39.63 ± 16.3	8	-82.50 ± 17.7	NS*
Change from Month 0 to 2	8	-64.88 ± 17.9	8	-41.13 ± 18.6	8	-66.75 ± 16.1	8	-88.25 ± 18.2	NS*
Change from Month 0 to 3	8	-76.63 ± 10.5	8	-58.00 ± 25	8	-78.13 ± 13.2	8	-111.88 ± 18.6	NS*
Change from Month 0 to 4	8	-62.75 ± 15.6	8	-48.13 ± 19.9	8	-93.38 ± 15.6	8	-121.88 ± 16.7	0.0487

0 to 4									
Month 0 vs 1**		NS*		NS*		0.0625		<0.0100	
Month 0 vs 2**		0.0156		0.0547		0.0156		0.0156	
Month 0 vs 3**		<0.0100		0.0391		0.0156		<0.0100	
Month 0 vs 4**		0.0156		0.0781		<0.0100		<0.0100	

* NS = Not significant (ie. p-values > 0.1)

** Wilcoxin signed-rank test

[0081] Table 14 illustrates that illustrative pet food composition including lipoic acid and calcium pyruvate resulted in reduced serum urea nitrogen levels in dogs fed the illustrative pet food composition over a four month period.

Table 14: Serum Urea Nitrogen

Parameter Measured		Formula 1		Formula 2		Formula 3		Formula 4	Treatment Effect (Kruskal-Wallis)
—	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	—
- Observed Month 0	8	11.71 $\pm$ 0.5	8	14.94 $\pm$ 3.33	8	13.92 $\pm$ 1.42	8	11.59 $\pm$ 1.14	NS*
- Observed Month 1	8	13.70 $\pm$ 0.78	8	14.70 $\pm$ 1.76	8	17.16 $\pm$ 1.73	8	14.45 $\pm$ 1.85	NS*
- Observed Month 2	8	13.30 $\pm$ 0.87	8	12.93 $\pm$ 0.89	8	16.66 $\pm$ 2.02	8	14.99 $\pm$ 1.66	NS*
- Observed Month 3	8	13.95 $\pm$ 0.81	8	12.69 $\pm$ 0.78	8	15.18 $\pm$ 1.16	8	14.09 $\pm$ 1.32	NS*
- Observed Month 4	8	14.54 $\pm$ 0.79	8	12.65 $\pm$ 0.9	8	15.36 $\pm$ 0.92	8	14.10 $\pm$ 1.32	NS*
Change from Month 0 to 1	8	1.99 $\pm$ 0.8	8	-0.24 $\pm$ 1.93	8	3.15 $\pm$ 0.78	8	2.86 $\pm$ 1	NS*
Change from Month 0 to 2	8	1.59 $\pm$ 0.69	8	-2.01 $\pm$ 2.64	8	2.65 $\pm$ 0.95	8	3.40 $\pm$ 1.32	NS*
Change	8	2.24 $\pm$ 0.79	8	-2.25 $\pm$ 3.41	8	1.16 $\pm$ 1.49	8	2.50 $\pm$	NS*

Parameter Measured		Formula 1		Formula 2		Formula 3		Formula 4	Treatment Effect (Kruskal-Wallis)
—	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	N	Mean $\pm$ SEM	—
from Month 0 to 3								0.47	
Change from Month 0 to 4	8	2.83 $\pm$ 0.86	8	-2.29 $\pm$ 3.54	8	1.35 $\pm$ 1.77	8	2.51 $\pm$ 0.45	NS*
Month 0 vs 1**		0.0234		NS*		<0.0100		0.0156	
Month 0 vs 2**		0.0547		NS*		0.0156		0.0469	
Month 0 vs 3**		0.0391		NS*		NS*		<0.0100	
Month 0 vs 4**		0.0156		NS*		NS*		<0.0100	

* NS = Not significant (i.e., p-values > 0.1)

** Wilcoxin signed-rank test

[0082] The invention is not to be limited in scope by the specific embodiments disclosed in the examples, which are intended as illustrations of a few aspects of the invention, and any embodiments, which are functionally equivalent, are within the scope of this invention. Indeed, various modifications of the invention in addition to those shown and described herein will become apparent to those skilled in the art and are intended to fall within the appended claims.

[0083] For any references that have been cited, the entire disclosures of which are incorporated herein by reference.

CLAIMS

What is claimed is:

1. A composition comprising pyruvic acid or a salt thereof.
2. The composition of claim 1 further comprising lipoic acid or a salt thereof.
3. The composition of claim 1 or claim 2, wherein pyruvic acid or a salt thereof is present in the composition in an amount of 5 ppm to 20000 ppm.
3. The composition of any preceding claim, wherein pyruvic acid or a salt thereof is present in the composition in an amount of 10 ppm to 10000 ppm.
4. The composition of any preceding claim, wherein pyruvic acid or a salt thereof is present in the composition in an amount of 50 ppm to 5000 ppm.
5. The composition of any preceding claim, wherein pyruvic acid or a salt thereof is present in the composition in an amount of 100 ppm to 2500 ppm.
6. The composition of any one of claims 2-5, wherein lipoic acid or a salt thereof is present in the composition in an amount of about 5 ppm to about 5000 ppm.
7. The composition of any one of claims 2-6, wherein lipoic acid or a salt thereof is present in the composition in an amount of 10 ppm to 4000 ppm.
8. The composition of any one of claims 2-7, wherein lipoic acid or a salt thereof is present in the composition in an amount of 50 ppm to 3000 ppm.
9. The composition of any one of claims 2-8, wherein lipoic acid or a salt thereof is present in the composition in an amount of 100 ppm to 2000 ppm.
10. The composition of any one of claims 2-9, wherein lipoic acid or a salt thereof is present in the composition in an amount of 500 ppm to 1000 ppm.

11. The composition of any preceding claim, wherein the composition further comprises a protein, fat, carbohydrate, fiber, and combinations thereof.
12. The composition of any preceding claim, wherein the composition is a dog food.
13. The composition of any preceding claim, wherein the composition is a cat food.
14. The composition of any preceding claim, wherein the composition is a food, a nutritional diet, a supplement, an animal treat, or a toy.
15. The composition of any preceding claim, which is in the form of a moist food.
16. The composition of any preceding claim, which is in the form of a dry food.
17. A composition comprising lipoic acid or a salt thereof and pyruvic acid or a salt thereof.
18. A method for preventing or treating obesity in a companion animal, which comprises administering to the companion animal a composition comprising an effective amount of pyruvic acid or a salt thereof.
19. The method of claim 18 further comprising an effective amount of lipoic acid or a salt thereof.
20. The method of claim 18 or claim 19, wherein pyruvic acid or a salt thereof is present in the composition in an amount of 5 ppm to 20000 ppm.
21. The method of any one of claims 18-20, wherein pyruvic acid or a salt thereof is present in the composition in an amount of 10 ppm to 10000 ppm.
22. The method of any one of claims 18-21, wherein pyruvic acid or a salt thereof is present in the composition in an amount of 50 ppm to 5000 ppm.
23. The method of any one of claims 18-22, wherein pyruvic acid or a salt thereof is present in the composition in an amount of 100 ppm to 2500 ppm.

24. The method of any one of claims 18-23, wherein the composition further comprises a protein, fat, carbohydrate, fiber, and combinations thereof.
25. The method of any one of claims 19-24, wherein lipoic acid or a salt thereof is present in the composition in an amount of 5 ppm to 5000 ppm.
26. The method of any one of claims 19-25, wherein lipoic acid or a salt thereof is present in the composition in an amount of 10 ppm to 4000 ppm.
27. The method of any one of claims 19-26, wherein lipoic acid or a salt thereof is present in the composition in an amount of 50 ppm to 3000 ppm.
28. The method of any one of claims 19-27, wherein lipoic acid or a salt thereof is present in the composition in an amount of 100 ppm to 2000 ppm.
29. The method of any one of claims 19-28, wherein lipoic acid or a salt thereof is present in the composition in an amount of 500 ppm to 1000 ppm.
30. The method of any one of claims 18-29, wherein the composition further comprises a protein, fat, carbohydrate, fiber, and combinations thereof.
31. The method of any one of claims 18-30, wherein the composition is a dog food.
32. The method of any one of claims 18-31, wherein the composition is a cat food.
33. The method of any one of claims 18-32, wherein the composition is a food, a nutritional diet, a supplement, an animal treat, or a toy.
34. The method of any one of claims 18-33, which is in the form of a moist food.
35. The method of any one of claims 18-34, which is in the form of a dry food.
36. The method of any one of claims 18-35, wherein the companion animal is a dog.

37. The method of any one of claims 18-36, wherein the companion animal is a cat.
38. The method of any one of claims 18-37, wherein the administration is oral feeding.
39. A method for managing weight in a companion animal, which comprises administering to the companion animal a composition comprising an effective amount of pyruvic acid or a salt thereof.
40. The method of claim 39 further comprising an effective amount of lipoic acid or a salt thereof.
41. A method for decreasing body fat in a companion animal, which comprises administering to the companion animal a composition comprising an effective amount of pyruvic acid or a salt thereof.
42. The method of claim 41 further comprising an effective amount of lipoic acid or a salt thereof.
43. A method for increasing lean body mass in a companion animal, which comprises administering to the companion animal a composition comprising an effective amount of pyruvic acid or a salt thereof.
44. The method of claim 43 further comprising an effective amount of lipoic acid or a salt thereof.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/021189

A. CLASSIFICATION OF SUBJECT MATTER

INV. A23K1/16 A23K1/18 A23L1/29 A61P3/04
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A23K A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, FSTA, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 198 36 450 A1 (SUEDDEUTSCHE KALKSTICKSTOFF [DE]) 17 February 2000 (2000-02-17)	1,3-5, 11-16, 18, 20-24, 30-39, 41,43
Y	page 2, line 1 - line 20 page 3, line 47 - line 50 page 4, line 20 - line 39 ----- -/--	2,6-10, 17,19, 25-29, 40,42,44

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

28 April 2010

Date of mailing of the international search report

27/05/2010

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Vermeulen, Stéphane

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/021189

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 344 996 A (SUEDEDEUTSCHE KALKSTICKSTOFF [DE]) 28 June 2000 (2000-06-28)	1,3-5, 11-16, 18, 20-24, 30-39, 41,43
Y	page 1, line 9 - line 17 page 4, line 27 - line 34 claim 17	2,6-10, 17,19, 25-29, 40,42,44
Y	----- WO 2007/063095 A1 (BASF AG [DE]; KLATT MARTIN JOCHEN [DE]; HASSELWANDER OLIVER [DE]; MATU) 7 June 2007 (2007-06-07) page 4, line 23 - line 31 page 8, line 10 - line 23 page 12, line 31 - page 13, line 20 page 13, line 30 - page 14, line 4 -----	2,6-10, 17,19, 25-29, 40,42,44
Y	US 2003/224061 A1 (PACIORETTY LINDA M [US] ET AL) 4 December 2003 (2003-12-04) paragraph [0018] - paragraph [0020] paragraph [0047] claims 22,26,27 -----	2,6-10, 17,19, 25-29, 40,42,44
X	US 6 277 842 B1 (CARTHON JAMES ALEXANDER [US]) 21 August 2001 (2001-08-21) column 1, line 5 - line 10 column 3, line 45 - line 50 column 3, line 57 - line 61 column 4, line 11 - line 18 column 5, line 19 - line 28 claims 1,5,9 -----	1-44
X	EP 1 875 816 A2 (FOREST CARL A [US]; MCCLEARY EDWARD LARRY [US]; MCCLEARY CHRISTINE [US]) 9 January 2008 (2008-01-09) paragraph [0006] paragraph [0010] - paragraph [0011] paragraph [0076] paragraph [0218] -----	1-44

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2010/021189

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19836450	A1	17-02-2000	NONE
GB 2344996	A	28-06-2000	NONE
WO 2007063095	A1	07-06-2007	DE 102005057178 A1 19-07-2007
US 2003224061	A1	04-12-2003	AU 2003251394 A1 19-12-2003 WO 03101469 A1 11-12-2003
US 6277842	B1	21-08-2001	NONE
EP 1875816	A2	09-01-2008	NONE