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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Por medio de la presente me permito solicitar el resultado del examen de fondo realizado sobre la patente que se tramita bajo el expediente indicado en la referencia, toda vez que dicho examen fue solicitado el día 23 de mayo de 2009 y hasta la fecha no he obtenido respuesta alguna sobre el asunto aquí citado.

Con respecto a su despacho, se haga entrega del resultado del examen de fondo.

Respectivamente

CARLOS ANDRÉS MEJÍA DÍAZ

C.C. 90.033.756

T.P. 146.355 C.E.U.

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(19) **United States**(12) **Patent Application Publication**
Naidu et al.(10) **Pub. No.: US 2006/0269535 A1**(43) **Pub. Date: Nov. 30, 2006**(54) **METALLO-LACTOFERRIN-COENZYME
COMPOSITIONS FOR TRIGGER AND
RELEASE OF BIOENERGY****Publication Classification**(76) **Inventors:** **A. Satyanarayan Naidu**, Diamond Bar,
CA (US); **A.G. Tezus Naidu**, Diamond
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Diamond Bar, CA (US)(51) **Int. Cl.****A61K 38/43** (2006.01)**A61K 38/40** (2006.01)**A61K 31/715** (2006.01)**A61K 31/737** (2006.01)**A61K 31/718** (2006.01)(52) **U.S. Cl.** **424/94.1; 514/6; 514/54****Correspondence Address:****KNOBBE MARTENS OLSON & BEAR LLP**
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614 (US)

(57)

ABSTRACT

Formulations are provided for the trigger and release of bioenergy. The formulations generally include a trigger complex, an elemental complex and a coenzyme-vitamin B complex. The trigger complex is high in fiber and includes at least one metal-binding protein in an alkaline buffer system. The elemental complex includes one or more trace element as a suitable salt. The coenzyme-vitamin B complex includes one or more coenzyme, coenzyme precursor and/or B-vitamin. The compositions can be administered orally in a variety of forms.

(21) **Appl. No.: 11/442,473**(22) **Filed: May 26, 2006****Related U.S. Application Data**(60) **Provisional application No. 60/686,257, filed on May 31, 2005.**

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[0015] Among the B-complex vitamins, thiamine (vitamin B1) is required for carbohydrate metabolism. It combines with ATP to form thiamine diphosphate, a coenzyme in carbohydrate metabolism that facilitates the decarboxylation of pyruvic acid and α -ketoglutaric acid. This coenzyme is also a part of transketolation reactions. Thiamine is also a coenzyme in the utilization of pentose in the hexose monophosphate shunt.

[0016] Riboflavin (vitamin B2) is required for tissue respiration. It is converted to the coenzyme riboflavin 5-phosphate (flavin mononucleotide, FMN) and then to the coenzyme flavin adenine dinucleotide (FAD). These act as hydrogen carriers for several enzymes known as flavoproteins, which are involved in oxidation-reduction reactions of organic substrates and in intermediary metabolism. Riboflavin is a cofactor for various respiratory enzymes such as glutaryl coenzyme A dehydrogenase, erythrocyte glutathione reductase, sarcosine dehydrogenase, electron transferring flavoprotein (ETF) dehydrogenase, and NADH dehydrogenase.

[0017] Niacin-Niacinamide (vitamin B3) includes niacin (nicotinic acid) and niacinamide (nicotinamide). The term niacin refers specifically to nicotinic acid, but is also used collectively to refer to both nicotinic acid and nicotinamide. Niacinamide is required for lipid metabolism, tissue respiration, and glycogenolysis. Niacinamide is incorporated into the coenzymes, NAD and NADP that act as hydrogen-carrier molecules.

[0018] Pantothenic acid (vitamin B5) is required for intermediary metabolism of carbohydrates, proteins and lipids. It is a precursor of coenzyme A, which is required for acetylation reactions in gluconeogenesis, in the release of bio-E from carbohydrates, the synthesis and degradation of fatty acids, and the synthesis of sterols, steroid hormones, porphyrins, acetylcholine and other compounds. Pantothenic acid also appears to be essential to normal epithelial function.

[0019] Pyridoxine (vitamin B6) is required for amino acid metabolism. It is also involved in carbohydrate and lipid metabolism. In the body, pyridoxine is converted to coenzymes pyridoxal phosphate and pyridoxamine phosphate, in a wide variety of metabolic reactions. These reactions include transamination of amino acids, conversion of tryptophan to niacin, synthesis of gamma-aminobutyric acid (GABA) in the central nervous system, metabolism of serotonin, norepinephrine and dopamine, metabolism of polyunsaturated fatty acids and phospholipids, and the synthesis of heme, a hemoglobin constituent. Pyridoxine is involved with several of the reactions important for the overall metabolism of nitrogen; therefore, pyridoxine requirements are related to the total amino acid nitrogen burden to be metabolized. Pyridoxine is also a cofactor for enzymes involved in one of two pathways for the metabolism of homocysteine.

[0020] Folic acid (vitamin B9) converts to tetrahydrofolate after physiological absorption. In humans, tetrahydrofolate-based coenzymes play a major role in intracellular metabolism and in the rate-limiting steps of DNA synthesis. Folic acid is also involved in the metabolism of homocysteine.

[0021] Cobalamin (vitamin B12) is required for nucleoprotein and myelin synthesis, cell growth reproduction, and

erythropoiesis. Synthetic vitamin B12 (cyanocobalamin and methylcobalamin) converts to coenzyme B12, which is essential for the conversion of methylmalonate to succinate, and the synthesis of methionine from homocysteine. Vitamin B12 is involved in maintaining sulfhydryl groups in the reduced form required by enzymes involved in fat and carbohydrate metabolism and protein synthesis.

SUMMARY OF THE INVENTION

[0022] Further aspects, features and advantages of this invention will become apparent from the detailed description of the preferred embodiments which follow.

[0023] Embodiments of the invention are directed to compositions having the following components:

[0024] a trigger complex which includes a metal-binding protein and at least one hydrocolloid compound at alkaline pH,

[0025] an elemental complex which includes at least one metal salt, and

[0026] a coenzyme complex which includes at least one coenzyme or coenzyme precursor.

[0027] In preferred embodiments, the metal-binding protein may be selected from transferrin, ovotransferrin, ceruloplasmin and lactoferrin. In a more preferred embodiment, the metal-binding protein is lactoferrin. In yet more preferred embodiments, the metal-binding protein is Fe(III)-lactoferrin, Cu(II)-lactoferrin or Zn(II)-lactoferrin. In a most preferred embodiment, the lactoferrin is lactoferrin-(TCR).

[0028] Preferably, the hydrocolloid compound(s) of the trigger complex are selected from edible celluloses, arabinogalactans, β -glucans, arabinoxylans, glucuronoxylans, xyloglucans, galactomannans, methyl cellulose, hydroxypropylmethyl cellulose (HPMC), inulin, oligofructans, xanthan gum, guar gum, locust bean gum, gum acacia, gum karaya, gum tragacanth, resistant starches, maltodextrins, chemically synthesized polydextrose, lactulose, cellulose derivatives, methyl cellulose, hydroxypropylmethylcellulose, egg lecithin, soybean lecithin, vegilecithin, vitellin, short chain fructooligosaccharides (FOS), transgalactooligosaccharides (TOS), levan, oligofructose, xylooligosaccharides (XOS), curdlan, chitin, chitosan, collagen and chondroitin. More preferably, the hydrocolloid includes maltodextrins, chitin, chitosan, cellulose derivatives, glucomannan, guar gum, locust bean gum, prickly pear cactus and combinations thereof.

[0029] In preferred embodiments, an alkaline pH is provided by a carbonate/bicarbonate buffer system.

[0030] Preferably, the elemental complex includes one or more metal salts such as iron, copper, zinc, manganese, and chromium.

[0031] In preferred embodiments, the coenzyme complex includes one or more cofactor(s) such as coenzyme Q10, NADH, NADPH, coenzyme R and B-complex vitamins. In preferred embodiments, the B-complex vitamins are Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin B9, Vitamin B12, or combinations thereof.

[0032] In some preferred embodiments, compositions according to the invention additionally include D-ribose, L-arginine, L-carnitine or combinations thereof.

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[0033] Preferred embodiments of the invention include a food or beverage which includes any of the compositions described above.

[0034] Preferred embodiments of the invention are directed to compositions which include:

[0035] an elemental complex having at least one component selected from iron, copper, zinc, chromium and manganese;

[0036] a coenzyme complex which includes one or more of coenzyme Q10, coenzyme R, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin B9, and Vitamin B12; and

[0037] a trigger complex which includes a dietary fiber, lactoferrin and a bicarbonate buffer.

[0038] In preferred embodiments, additional components are selected from D-ribose, L-arginine, and L-carnitine or derivatives thereof.

[0039] In preferred embodiments, the dietary fiber includes maltodextrin, glucomannan, guar gum, locust bean gum, prickly pear cactus and combinations thereof.

[0040] In preferred embodiments, the lactoferrin is lactoferrin-(TCR).

[0041] Preferred embodiments of the invention are directed to formulations for weight management which include the elemental complex, the coenzyme complex and the trigger complex as described above, and additional components selected from: dihydroxy acetone, inositol, 5-HTP, choline, milk protein concentrate, and pyruvate.

[0042] Preferred embodiments of the invention are directed to formulations for exercise recovery which include the elemental complex, the coenzyme complex and the trigger complex as described above, and additional components selected from the following ingredients: L-taurine, N-acetyl creatine, dehydroepiandrosterone (DHEA), one or more amino acids, choline, inositol hexanicotinate, and protein powder.

[0043] Preferred embodiments of the invention are directed to formulations for diabetes control which include the elemental complex, the coenzyme complex and the trigger complex as described above, and additional components selected from the following ingredients: chromium, magnesium, banaba leaf extract, cinnamon bark extract, fenugreek extract, and *gymnema* leaf extract. More preferably, the lactoferrin concentration of the trigger complex is 50-500 mg per serving.

[0044] Preferred embodiments of the invention are directed to formulations for control of hyperlipidemia which include the elemental complex, the coenzyme complex and the trigger complex as described above, and additional components selected from the following ingredients: policosanol, sitostanol, octacosanol, flaxseed oil and blond psyllium.

[0045] Preferred embodiments of the invention are directed to formulations for immuno-compromised conditions which include the elemental complex, the coenzyme complex and the trigger complex as described above, and additional components selected from the following ingredi-

ents: superoxide dismutase, lysozyme, lactoperoxidase, 1-theanine, vitamin-E, and blond psyllium.

[0046] Preferred embodiments of the invention are directed to formulations for detoxification support which include the elemental complex, the coenzyme complex and the trigger complex as described above, and additional components selected from the following ingredients: *Lactobacillus* spp., *Bifidobacterium* spp., L-theanine, cranberry root extract, tumeric root extract, inulin and blond psyllium.

[0047] Embodiments of the invention are directed to a method of weight management which includes administering a weight loss bar which includes the elemental complex, the coenzyme complex and the trigger complex as described above, and additional components selected from: dihydroxy acetone, inositol, 5-HTP, choline, milk protein concentrate, and pyruvate, as a meal supplement.

[0048] Embodiments of the invention are directed to a method of weight management which includes the steps of mixing the weight loss formulation described above which includes the elemental complex, the coenzyme complex and the trigger complex as described above, and additional components selected from: dihydroxy acetone, inositol, 5-HTP, choline, milk protein concentrate, and pyruvate, with milk or water and drinking the mixture as a meal supplement.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0049] While the described embodiment represents the preferred embodiment of the present invention, it is to be understood that modifications will occur to those skilled in the art without departing from the spirit of the invention. The scope of the invention is therefore to be determined solely by the appended claims.

Definitions

[0050] The term "coenzyme" has its usual and customary meaning and refers to a small molecule (not a protein but sometimes a vitamin) essential for the activity of some enzymes.

[0051] The term "NADH" has its usual and customary meaning as the reduced form of nicotinamide adenine dinucleotide and also refers to the active coenzyme form of Vitamin B3.

[0052] The term "Flavone" refers to a class of plant secondary metabolites based around a phenylbenzopyrone structure having antioxidant activity.

[0053] The term "B-vitamin" has its usual and customary meaning and includes any B-vitamin including but not limited to vitamin B1 (thiamine), vitamin B2 (riboflavin), vitamin B3 (niacin/niacinamide), vitamin B5 (pantothenic acid), vitamin B6 (pyridoxine), vitamin B9 (folic acid), and vitamin B12 (cobalamin).

[0054] The term "Metalloenzyme" has its usual and customary meaning and refers generally to an enzyme containing a bound metal atom (e.g., cobalt, copper, iron, molybdenum, or zinc) as an integral part of its structure. Specific examples include iron metalloenzymes such as lactoferrin and transferrin; copper containing metalloenzymes such as ferroxidase I, ceruloplasmin, and cytochrome c oxidase; and

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manganese metalloenzymes such as arginase, phosphoenolpyruvate decarboxylase, glutamine synthetase and manganese superoxide.

[0055] The term "coenzyme Q", also known as "ubiquinone" or "ubiquinol", has its usual and customary meaning and refers to a biologically active quinone with an isoprenoid side chain. The various kinds of Coenzyme Q can be distinguished by the number of isoprenoid side chains they have. The most common CoQ in human mitochondria is Q10.

[0056] The term "biotin" (coenzyme R) has its usual and customary meaning and refers to a coenzyme in bicarbonate-dependent carboxylation reactions.

[0057] The term "trigger complex" as used herein refers to a composition that contains at least one metal-transport protein such as lactoferrin, transferrin, ovotransferrin, or ceruloplasmin; and one or more hydrocolloid compounds in an alkaline buffer system.

[0058] The term "elemental complex" as used herein refers to a complex of trace elements in appropriate salt forms. These elements may include but are not limited to iron, copper, zinc, manganese, and/or chromium.

[0059] The term "coenzyme/vitamin B complex" as used herein refers to a complex of coenzymes/coenzyme precursor and B vitamins which may include but are not limited to one or more of coenzyme Q10, coenzyme R and B-complex vitamins.

[0060] The term "hydrocolloid" is a substance that forms a gel with water and as used herein has its usual and customary meaning which specifically includes dietary fiber compounds.

[0061] Embodiments of the invention are directed to methods to formulate compositions for release of bio-E in the form of ATP.

[0062] One object of the present invention is to provide an energy composition, which gives a direct increase of the intracellular level of ATP. The bio-E formulations are suitable for several applications, including but not limited to human and animal health, weight loss, support for diabetic and pre-diabetic conditions, control of hyperlipidemia, support for patients suffering from low energy as a disease side effect (eg. AIDS), chronic fatigue syndrome, neutropenia, post-radiation treatment effects, celiac disease, and support for patients undergoing withdrawal and/or detoxification.

[0063] In preferred embodiments, bio-E formulations may include one or more of the following complexes: a trigger complex, and an elemental complex, and a coenzyme/vitamin-B complex.

[0064] In preferred embodiments, the trigger complex includes a metal-transport protein such as lactoferrin, transferrin, ovotransferrin, and ceruloplasmin. However, any protein that functions to transport essential metals such as iron(III), copper(II), Zn(II), Mn(II) and Cr(II), may be used as a protein component of the trigger complex. In a most preferred embodiment, the trigger complex includes lactoferrin.

[0065] Lactoferrin (LF) is an iron-binding glyco-protein present in milk and various mammalian secretions (e.g. saliva, tears, mucus, and seminal fluids). Crystallographic

studies of LF indicate a bilobate structure (N-terminus and C-terminus lobes) with one iron-binding site in each lobe. LF has ability to reversibly bind two Fe^{3+} ions per lobe in coordination with two CO_3^{2-} ions.

[0066] LF has been found to be an excellent component for the trigger complex. The N- and C-lobes of LF bind/release iron, as well as copper or other essential metal ions over a broad range of pH (acid-alkaline) conditions. As discussed above, metal ions are an essential component of physiological energy production. Iron is a component of cytochromes, and Rieske proteins involved in electron transport as well as Fe—S proteins. While iron and other essential metal ions can be added with dietary supplements, this added iron is not necessarily bioavailable. LF has the physiological role to scavenge and release metal ions, particularly iron, as needed in the body. Therefore, supplying metal ions bound to LF assures that these metal ions will be bioavailable.

[0067] In addition, as LF binds metal ions in a reversible manner, iron bound to LF complex will not be dissociated where release would be unfavorable. It is particularly important that the concentration of the metal ions is in an optimal range. If the concentration is too high, the metal ion may act as an enzyme inhibitor. If the concentration is too low, then the metal ion becomes rate limiting. The inclusion of LF in the trigger complex assures that the metal ions will be provided within an optimal range.

[0068] Furthermore, LF demonstrates a potent antioxidant activity for extended periods of time, i.e. >48 h. This antioxidant activity of LF is important because free radicals such as superoxide and other reactive oxygen species are formed as a side product of the production of bio-E. LF provides an effective physiological free radical scavenging system. Furthermore, as the antioxidant function of LF relies upon reduction of iron to the ferrous form, LF, unlike plant-derived free radical scavengers, is recyclable and not readily depleted. Because of these properties, LF, when incorporated into the trigger complex, will effectively scavenge free radicals that are continuously generated by the electron transport chain (ETC), without any interference with ATP production.

[0069] LF also acts as an antimicrobial agent. In preferred embodiments, the ATP generation that is promoted by the bio-E formulations according to embodiments of the invention occurs in the stomach. Competition by the natural flora in the gut for ATP produced by the bio-E system is controlled by the antimicrobial function of LF present in the complex.

[0070] The LF useful in accordance with the present invention include LF isolated from mammalian sources (humans, cows, sows, mares, transgenic animals and the like), biological secretions such as colostrum, transitional milk, matured milk, milk in later lactation, and the like, or processed products thereof such as skim milk and whey. Also useful is recombinant LF produced in either prokaryotic and eukaryotic cells. The LF is isolated by any conventional method, such as by chromatography, ion-exchanger, molecular-sieve or affinity column. Suitable lactoferrin is available from various commercial sources (N-terminus or Glnbia from USA, Tatua or Fonterra from New Zealand, MG Nutritionals from Australia, Morinaga Milk Company from Japan, DMV International from the Netherlands). In

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preferred embodiments, the LF in the formulations described herein is non-immobilized, i.e. free dispersed native (fdn) form.

[0071] In most preferred embodiments, LF-“Treated for Contamination Reduction (TCR)”, hereafter referred to as LF-TCR (as described in Naidu U.S. Pat. Appl. No. 20050197495, published Sep. 8, 2005) is suitable for the bio-E applications. Briefly, this TCR process includes the successive steps of treating a commercial LF preparation with a surfactant, an antioxidant and a polyphenol to form purified LF (LF-TCR). The LF preparation is mixed with the treatment agents. Typical surfactants include food-grade detergents, bile salts and plant saponins. Typical antioxidants which may be used include Vitamin A, Vitamin C, Vitamin E and metal chelators. Typical polyphenols include oleoresins, aquaresins, terpenes, flavonoids and biliproteins. The treated LF preparation is then dried to provide LF-TCR.

[0072] Preferably, the trigger complex also includes a strong alkaline system. In some embodiments, the buffer system is a carbonate/bicarbonate system, a Tris buffer system, a phosphate buffer system, a borate buffer system or a citrate buffer system. The buffers may be present as salts, preferably, salts of sodium, potassium or calcium. Preferably, the buffer system provides a pH from 7.1-14.0, more preferably from 7.1-8.5.

[0073] In preferred embodiments, the trigger complex includes a hydrocolloid-base. Hydrocolloids are hydrophilic polymers, of vegetable, animal, microbial or synthetic origin, that generally contain many hydroxyl groups and may be polyelectrolytes. They are naturally present or added to control the functional properties of chemicals in an aqueous system. Most important amongst these properties are viscosity (including thickening and gelling) and water binding but also significant are many others including emulsion stabilization, prevention of ice recrystallization and organoleptic properties. Other more specialist applications include adhesion, suspension, flocculation, foam stabilization and film formation. Bioactive molecules are very complex chemicals and this together with the multifactorial functionality of the bio-E formulations several different hydrocolloids are required. Without intending to be bound by theory, it is postulated that the dietary fiber creates an interim pH gradient in a sponge or gel matrix due to the alkalinity of the trigger complex provided by the buffering agent. In the acidic environment of the stomach, a pH gradient is established. Conditions are then ideal for the generation of ATP. The acid-base interaction triggers the ETC, to initiate the ATP synthesis. In preferred embodiments the ATP synthase is provided by the endogenous ATP synthase present in the stomach, released from the interstitial lumen. In some preferred embodiments, an extract from yeast, preferably nutritional yeast or brewers' yeast, nutritional supplements which include *chlorella* or *spirulina* or the like is added to the bio-E formulation to further boost ATP synthase levels. While the gastric juice is acidic and the administration of any alkaline compound(s) into such milieu results in an instant neutralization reaction, certain dietary fibers slow down such acid-base titrations and establish an interim pH gradient.

[0074] Hydrocolloid compounds suitable for the establishment of pH gradients include but are not limited to, edible celluloses; hemicelluloses such as arabinogalactans, β -glucans, arabinoxylans, glucuronoxylans, xyloglucans, and

galactomannans; cellulose derivatives such as methyl cellulose and hydroxypropylmethyl cellulose (HPMC); polyfructoses such as inulin and oligofructans; gums and mucilages such as xanthan gum, guar gum, locust bean gum, gum acacia, gum karaya, gum tragacanth; resistant starches and maltodextrins (both garden variety, Benefiber® and Fiber-sol® brand); chemically synthesized polydextrose; lactulose; cellulose derivatives (eg. methyl cellulose, hydroxypropylmethylcellulose); lecithins such as egg lecithin (ovolecithin), soybean lecithin, vegilecithin, and vitellin; short chain fructooligosaccharides (FOS); transgalactooligosaccharides (TOS); levan; oligofructose; xylooligosaccharides (XOS); curdlan; and fibers from animal origin such as chitin, chitosan, collagen and chondroitin.

[0075] In preferred embodiments, the bio-E formulations include an elemental complex. Preferably, the elemental complex includes trace metals in appropriate salt forms, which may include iron, copper, zinc, manganese, and/or chromium in preferred embodiments. In a most preferred embodiment, the metals are provided as covalently bound to LF. Iron, Copper, Zinc and other metal ions can be covalently bound to LF. As discussed above, when complexed with LF, the metal is in a bio-available form that can be used by the body. The elements are highly effective in the formulation when used as metallo-LF complexes, particularly, the Fe(III)-LF and Cu(II)-LF forms.

[0076] In preferred embodiments, the bio-E formulations include a coenzyme/vitamin-B complex. In preferred embodiments, the coenzyme/vitamin B complex includes one or more of coenzyme Q10, NADH, coenzyme R, and B-complex vitamins (B1, B2, B3, B5, B6, B9, B12). Furthermore, bioactive compounds such as D-ribose, L-arginine, and L-carnitine showed a potential overall synergy to enhance the ATP release when incorporated into the formulation. Inclusion of LF in the coenzyme/vitamin-B complex may facilitate bioavailability of these vitamin cofactors.

[0077] The trigger complex, LF in particular, in combination with specific coenzymes, including but not limited to coenzyme Q10, and NADH demonstrated a catalytic synergy in releasing cellular and extra-cellular ATP.

[0078] The bio-E formulations are suitable for delivery in various forms, including but not limited to tablets (chewables, effervescent), caplets, capsules, suppositories, powders, energy drinks, energy bars, patches, creme, infusions, and other forms that are commonly practiced in the art of manufacturing nutritionals, supplements and therapeutics for total body health and clinical nutrition. In some preferred embodiments, the bio-E formulation may be provided in either powdered or concentrated liquid form which is reconstituted by admixing the powdered or concentrated liquid composition with water. In some preferred embodiments, the bio-E formulation is flavored.

[0079] The bio-E formulations could be administered by various routes, the most preferred is oral, but also by other routes, including but not limited to sublingual, intravenous, intraperitoneal, intramuscular, subcutaneous and vaginal, for clinical nutrition (i.e. chronic fatigue syndrome, diabetes, HIV, cancer, post-operative recovery); sports nutrition (i.e. athletic performance, body building); and weight management.

[0080] The bio-E formulations may be formed by methods well known in the art. When preparing dosages forms

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incorporating the compositions of the present invention, the nutritional components are normally blended with conventional excipients such as binders, including gelatin, pregelatinized starch, and the like; lubricants, such as hydrogenated vegetable oil, stearic acid and the like; diluents, such as lactose, mannose, and sucrose; disintegrants, such as carboxymethyl cellulose and sodium starch glycolate; suspending agents, such as povidone, polyvinyl alcohol, and the like; absorbents, such as silicon dioxide; preservative, such as methylparaben, propylparaben, and sodium benzoate; surfactants, such as sodium lauryl sulfate, polysorbate 80, and the like; and colorants, such as F.D & C. dyes and the like.

[0081] For preparing the formulations as described above, inert, pharmaceutically acceptable carriers are used which are either solid or liquid form. Solid form preparations include powders, tablets, dispersible granules, capsules, and cachets. A solid carrier is suitably one or more substances which may also act as diluents, flavoring agents, solubilizers, lubricants, suspending agents, binders or tablet disintegrating agents. The solid carrier material also includes encapsulating material. In powders, the carrier is finely divided active compounds. In the tablet, the active compound is mixed with the carrier having the necessary binding properties in suitable proportions and compacted in the shape and size desired. Suitable solid carriers include, but are not limited, to magnesium carbonate, magnesium stearate, talc, sugar, lactose, pectin, dextrin, starch, gelatin, tragacanth, methylcellulose, sodium carboxymethylcellulose, a low melting wax, cocoa butter, and the like. The term preparation is intended to include the formulation of the active compounds with encapsulating material as the carrier providing a capsule in which the active component (with or without other carriers) is surrounded by carrier, which is thus in association with it. Tablets, powders, cachets, and capsules may be used in a solid dosage form suitable for oral administration.

[0082] Liquid form preparations include solutions, suspensions, and emulsions. Aqueous solutions suitable for oral use are prepared by dissolving the active component in water or other suitable liquid and adding suitable colorants, flavors, stabilizing agents, and thickening agents as desired. Aqueous solutions suitable for oral use may also be made by dispersing the finely divided active component in water or other suitable liquid with viscous material, such as natural or synthetic gums, resins, methylcellulose, sodium carboxymethylcellulose, and other suspending agents known in the art.

[0083] Also included are solid form preparations which are intended to be converted, shortly before use, to liquid form preparations for either oral or parental administration. Such liquid forms include solutions, suspensions, and emulsions. These particular solid form preparations are provided in unit dose form and as such are used to provide a single liquid dosage unit. Alternatively, sufficient solid preparation may be provided so that the after conversion to liquid form, multiple individual liquid doses may be obtained by measuring predetermined volumes of the liquid form preparation as with a syringe, teaspoon, or other volumetric contained.

[0084] The solid and liquid forms may contain, in addition to the active material, flavorants, colorants, stabilizers, buffers, artificial and natural sweeteners, dispersants, thickeners, solubilizing agents, and the like. The liquid utilized for

preparing the liquid form preparation is suitably water, isotonic water, ethanol, glycerin, propylene glycol, and the like, as well as combinations thereof. The liquid utilized will be chosen with regard to the route of administration.

[0085] Preferably, the preparations are unit dosage form. In such form, the preparation is subdivided into unit doses containing appropriate quantities of the active components. The unit dosage form can be a packaged preparation, such as packaged tablets or capsules. The unit dosage can be a capsule, cachet, or tablet itself or it can be the appropriate number of any of these in packaged form.

[0086] The quantity of active material in a unit dose of preparation is varied according to the particular application and potency of the active ingredients.

[0087] Determination of the proper dosage for a particular situation is within the skill of the art. For convenience, the total daily dosage may be divided and administered in portions during the day if desired. Controlled and uncontrolled release formulations are also included.

[0088] The energy drink or tablet could be taken as often as needed to increase energy. Bio-E formulations according to embodiments of the invention provide ideal conditions for physiological energy production. The bio-E formulations provide ideal conditions for making ATP while relying upon the body's own capacity for producing ATP. Addition of sugars and high calorie components are not necessary to obtain the effect. Accordingly, bio-E formulations may be used in weight loss and calorie burning.

[0089] Bio-E formulations have the advantage that they provide for release of energy without additives such as caffeine. The components are all natural, physiological biomolecules and ions that rely upon stimulation of the user's own system to release energy and possibly promote weight loss.

EXAMPLE 1

Exemplary Trigger Complex

[0090] A non-limiting example of a Trigger Complex with the active ingredients is shown in the following Table 1.

TABLE 1

Active Ingredient	Effective range (mg)	Preferred range (mg)	Per Serving (mg)
Lactoferrin	0.001-10,000	5-500	30
Sodium bicarbonate	0.1-10,000	10-1000	200
Potassium bicarbonate	0.1-10,000	10-1000	200
Magnesium (II)	1-1000	4-400	40
Citric acid	0.1-10,000	10-1000	200
Maltodextrin	10-100,000	100-10,000	1500

[0091] The above ingredients are mixed/milled to a fine blend as is or in combination with the ingredients of the Elemental Complex and/or the Coenzyme/Vitamin-B complex to make the final blend. LF could be used in free-dispersed native form (fdn) or could be used as admixtures of metal-unsaturated, partially saturated and fully saturated LF forms. The above LF preparations further processed to LF-(TCR) form is the most preferred ingredient suitable for the bio-E applications. Depending upon the required viscos-

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fat). Use of the formulation exemplified in Table 8 is helpful in achieving this ideal range.

TABLE 8

Complex/Ingredient	Composition per Serving	
	Amount (g)	% wt/wt
ELEMENTAL COMPLEX	(0.05 g)*	0.1%
COENZYME COMPLEX	(0.05 g)*	0.1%
TRIGGER COMPLEX (bio-E)	(5.6 g)*	11.2%
Lactoferrin-(TCR)	0.1 g	
Sodium bicarbonate	0.1 g	
Potassium bicarbonate	0.1 g	
Magnesium	0.1 g	
Citric acid	0.2 g	
Prickly pear cactus	1.5 g	
Locust bean gum	1.5 g	
Guar gum	2.0 g	
FUNCTIONAL INGREDIENTS	(5.2 g)*	10.4%
Vanadium (Vanadyl sulfate)	0.01 g	
Banaba Extract (1% corosolic acid)	0.05 g	
Cinnamon	0.05 g	
Fenugreek (<i>Trigonella foenum</i>) seed extract	0.04 g	
Gymnema Sylvestre	0.05 g	
Blond psyllium	5.0 g	
EXCIPIENTS	(39.1 g)*	78.2%
Total weight*	50 g	100%

[0123] As shown above in Table 8, the Trigger Complex of the bio-E system is reformulated with prickly pear cactus, locus bean gum and guar gum to suit the diabetes-support formulation.

[0124] Diabetes is associated with abnormally high levels of glucose-modified proteins bearing advanced glycation endproducts (AGEs) in tissue and plasma. Elevated AGEs could block the activity of endogenous antimicrobial agents and predispose the diabetic individuals to microbial infections. AGEs interact with two specific binding domains on LF molecule to inactivate the bacterial agglutination and antimicrobial activity of this protein. A common 17-18 amino acid cysteine loop was identified in LF molecule as AGE-Binding Cysteine-bounded Domain, (ABCD motif). Similar ABCD motifs are also present in other antimicrobial proteins such as defensins. Synthetic peptides corresponding to ABCD motifs in LF could bind competitively to AGEs and may provide a basis for the development of new approaches to prevent diabetic infections [Li, 1998]. Due to its critical role in diabetes, LF concentration in the trigger complex is increased to 100 mg per serving. (Li Y M. Glycation ligand binding motif in lactoferrin. Implications in diabetic infection. Adv Exp Med Biol 443:57-63, 1998).

[0125] Preferred embodiments of the formulation for control and prevention of diabetes has the following additional beneficial components. Chromium in the elemental complex plays a role in regulating the uptake of sugars into the cell. Chromium supplements (30-600 mcg a day) may be helpful to people suffering from diabetes or persons with a pre-diabetic condition. Chromium is preferably supplied as chromium picolinate or chromium histidine.

[0126] Low magnesium correlates with diabetes and risk of developing diabetes. Many people, especially older people, do not get enough magnesium. Preferred embodiments of the formulations contain 100-500 mg magnesium.

In preferred embodiments, magnesium may be supplied as magnesium acetate, aspartate, carbonate, chloride, citrate, glycinate, hydroxide, lactate, oxide, or pidolate.

[0127] Preferred embodiments of the invention include other functional ingredients such as the phytochemical extracts from banaba leaf, cinnamon bark, fenugreek seed and *gymnema* leaves. Banaba leaf extract contains a triterpenoid compound known as corosolic acid that stimulates glucose transport into cells. Banaba plays a role in regulating sugar and insulin levels in the blood. For certain individuals, fluctuations in blood sugar and insulin are related to appetite, hunger and various food cravings, particularly craving for carbohydrates such as bread and sweets. By maintaining the blood sugar and insulin levels in check, banaba may be an effective supplement for promoting weight loss. Cinnamon bark contains 60-80% of volatile oils, cinnamaldehyde in particular, which has been suggested for antispasmodic, antifatulent, and appetite stimulant effects. Methyl-hydroxy chalcone polymer (MHCP), an active constituent of cinnamon has been reported to improve insulin sensitivity. Fenugreek seeds contain a high proportion (40%) of mucilage, a soluble fiber. Mucilage forms a gelatinous structure (similar to guar gum) that may have effects on slowing the digestion and absorption of food in the intestinal tract. Such effect could result in a slow and steady rise of blood sugar in certain diabetic individuals. Other compounds such as the saponins in fenugreek seeds may have a beneficial role in lowering the cholesterol production in the liver. *Gymnema sylvestre* leaves contain gymnemic acids, which are known to suppress glucose transport from the intestine to the blood stream. *Gymnema* also contains a small protein, gumar, that can interact with receptors on the tongue to decrease the sensation of sweetness in many foods. This dual action has been shown to reduce blood sugar and cholesterol levels in diabetic individuals and may provide health benefits by controlling appetite and food cravings.

[0128] Preferred embodiments of the invention include one or more fibrous hydrocolloids. The fibrous polysaccharides of guar gum, locust bean gum and prickly pear cactus in the trigger complex and blond psyllium cumulatively decrease serum cholesterol levels by adsorbing dietary fats in the gastrointestinal tract and by reducing systemic absorption of the fat. The hydrocolloidal blend could induce hypoglycemic effects within 3-4 hours after ingestion of the formula and can last up to 6 hours. The fiber also seems to increase cholesterol elimination in fecal bile acids.

EXAMPLE 9

Exemplary Bio-E Formulation for the Control of Hyperlipidemia

[0129] The two primary lipids found in blood are cholesterol and triglycerides. An elevated level of these two lipid forms is generally referred to as hyperlipidemia, which is associated with increased risk of heart disease and stroke. Formulations according to embodiments of the present invention facilitate an optimal intake, metabolism of total fats and increased energy for physical activity. Both increased physical activity and regulation of fats obtained from dietary sources are useful strategies in coping with hyperlipidemia. A non-limiting example of a bio-E formula for control of hyperlipidemia is shown in Table 9.

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TABLE 9

Complex/Ingredient	Composition per Serving	
	Amount (g)	% wt/wt
ELEMENTAL COMPLEX	(0.05 g)*	0.1%
COENZYME COMPLEX	(0.05 g)*	0.1%
TRIGGER COMPLEX (bio-E)	(5.6 g)*	11.2%
Lactoferrin-(TCR)	0.1 g	
Sodium bicarbonate	0.1 g	
Potassium bicarbonate	0.1 g	
Magnesium	0.1 g	
Citric acid	0.2 g	
Prickly pear cactus	1.5 g	
Locust bean gum	1.5 g	
Guar gum	2.0 g	
FUNCTIONAL INGREDIENTS	(5.6 g)*	11.2%
Policosanol	0.01 g	
Sitostanol	0.08 g	
Octacosanol	0.01 g	
Flaxseed Oil	0.5 g	
Blond psyllium	5.0 g	
EXCIPIENTS	(38.7 g)*	77.4%
Total weight*	50 g	100%

[0130] As shown above in Table 9, the Trigger Complex of the bio-E system is similar to the one described for diabetes control formulation described in Example 8. Furthermore, blond psyllium in the composition provides a similar hydrocolloidal format (with polysaccharides of the trigger complex) for the management of hyperlipidemia.

[0131] Other functional ingredients such as the phytosterols, including but not limited to, policosanol, sitostanol and octacosanol are incorporated in the bio-E hyperlipidemia-control formulation. Policosanol has been suggested to inhibit cholesterol synthesis in the liver. The Cuban sugarcane-derived policosanol is reported to lower cholesterol, reduce the risk of blood clots and enhance circulation. Sitostanol, alone and in combination with other plant sterols, reduces blood cholesterol levels by blocking systemic absorption of triglycerides. Octacosanol, a 28-carbon waxy alcohol, improves oxygen utilization during anaerobic glycolysis and helps to remove lactic acid by increasing the efficacy of tricarboxylic acid cycle. Octacosanol also suppresses lipid accumulation in the adipose tissue and increases the mobilization of free fatty acids from fat cells in the muscle. Octacosanol could lower the LDL cholesterol levels and raise the HDL cholesterol levels by regulating the cholesterol production by liver. Preferred formulations for hyperlipidemia control may include alpha-linoleic acids and/or omega-3 fatty acids to lower both triglycerides and cholesterol.

EXAMPLE 10

Exemplary Bio-E Formulation for Celiacs

[0132] Celiac disease refers to a genetic inability to absorb gluten, a protein found in wheat, barley, rye, and some oat products. Exposure to gluten causes inflammation of the membrane that lines the small intestine. Besides abdominal pain and swelling, lack of energy results from the lessened ability to absorb nutrients.

[0133] In order to provide an energy supplementation for individuals with celiac conditions, bio-E can be formulated

with gluten-free ingredients. The trigger complex and functional components of bio-E formulation could be selected from the list of ingredients that are compatible with the dietary requirements of individuals affected with celiac conditions.

EXAMPLE 11

Exemplary Bio-E Formulation for Immuno-Compromised Conditions

[0134] Bio-E formulations according to embodiments of the invention are beneficial for patients suffering from immuno-compromised conditions such as neutropenia, diseases of neutrophil dysfunction, chronic fatigue syndrome, radiation-associated side effects, and immune deficiency syndromes (e.g. AIDS). These immuno-compromised conditions manifest in lower energy levels due to disease symptoms or disease treatments.

[0135] Besides manifesting a low physiological energy state, neutrophil deficiency and/or dysfunction is one of the major underlying conditions in the immuno-compromised host. Body levels of several neutrophil secretory components (eg. LF, superoxide dismutase, lysozyme, peroxidases) that are essential for protection against harmful pathogens and allergens may be diminished or absent during immuno-compromised conditions. Therefore, the bio-E formulation of the present invention has been enriched with natural host defense factors to provide protection to the immuno-compromised host from potential infections. A non-limiting example of bio-E formulation for the support of immuno-compromised host is shown in Table 10.

TABLE 10

Complex/Ingredient	Composition per Serving	
	Amount (g)	% wt/wt
ELEMENTAL COMPLEX	(0.05 g)*	1.1%
COENZYME COMPLEX	(0.05 g)*	1.1%
TRIGGER COMPLEX (bio-E)	(2.13 g)*	47.3%
Lactoferrin-(TCR)	0.1 g	
Sodium bicarbonate	0.1 g	
Potassium bicarbonate	0.1 g	
Magnesium (31% as citrate)	0.13 g	
Citric acid	0.2 g	
Lecithin	0.1 g	
Maltodextrin	1.5 g	
FUNCTIONAL INGREDIENTS	(1.0 g)*	22.2%
Superoxide dismutase (SOD)	0.025 g	
Lysozyme (from hen egg)	0.025 g	
Lactoperoxidase (from cow milk)	0.025 g	
L-theanine (from Green tea)	0.025 g	
Vitamin-E (α -D-tocopheryl acetate)	0.1 g	
Blond psyllium	0.6 g	
EXCIPIENTS	(~1.3 g)*	28.3%
Total weight*	(4.5 g)*	100%

[0136] As shown above in Table 10, the bio-E formula is enriched with functional ingredients such as antimicrobial agents (eg. LF, lactoperoxidase (LPO), and lysozyme (LZ)) and antioxidants (eg. superoxide dismutase (SOD), L-theanine and vitamin-E).

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[0137] Superoxide dismutase (SOD) is an essential enzyme found in all living cells. It catalyzes the conversion of toxic superoxide to oxygen and hydrogen peroxide. The action of SOD is believed to prevent oxygen-related damage to body tissues. The SOD useful in accordance with the present invention include SOD extracted from melon fruit, commercially available from Isocell Nutra, France.

[0138] Lysozyme (LZ) also known as muraminidase is ubiquitous in both the animal and plant kingdoms, which plays an important role in the natural defense mechanism. LZ is a potent antimicrobial system that promotes catalysis by inducing steric stress in the substrate, most effective against gram-positive bacteria. The LZ useful in accordance with the present invention include LZ isolated from hen egg, commercially available from Inovatech, Canada.

[0139] Lactoperoxidase (LPO) is a hemoprotein also present in milk, tears, and saliva. LPO constitutes one of the non-immunoglobulin defense factors in the mucosal secretions. LPO catalyzes the oxidation of electron donors by peroxide to generate highly reactive products with a wide range of antimicrobial properties. The LPO useful in accordance with the present invention include LPO isolated from mammalian sources (humans, cows, sows, mares, transgenic animals and the like), biological secretions such as colostrum, transitional milk, matured milk, milk in later lactation, and the like, or processed products thereof such as skim milk and whey. Suitable LPO is available from various commercial sources (Tatua or Fonterra from New Zealand, Morinaga Milk Company from Japan, DMV International from the Netherlands).

EXAMPLE 12

Exemplary Bio-E Formulation for Detoxification Support

[0140] Bio-E formulations according to the invention are beneficial for any person going through detoxification or drug withdrawal, including but not limited to withdrawal from nicotine, alcohol, pain killers, and opiates because they provide optimal conditions for the body to use its own resources to provide energy in the form of ATP and because formulations according to the invention include additional components to promote overall good health.

[0141] Most detoxification conditions, colon cleansing systems in particular, could eliminate several host mucosal components, nutrients and beneficial probiotic bacteria from the physiological system. Therefore, it is important to refurbish the microenvironment of the mucosal system that has undergone the detoxification process. Furthermore, during the recovery phase following the detoxification procedure, it is necessary to protect the treated physiological system with appropriate defense factors. Accordingly, the bio-E system of the present invention has been formulated with probiotic lactic acid bacteria (eg. *Lactobacillus* spp. and *Bifidobacterium* spp.) to reinforce the physiological system that has undergone a detoxification process. A non-limiting example of bio-E formulation for the supplementation of detoxification systems is shown in Table 11.

TABLE 11

Complex/Ingredient	Composition per Serving	
	Amount (g)	% wt/wt
ELEMENTAL COMPLEX	(0.05 g)*	0.6%
COENZYME COMPLEX	(0.05 g)*	0.6%
TRIGGER COMPLEX (bio-E)	(1.7 g)*	21.2%
Lactoferrin-(TCR)	0.1 g	
Sodium bicarbonate	0.2 g	
Potassium bicarbonate	0.1 g	
Magnesium (31% as citrate)	0.1 g	
Citric acid	0.2 g	
Maltodextrin	1.0 g	
FUNCTIONAL INGREDIENTS	(4.15 g)*	51.9%
<i>Lactobacillus</i> spp. (50 billion CFU/g)	0.25 g	
<i>Bifidobacterium</i> spp. (50 billion CFU/g)	0.25 g	
L-theanine (green tea extract)	0.05	
Cranberry extract	0.05	
Turmeric root extract	0.05	
Inulin	0.5 g	
Blond psyllium	3.0 g	
EXCIPIENTS	(~2.06 g)*	25.7%
Total weight*	8 g	100%

[0142] As shown above in Table 11, the bio-E formula is supported with prebiotic systems (eg. LF and inulin), probiotic flora (eg. *Lactobacillus* spp., *Bifidobacterium* spp.) and antimicrobial/antioxidant systems (eg. cranberry and turmeric root extracts).

[0143] The formulations of the present invention can further include probiotic lactic acid bacteria (LAB) in a viable cell preparation or a non-viable cell preparation in the form of a freeze-dried powder or an emulsion for delivery with bio-E formulations.

[0144] The probiotic organisms envisaged in accordance with this invention include a physiologically effective dosage of at least one LAB strain, typically in the form of a freeze-dried powder or emulsion, such as the strains of bacteria of the genus *Lactobacillus* including *L. acidophilus*, *L. amylovorus*, *L. animalis*, *L. bavaricus*, *L. brevis*, *L. bulgaricus*, *L. casei* spp. *casei*, *L. casei* spp. *rhannosus*, *L. crispatus*, *L. delbrueckii* ssp. *lactis*, *L. eichmanni*, *L. fermentum*, *L. helveticus*, *L. jensenii*, *L. kefir*, *L. paracasei*, *L. pentosus*, *L. plantarum*, *L. reuteri*, *L. salivarius*, and *L. sake*; the genus *Leuconostoc* including *Leu. cremoris* and *Leu. lactis*; the genus *Bifidobacterium* including *B. adolescentis*, *B. animalis*, *B. bifidum*, *B. breve*, *B. infantis*, *B. longum*, and *B. thermophilum*; the genus *Pediococcus* including *Ped. acidilactici* and *Ped. pentosus*; the genus *Peptostreptococcus* including *Pep. assacharolyticus*, and *Pep. productus*; the genus *Propionibacterium* including *Pro. acidipropionici*, *Pro. freudenreichii*, *Pro. jensenii*, and *Pro. theonii*; the genus *Streptococcus* including *S. cremoris*, *S. faecium*, *S. lactis*, *S. raffinolactis*, and *S. thermophilus*. The probiotic organisms are collectively known as "lactic acid bacteria"; or "LAB".

[0145] The effective dosages of probiotic in a mixed composition range between 10^2 to 10^{12} colony forming units; preferably between 10^5 to 10^{10} colony forming units per serving. Wherein the non-viable counts of probiotic in a mixed composition range between 10^2 to 10^{12} colony forming units; preferably between 10^5 to 10^{10} colony forming units per serving.

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[0146] Although the above supplements have been described with reference to specific formulations, it will be recognized that these supplements may be included in other formulations as disclosed herein for their well known benefits.

[0147] It will be understood by those of skill in the art that numerous and various modifications can be made without departing from the spirit of the present invention. Therefore, it should be clearly understood that the forms of the present invention are illustrative only and are not intended to limit the scope of the present invention.

What is claimed is:

1. A composition comprising:

a trigger complex comprising a metal-binding protein and at least one hydrocolloid compound at alkaline pH,

an elemental complex comprising at least one metal salt, and

a coenzyme complex comprising at least one coenzyme or coenzyme precursor.

2. The composition of claim 1, wherein the metal-binding protein is selected from the group consisting of transferrin, ovotransferrin, ceruloplasmin and lactoferrin.

3. The composition of claim 2, wherein the metal-binding protein is lactoferrin.

4. The composition of claim 3, wherein the lactoferrin is lactoferrin-(TCR).

5. The composition of claim 1, wherein the hydrocolloid compound is selected from the group consisting of edible celluloses, arabinogalactans, β -glucans, arabinoxylans, glucuronoxylans, xyloglucans, galactomannans, methyl cellulose, hydroxypropylmethyl cellulose (HPMC), inulin, oligofructans, xanthan gum, guar gum, locust bean gum, gum acacia, gum karaya, gum tragacanth, resistant starches, maltodextrins, chemically synthesized polydextrose, lactulose, cellulose derivatives, methyl cellulose, hydroxypropylmethylcellulose, egg lecithin, soybean lecithin, vegilecithin, vitellin, short chain fructooligosaccharides (FOS), transgalactooligosaccharides (TOS), levan, oligofructose, xylooligosaccharides (XOS), curdian, chitin, chitosan, collagen and chondroitin.

6. The composition of claim 1, wherein the alkaline pH is provided by a carbonate/bicarbonate buffer system.

7. The composition of claim 1, wherein the elemental complex comprises one or more metal salts selected from the group consisting of iron, copper, zinc, manganese, and chromium.

8. The composition of claim 1, wherein the metal-binding protein is Fe(III)-lactoferrin, Cu(II)-lactoferrin or Zn(II)-lactoferrin.

9. The composition of claim 1, wherein the hydrocolloid is selected from the group consisting of maltodextrins, chitin, chitosan, cellulose derivatives, glucomannan, guar gum, locust bean gum, prickly pear cactus and combinations thereof.

10. The composition of claim 1, wherein the coenzyme complex comprises one or more cofactor selected from the group consisting of coenzyme Q10, NADH, NADPH, coenzyme R and B-complex vitamins.

11. The composition of claim 10, wherein the B-complex vitamins are selected from the group consisting of Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin B9, Vitamin B12, and combinations thereof.

12. The composition of claim 1, further comprising D-ribose, L-arginine, L-carnitine or combinations thereof.

13. A food or beverage comprising the composition of claim 1.

14. A composition comprising:

an elemental complex comprising at least one selected from the group consisting of iron, copper, zinc, chromium and manganese;

a coenzyme complex comprising at least two selected from the group consisting of coenzyme Q10, coenzyme R, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin B9, and Vitamin B12; and

a trigger complex comprising a dietary fiber, lactoferrin and a bicarbonate buffer.

15. The composition of claim 14, further comprising at least one additional component selected from the group consisting of D-ribose, L-arginine, and L-carnitine or derivatives thereof.

16. The composition of claim 14, wherein the dietary fiber comprises maltodextrin, glucomannan, guar gum, locust bean gum, prickly pear cactus and combinations thereof.

17. The composition of claim 14, wherein the lactoferrin is lactoferrin-(TCR).

18. A formulation for weight management comprising the composition of claim 16, and further comprising at least two of the following ingredients: dihydroxy acetone, inositol, 5-HTP, choline, milk protein concentrate, and pyruvate.

19. A formulation for exercise recovery comprising the composition of claim 16, and further comprising at least two of the following ingredients: L-taurine, N-acetyl creatine, dehydroepiandrosterone (DHEA), one or more amino acids, choline, inositol hexanicotinate, and protein powder.

20. A formulation for diabetes control comprising the composition of claim 16, and further comprising at least two of the following ingredients: chromium, magnesium, banaba leaf extract, cinnamon bark extract, fenugreek extract, and *Gymnema* leaf extract.

21. The formulation of claim 20, wherein the lactoferrin concentration is 50-500 mg per serving.

22. A formulation for control of hyperlipidemia comprising the composition of claim 16, and further comprising at least two of the following ingredients: policosanol, sitostanol, octacosanol, flaxseed oil and blond psyllium.

23. A formulation for immuno-compromised conditions comprising the composition of claim 16, and further comprising at least two of the following ingredients:

superoxide dismutase, lysozyme, lactoperoxidase, L-theanine, vitamin-E, and blond psyllium.

24. A formulation for detoxification support comprising the composition of claim 16, and further comprising at least two of the following ingredients: *Lactobacillus* spp., *Bifidobacterium* spp., L-theanine, cranberry root extract, tumeric root extract, inulin and blond psyllium.

25. A method of weight management which comprises administering a weight loss bar comprising the formulation of claim 18 as a meal supplement.

26. A method of weight management which comprises mixing the formulation of claim 18 with milk or water and drinking the mixture as a meal supplement.

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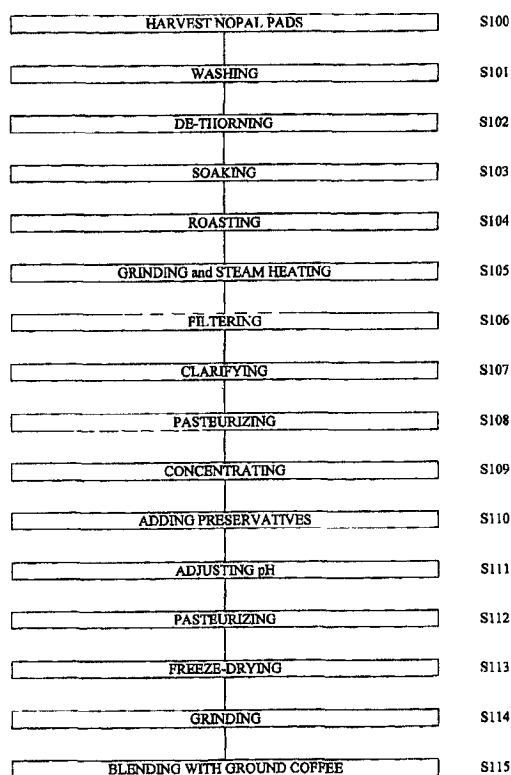
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- (71) Applicant and
(72) Inventor: **AMATO, Teri** [US/US]; 5708 226th Street,
Bayside, NY 11364 (US).
- (72) Inventors; and
(75) Inventors/Applicants (for US only): **AGARWALA, Om,**
P. [US/US]; 616 Via Linda Court, Las Vegas, NY 89144
(US). **AGARWALA, Chandrakala** [US/US]; 616 Via
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- (74) Agents: **BARON, Ronald, J.** et al.; Hoffman & Baron,
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[Continued on next page]

(54) Title: COMPOSITIONS CONTAINING A NOPAL CACTUS ISOLATE AND METHOD FOR MAKING SAME



(57) Abstract: Compositions and methods of making compositions containing nopal cactus isolates derived from the juice and/or soluble solid fractions of nopal pads. In another aspect, the invention relates to comestible containing the nopal cactus isolates. In yet another aspect, the invention relates to compositions for making tea, tea compositions and methods of making such compositions, which contain nopal cactus isolates.

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COMPOSITIONS CONTAINING A NOPAL CACTUS ISOLATE AND METHOD FOR MAKING SAME

5 This application is a continuation-in-part of U.S. Application Serial No. 10/847,217, filed on May 17, 2004, the contents of which is incorporated by reference.

BACKGROUND OF THE INVENTION

10 The present invention relates to dietary supplements and compositions containing nopal cactus isolates derived from the juice and/or soluble solid fractions of nopal pads and methods of preparing the supplements and compositions. The invention also specifically relates to compositions for making coffee, coffee compositions and methods for making such compositions, which contain the nopal cactus isolates.

15 In developed countries around the world, there is a tremendous interest in personal fitness and wellness. At the same time there is a disturbing trend that people, including adults and children are becoming overweight. By overweight, it is meant that the subject has exceeded acceptable weight range and percent body fat generally considered as healthy determined by factors including, but not necessarily limited to
20 age, height, sex, and body type. For example, over 50% of the human population in the United States is considered overweight, approximately 20% being obese. Obesity produces a wide range of health concerns including sleep apnea, orthopedic complications, arterial sclerosis, diabetes and heart disease. All these undesirable conditions contribute in development of an unsatisfactory quality of life and in some
25 cases premature death.

 Many studies have been conducted to identify the factors that contribute to being overweight. The main factors include high caloric density in foods, large portion sizes, diets that are rich in fat, decreasing amounts of exercise, high
30 availability of food, increased numbers of eating occasions, low knowledge of actual foods and portions eaten by the consumer, lack of information on energy expenditure

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BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a flowchart showing a process for preparing a coffee blend containing isolate granules from nopal cactus pads according to a preferred embodiment of the present invention.

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DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to dietary supplements and compositions containing nopal cactus isolates, methods of making such supplements and methods for improving health by consuming such supplements. The isolates are preferably derived from the juice and/or soluble solid fractions of nopal pads of the *opuntia ficus*
10 *indica* and/or *opuntia streptacantha lemaire* variety.

The nopal cactus isolates according to the invention maximize the effects of lowering cholesterol, stabilizing blood glucose and insulin levels and promoting healthy weight management, which can reduce the risks of coronary heart disease and diabetes without the side effects and disadvantages of other supplements or products
15 currently being used. While not being bound by theory it is believed that the nopal cactus isolates of the present invention maximize the concentration and availability of phytonutrients which are naturally contained in the nopal pad juice and soluble solid fractions and which are effective for lowering cholesterol, stabilizing blood glucose and insulin levels and promoting healthy weight management. It is also believed that
20 by isolating the juice and soluble solid fractions from the insoluble fiber and solid materials, the availability and uptake of the desired phytonutrients is improved.

The nopal cactus isolates are also prepared in such a way as to enhance the flavor of the nopal pad juice and resulting isolate, and to achieve a particle size and density which is compatible with a selected foodstuff or supplement, e.g., ground
25 coffee or tea. This results in food products having superior flavor, while maximizing the delivery and uptake of the phytonutrients naturally found in the nopal pad juice and soluble solid fractions.

Consuming coffee which contains the nopal pad isolates is a convenient and effective way to obtain the health benefits of the nopal isolates. It is also believed that
30 the nopal isolates and coffee work together synergistically to increase metabolism,

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reduce obesity and control weight, while at the same time lowering cholesterol and blood glucose and insulin levels.

In one aspect, the invention relates to a composition for making coffee which includes a nopal cactus isolate, derived from the juice and/or soluble solid fractions of
5 nopal pads of the *opuntia ficus indica* variety, and roasted ground coffee beans.

The nopal cactus isolate can be freeze-dried. Preferably, the freeze-dried isolate is present in an amount to enhance weight reduction and/or reduce cholesterol as a result of consuming the coffee made from the composition.

It is preferred that the nopal pads are young nopal pads harvested prior to
10 flowering of the cactus plant. It is also preferred that the nopal pads are roasted in a controlled manner to enhance the flavor of the isolate. More specifically, the isolate can have a flavor that is compatible with brewed coffee.

The composition can be in a form suitable for making coffee by a method selected from the group consisting of drip, percolation, press, espresso, latte, instant
15 coffee and flow-through bag. Preferably, the coffee made by the present composition is intended to be served hot. Thus, it is also contemplated that the composition can be brewed into coffee and then the brewed coffee can be freeze-dried or otherwise formed into a reconstitutable powder that, when reconstituted with hot water, provides a nutritionally superior product to simple brewed coffee, and that possesses the health
20 benefits of the nopal pad isolate.

It is also contemplated that the coffee can contain other ingredients to provide additional health benefits or to improve the drinking experience. Preferably, the ingredients that provide additional health benefits are natural health promoting ingredients, such as, for example, Bitter Orange, Gracinia Cambogia or Kola Nut
25 Extract.

Ingredients that improve the drinking experience can include sweeteners, whitening agents or flavorants. Preferred flavorants include spices such as cinnamon, mint, peppermint, cardamom, ginger and nut flavors.

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cleavage or breakdown of the long chain glucomannons and polyphenols found in the juice and soluble solid fractions of the nopal pads.

The isolate is preferably derived from young nopal pads harvested prior to flowering of the plant. Preferably, the nopal pads are roasted in a controlled manner
5 prior to juicing to enhance the flavor of the isolate.

It is contemplated that the isolate can be added to any suitable carrier or edible additive. In one embodiment, the supplement is in liquid form with the isolate being added to any of a variety of water-based foodstuffs, such as drinks, for example, flavored water, juice drinks, sports drinks or drink mixes. Preferably, the supplement
10 is the form of a hot beverage, for example, a brewed or instant tea or coffee. The brewed tea or coffee can be produced by brewing a composition containing tea leaves and the nopal isolate or a composition containing ground coffee and the nopal isolate, respectively. The instant tea or coffee can be produced by freeze-drying or otherwise forming the brewed tea or coffee into a reconstitutable powder that can be
15 reconstituted with hot water. Alternatively, a standard instant tea or coffee can be blended with a reconstitutable nopal isolate powder. Preferably, the supplement is in a form selected from the group consisting of a juice, coffee and tea.

In yet another aspect, the invention is directed to a method for making a dietary supplement, which includes roasting nopal cactus pads of the *opuntia ficus*
20 *indica* and/or *opuntia streptacantha lemaire* cactus variety; grinding the roasted pads; substantially separating juice and soluble solid fractions from insoluble fractions of the ground and roasted pads; and freeze-drying the juice and soluble fractions to form a powder.

The method can include blending the powder with ground roasted coffee
25 beans to provide a composition suitable for brewing coffee. In such a case, the roasting step is preformed under conditions to make the taste compatible with brewed coffee.

The method can also include, prior to freeze-drying, the steps of heating the ground nopal pads to inactivate the cellulase enzyme naturally present in fresh nopal
30 pads; filtering out the insoluble pulp from the nopal pad juice and soluble solid

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In a preferred embodiment, the invention is directed to a nopal composition which includes a water soluble solidified isolate derived from nopal pads of the *opuntia* genus. The nopal pads are preferably of a variety selected from the group consisting of *opuntia ficus indica*, *opuntia streptacantha lemaire* and combinations thereof. In one embodiment, the solid isolate consists essentially of juice and water soluble solid fractions of the nopal pads. Preferably, the isolate is freeze-dried.

The nopal pads are preferably young nopal pads harvested prior to flowering of the cactus plant. The nopal pads are also preferably roasted in a controlled manner to enhance the flavor of the isolate. In one embodiment, the isolate is in a form of a dispersion of solid particles. The isolate is preferably rich in phytonutrients naturally found in the water soluble fractions of said nopal pads. These phytonutrients are preferably substantially preserved and concentrated in the isolate. Preferably, the solid isolate has a solubility of at least about 150 g/liter of water, more preferably at least about 200g/liter of water and most preferably about 250g/liter of water (measured at 20°C). In one embodiment, the solid isolate can be reconstituted to a liquid by adding water and mixing.

Typically, the solid isolate is a dispersion of solid particles having a moisture content of less than about 10 wt%. The isolate can be in a form selected from the group consisting of pellets, granules and powder. The solid isolate can be stored for extended periods of time and can be added as an ingredient to a variety of foods or beverages.

The invention is also directed to a comestible that includes a water soluble isolate derived from nopal pads of the *opuntia* genus and at least one other edible ingredient. Preferably, the nopal pads are of a variety selected from the group consisting of *opuntia ficus indica*, *opuntia streptacantha lemaire* and combinations thereof. The comestible can be in a form selected from the group consisting of a drink, including, e.g., flavored water, juice, flavored milk drinks and hot chocolate; powdered drink mix; fruit based or herbal infusion; brewable mixture; soup; yogurt; pudding; chocolate; candy; and ingredients thereof. In one embodiment, the comestible is freeze-dried. Preferably, the isolate is a solid material and, more preferably, a freeze-dried solid material.

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The dried leaves, stems and/or buds of the shrub *Camellia sinensis* can include classifications of teas selected from the group consisting of black tea, green tea, oolong, white tea and blends thereof. Additionally, the dried leaves and/or buds can include specific classifications of teas selected from the group consisting of pu-erh, 5 brick tea, yellow tea, chong cha, kukicha, lapsang souchong, rize tea and blends thereof. In one embodiment, the dried leaves, stems and/or buds of the shrub *Camellia sinensis* are at least partially decaffeinated.

It is also contemplated that the composition for making tea can contain other ingredients that provide additional health benefits or improve the drinking experience. 10 Ingredients that provide additional health benefits can include natural health promoting ingredients, such as, for example, Bitter Orange, Gracinia Cambogia or Kola Nut Extract. Ingredients that improve the drinking experience can include sweeteners, whitening agents or flavorants. Preferred flavorants include fruit flavors, flowers, herbs, spices or natural oils such as rosehip, chamomile, jasmine, cinnamon, 15 mint, peppermint, cardamom, ginger, nut flavors, and oil of bergamot.

In another aspect, the invention is directed to a method for making a water soluble solidified isolate derived from nopal pads of the *opuntia* genus. The method preferably includes roasting the nopal pads; substantially separating insoluble pulp from water soluble solid and juice fractions; and forming a solidified isolate from the 20 soluble solid and juice fractions. The isolate can be prepared according to the steps described above with respect to the coffee composition, however, with the roasting, pH and grinding tailored for the desired end use, i.e., the food or beverage product.

In another aspect, the invention is directed to a method for making a tea composition which includes combining a solid nopal isolate with dried leaves, stems 25 and/or buds of the shrub *Camellia sinensis*. The solid nopal isolate can be prepared as discussed above, but under specific roasting, pH and grinding conditions to achieve an isolate having a taste compatible with the desired tea product. Preferably, the nopal pads are roasted to about a level one (1) or level two (2) roast on the coffee roasting scale and the pH of the isolate is adjusted to substantially match the pH of the 30 resulting tea. For example, for a tea composition containing black tea, the pH is preferably adjusted to about 5. The solid isolate, e.g., a freeze-dried isolate, is

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogado
CARLOS ANDRÉS MORA DÍAZ
(Apoderado)

ASUNTO	Radicación	06127259
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	0 4 7 4,6
	Folios	023

Patente de Invención	☒	Patente de Modelo de Utilidad	☐
Vía Nacional	☒		
Vía PCT (fase nacional)	☐	Cap. I	☐
		Cap. II	☐
No. Sol. Internacional	no aplica		
Fecha de Presentación Internacional	no aplica		

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados:

- 1.1. Descripción: (Folios: 6 a 20) como se radicó inicialmente.
- 1.2. Reivindicaciones: 1 a 22 (Folios: 20 a 23) como se radicó inicialmente.
- 1.3. Prioridad: La solicitud no reclama prioridad.

2. Análisis de la Prioridad:

La presente solicitud no reivindicó prioridad.

3. Objeto de la invención:

La presente solicitud se titula: "Composición la cual incluye superóxido dismutasa y nopal para disminuir y prevenir la resaca".

El objeto de la presente solicitud se refiere a una composición para prevenir, proteger, minimizar y acelerar la recuperación de los síntomas típicos, asociados con la ingesta de alcohol, conocido comúnmente como resaca.

En el capítulo reivindicatorio se reclama lo siguiente:

Reivindicaciones 1 a 3 (folio: 20): Composición para proteger en contra, minimizar efectos de, y rápida recuperación de los síntomas asociados con la resaca inducida por alcohol caracterizada por tener como elementos primarios de su composición superóxido dismutasa y Cactus Nopal y los demás que hacen parte de éste capítulo reivindicatorio.

Reivindicación 4 y 5 (folios: 20 y 21): Composición... caracterizada por comprender el Sesamin.

Reivindicaciones 6 y 7 (folio: 21): Composición,... caracterizada por comprender ácido alfa lipoico.

Reivindicación 8 (folio: 21): Composición..., caracterizada por comprender Tiamina.

Reivindicación 9 (folio: 21): Composición... caracterizada por comprender Niacina.

Reivindicación 10 (folio: 21): Composición... caracterizada por comprender Vitamina B6.

Reivindicación 11 (folios: 21 y 22): Composición... caracterizada por comprender Folato.

Reivindicación 12 (folio: 22): Composición... caracterizada por comprender Vitamina B12.

Reivindicación 13 (folio: 22): Composición... caracterizada por comprender Ácido Pantoténico.

Reivindicación 14 (folio: 22): Composición... caracterizada por comprender extracto de semilla de cardo mariano.

Reivindicación 15 (folio: 22): Composición... caracterizada por comprender extracto de polen de flor.

Reivindicación 16 (folio: 22): Composición... caracterizada por comprender extracto de raíz de Elutero.

Reivindicación 17 (folio: 22): Composición... caracterizada por comprender

guggulsteronas E y Z.

Reivindicación 18 (folio: 23): Composición... caracterizada por comprender extracto de corteza de Sauce Blanco.

Reivindicación 19 (folio: 23): Composición... caracterizada por comprender Sclareolide.

Reivindicación 20 (folio: 23): Composición... caracterizada por comprender extracto de Hoja de Ginko Biloba.

Reivindicación 21 (folio: 23): Composición... caracterizada por comprender cafeína.

Reivindicación 22 (folio: 23): Composición... caracterizada por comprender Extracto de Resina Boswellia Serrata.

El problema planteado en esta solicitud es la necesidad de una composición mejorada para el tratamiento de la resaca.

La solución propuesta por la presente solicitud consiste en una composición caracterizada por tener como elementos primarios de su composición superóxido dismutasa y Cactus Nopal.

El objeto de la solicitud definido anteriormente se clasificó en la IPC A61K 35/38, 38/00.

4. De la solicitud de Patente

4.1. Reivindicaciones (artículo 30 D 486)

De acuerdo con lo revelado en el capítulo reivindicatorio, la reivindicación 1 no es concisa ni clara por cuanto no se especifican los "demás (elementos) que hacen parte de éste capítulo reivindicatorio" (ver folio: 20). En esta misma reivindicación se debe aclarar si "Cactus Nopal" es un extracto (de qué parte de la planta) o una formulación aparte.

Las reivindicaciones 4 a 22 (folios: 20 a 23) deberían formar parte de la reivindicación 1 que es la reivindicación general, de tal manera que queden allí consignadas todas las partes o componentes de la composición de una manera más clara.

5. Unidad de Invención (artículo 25 D 486)

Según lo anterior la (s) reivindicación (es) 4 a 22 (folios: 20 a 23), tal como están presentadas dichas reivindicaciones que se refiere(n) a una composición... caracterizada por comprender: sesamin, ácido alfa lipoico, tiamina, niacina, vitamina B6, vitamina B12, ácido pantoténico, extracto de semilla de cardo mariano, extracto de polen de flor, extracto de raíz de Elutero, guggulsteronas E y Z, extracto de corteza de sauce blanco, Sclareolide, extracto de hoja de Ginko Biloba, cafeína,

extracto de resina Boswellia Serrata, no guarda(n) unidad de invención con la reivindicación 1, que se relacionan con una composición que tiene superóxido dismutasa y Cactus Nopal.

6. **Análisis de la(s) Oposición(es):** (artículo 43 D. 486)

No se presentaron oposiciones al objeto reivindicado.

7. **Determinación del Estado de la Técnica:**

La fecha que se ha tenido en cuenta para determinar el Estado de la Técnica es:

Fecha de presentación de la solicitud nacional 20-12-2006.

Teniendo en cuenta la fecha indicada, se buscaron documentos del estado de la técnica relacionados, con fecha de publicación anterior a esta.

Se encontró como anterioridades que pueden afectar la patentabilidad del objeto de la presente solicitud:

Nº	Documento	Título	Fecha de Publicación
D1	US2006/0269535	Metallo-lactoferrin-coenzyme compositions for trigger and release of bioenergy	30 de noviembre de 2006
D2	WO2005/115131	Compositions containing a Nopal Cactus isolate and method for making same	8 de diciembre de 2005

8. **Análisis de patentabilidad (artículo 14 D486)**

8.1. Nivel inventivo (artículo 18 D486)

La presente Solicitud de Patente reivindica lo siguiente: Composición para proteger en contra, minimizar efectos de, y rápida recuperación de los síntomas asociados con la resaca inducida por alcohol caracterizada por tener como elementos primarios de su composición superóxido dismutasa y Cactus Nopal.

La anterioridad US 2006/0269535 (folios: 29 a 38) se relaciona con composiciones de coenzima metalo-lactoferrina para liberación de bioenergía; estas composiciones se pueden administrar vía oral en varias formas farmacéuticas. Las formulaciones contienen un complejo que incluye una proteína unida a un metal (tipo hierro, Fe⁺³), al menos un hidrocoloide como por ejemplo Cactus Nopal, un complejo elemental que incluye al menos una sal metálica y un complejo de coenzima que incluye al menos una coenzima (por ejemplo un complejo de vitamina B) o un precursor de coenzima. La formulación puede contener además un antioxidante como el superóxido dismutasa (SOD). Las vitaminas del complejo B son seleccionadas de: vitamina B1, vitamina B2, vitamina B3, vitamina B5, vitamina B6, vitamina B9, vitamina B12 y combinaciones de las mismas.

El documento WO 2005/115131 (folios: 39 a 45) se refiere a composiciones que contienen Cactus Nopal aislado y método para su elaboración; en este documento se mencionan algunos de los usos de los extractos del Cactus Nopal como por ejemplo para mantener niveles de colesterol, estabilizar la glucosa en sangre y de insulina y como promotor de un peso saludable reduciendo riesgos a nivel coronario y de diabetes. Estas composiciones pueden contener cafeína o te u otros extractos de otras plantas.

Estos documentos le revelan a la persona medianamente versada en la materia composiciones que contienen un extracto de Cactus Nopal junto con otros componentes, como por ejemplo vitaminas, antioxidantes como el SOD y extractos de otras plantas. Si bien el uso es diferente al que se muestra en la presente solicitud, de todas maneras las composiciones ya estaban sugeridas en el estado de la técnica sin importar el empleo final de las mismas.

El problema técnico planteado en esta solicitud: la necesidad de una composición mejorada para el tratamiento de la resaca, se había resuelto previamente mediante composiciones de superóxido dismutasa (SOD) y de extractos de Cactus Nopal ya conocidos(as). Por esta razón se considera que los componentes de las composiciones reivindicadas en la presente solicitud son evidentes para una persona medianamente versada en la materia.

La(s) reivindicación(es) 1 a 22 de esta solicitud no menciona(n) una característica que conceda un efecto inesperado o especial a las composiciones, que pueda considerarse como un aporte a la técnica, así que son obvios(as) para una persona versada en la materia.

Además, puesto que D1 y D2 divulgaban previamente composiciones de extractos de Cactus Nopal y de superóxido dismutasa (folios: 29 a 45), una persona conocedora de la materia motivada por tal sugerencia lograría el objeto de esta solicitud composiciones de superóxido dismutasa (SOD) y de extractos de Cactus Nopal; de manera que para una persona medianamente versada en la materia sería obvio combinar estos dos documentos. Por lo cual puede no haber Nivel Inventivo.

9. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

Nº	Documento Nº	Reivindicaciones afectadas	Requisito que afecta
D1	US2006/0269535	1 a 22	Nivel Inventivo
D2	WO 2005/115131	1 a 22	Nivel Inventivo

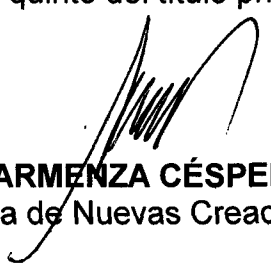
En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de la notificación de la presente comunicación. En caso

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de no dar respuesta al presente requerimiento o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única N° 10 de 2001.



ALIX CARMENZA CÉSPEDES DE VERGEL
Directora de Nuevas Creaciones (c)

El anterior requerimiento fue notificado por fijación en lista, de fecha 08 ABR. 2010

CONCEPTO TÉCNICO No. 1258	EXAMINADOR TÉCNICO Código No. 202005
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