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(54) Title: NUTRITIONAL COMPOSITIONS WITH HEART HEALTH BENEFITS

(57) Abstract: Nutritional compositions and methods useful for improving the heart health of an individual are disclosed. The liquid nutritional compositions include protein, carbohydrates and beta-glucan. In certain embodiments, the liquid nutritional compositions meet one or more of the following: contain at least 6.25 grams soy protein, contain at least 0.75 grams of beta-glucan, are clear or have a pH of 2-4.6.



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NUTRITIONAL COMPOSITIONS WITH HEART HEALTH BENEFITS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to and any benefit of U.S. Provisional Application No. 61/739,273, filed December 19, 2012, the entire contents of which are incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] Disclosed embodiments are in the field of nutritional compositions and more particularly in the field of nutritional compositions that provide cardiovascular benefits.

BACKGROUND

[0003] In certain applications, the clarity of a liquid nutritional composition can affect the appeal of the product and impact a consumer's decision regarding whether to purchase or consume the product. In certain applications, it is beneficial for a liquid nutritional composition to have a significant protein content, and in certain instances a significant amount of soy protein. However, the addition of large amounts of protein to a nutritional composition is often associated with an increase in product thickness or a cloudy appearance (or both), making the resulting product somewhat or significantly less pleasant to consume. Furthermore, the addition of viscous fiber sources such as beta-glucan have been known to similarly affect the appearance of liquid nutritional compositions

SUMMARY

[0004] Provided herein are liquid nutritional compositions (and related methods) useful in improving the heart health of individuals consuming them. The liquid nutritional compositions

include protein, carbohydrates and beta-glucan. In certain embodiments, the liquid nutritional compositions meet one or more of the following: contain at least 6.25 grams soy protein, contain at least 0.75 grams of beta-glucan, are clear, or have a pH of 2-4.6.

[0005] In a first embodiment, a clear, liquid nutritional composition for improving the heart health of an individual is provided. The clear, liquid nutritional composition comprises at least one source of viscous soluble fiber providing 0.004-0.02 grams of beta-glucan per Kcal of the nutritional composition; at least one source of protein in an amount sufficient to provide 6.25-20 grams of protein per serving; at least one source of carbohydrates; and not more than 1 gram of fat per 100 g of the nutritional composition.

[0006] In a second embodiment, a clear, shelf-stable liquid nutritional composition with heart health benefits is provided. The clear, shelf-stable liquid nutritional composition according to the second embodiment includes at least one source of protein in an amount sufficient to provide 9-15 grams protein per serving, at least one source of carbohydrates; 0.75-3 grams beta-glucan fiber per serving, and at most 1 gram of fat per 100 grams of the nutritional composition (*i.e.*, no more than 1 weight % fat based on total weight of the liquid nutritional composition). The composition is a composition for improving the heart health of an individual.

[0007] In a third embodiment, a method is provided for improving the cardiovascular health of an individual by providing to an individual in need thereof a liquid nutritional composition comprising: at most 1 gram total fat per 100 grams of the nutritional composition; at least one source of protein in an amount sufficient to provide 6.25-20 grams of protein per serving; at least one source of carbohydrates; vitamins and minerals; and at least one source of viscous soluble fiber providing between 0.75 and 3 grams of beta-glucan per serving. Consumption of the liquid nutritional composition results in an improvement in the cardiovascular health of the individual.

[0008] This embodiment also includes a liquid nutritional composition for use in improving the cardiovascular health of an individual in need thereof wherein the liquid nutritional composition comprises: at most 1 gram fat per 100 grams of the nutritional composition; at least one source of protein in an amount sufficient to provide 6.25-20 grams of protein per serving; at least one source of carbohydrates; vitamins and minerals; and at least one source of viscous soluble fiber providing 0.75-3 grams of beta-glucan per serving.

[0009] This embodiment also includes the use of a liquid nutritional composition in the manufacture of a medicament for use in improving the cardiovascular health of an individual in need thereof wherein the liquid nutritional composition comprises at most 1 gram total fat per 100 grams of the nutritional composition; at least one source of protein in an amount sufficient to provide 6.25-20 grams of protein per serving; at least one source of carbohydrates; vitamins and minerals; and at least one source of viscous soluble fiber providing between 0.75 and 3 grams of beta-glucan per serving.

DETAILED DESCRIPTION

[00010] Provided herein are liquid nutritional compositions (and related methods) useful in improving the heart health of individuals consuming them. The liquid nutritional compositions include protein, carbohydrates and beta-glucan. In certain embodiments, the liquid nutritional compositions meet one or more of the following: contain at least 6.25 grams soy protein, contain at least 0.75 grams of beta-glucan, are clear, or have a pH of 2-4.6.

[00011] In a first embodiment a clear, liquid nutritional composition for improving the heart health of an individual is provided. The clear, liquid nutritional composition comprises at least one source of viscous soluble fiber providing 0.004-0.02 grams of beta-glucan per Kcal of the nutritional composition; at least one source of protein in an amount sufficient to provide 6.25-20 grams of protein per serving; at least one source of carbohydrates; and at most 1 gram of fat per 100 grams of the nutritional composition.

[00012] In a second embodiment, a clear, shelf-stable liquid nutritional composition with heart health benefits is provided. The clear, shelf-stable liquid nutritional composition according to the second embodiment includes at least one source of protein in an amount sufficient to provide 9-15 grams protein per serving, at least one source of carbohydrates; 0.75-3 grams beta-glucan fiber per serving, and at most 1 gram of fat per 100 grams (*i.e.*, no more than 1 weight % fat based on total weight of the liquid nutritional composition). The composition is a composition for improving the heart health of an individual.

[00013] In a third embodiment, a method is provided for improving the cardiovascular health of an individual by providing to an individual in need thereof a liquid nutritional composition comprising: not more than 1 gram total fat per 100 grams; at least one source of protein in an amount sufficient to provide 6.25-20 grams of protein per serving; at least one

source of carbohydrates; vitamins and minerals; and at least one source of viscous soluble fiber providing 0.75-3 grams of beta-glucan per serving. Consumption of the liquid nutritional composition results in an improvement in the cardiovascular health of the individual.

[00014] This embodiment also includes a liquid nutritional composition for use in improving the cardiovascular health of an individual in need thereof wherein the liquid nutritional composition comprises: at most 1 gram fat per 100 grams of the nutritional composition; at least one source of protein in an amount sufficient to provide 6.25-20 grams of protein per serving; at least one source of carbohydrates; vitamins and minerals; and at least one source of viscous soluble fiber providing 0.75-3 grams of beta-glucan per serving.

[00015] This embodiment also includes the use of a liquid nutritional composition in the manufacture of a medicament for use in improving the cardiovascular health of an individual in need thereof wherein the liquid nutritional composition comprises at most 1 gram total fat per 100 grams of the nutritional composition; at least one source of protein in an amount sufficient to provide 6.25-20 grams of protein per serving; at least one source of carbohydrates; vitamins and minerals; and at least one source of viscous soluble fiber providing between 0.75 and 3 grams of beta-glucan per serving.

[00016] It is intended that when discussing the nutritional compositions disclosed herein, that the discussion may be applied to nutritional compositions useful in the presented methods as well.

[00017] The nutritional compositions and methods described herein are useful in improving the heart health of an individual (*i.e.*, when the nutritional compositions are consumed by an individual, they result in improved heart health for that individual). Heart health as used herein is closely related to the development of cardiovascular disease. That is, in certain embodiments, an improvement in heart/cardiovascular health refers a decrease in symptoms or risk factors for cardiovascular disease.

[00018] Cardiovascular disease refers to any disease that affects the cardiovascular system, principally cardiac disease, vascular diseases of the brain and kidney, and peripheral

arterial disease. The causes of cardiovascular disease are diverse but atherosclerosis and/or hypertension are the most common.

[00019] In the methods according to the third embodiment, the individual may be one who has been diagnosed with a heart condition, heart-related condition, heart disease or heart defect. Alternatively, the individual may be one who is at risk for developing a heart condition or heart disease such as by having one or more of the following risk factors: advanced age (65 or older), male gender, prior heart attack or stroke, high blood pressure, high cholesterol, smoker, physically inactive, obese, high triglycerides, imbalance of HDL/LDL ratio, overweight and diabetic. By improving the heart health is meant the general condition of the heart improves (or maintains when it would otherwise have worsened) which may be evidenced by at least one of a reduction in blood cholesterol, reduction in blood pressure, reducing the risk of heart disease, reduction in weight, reduction in measured triglyceride levels, among others.

[00020] The nutritional compositions according to the disclosed embodiments provide two ingredients that help to reduce the risk of heart disease. These ingredients are beta-glucan and soy protein. Barley beta-glucan fiber may help lower blood cholesterol levels as part of a heart healthy diet. Diets low in saturated fat and cholesterol that include 3 grams of soluble fiber from barley beta glucan per day may reduce the risk of heart disease. Likewise, soy protein may help lower blood cholesterol levels as part of a heart healthy diet. Diets low in saturated fat and cholesterol that include 25 grams of soy protein per day may reduce the risk of heart disease.

[00021] Definitions

[00022] The terminology as set forth herein is for description of the embodiments only and should not be construed as limiting the invention as a whole.

[00023] As used herein, the term "serving" is intended to be construed as any amount which is intended to be consumed in one sitting or within one hour or less.

[00024] As used herein, the term "shelf stable" or "stabilized," unless otherwise specified, refers to a nutritional composition that remains commercially stable after being packaged and then stored at 18-24° C for at least 3 months, including about 6-12 months, and also including about 12-18 months.

[00025] In certain embodiments according to the first, second and third embodiments disclosed herein, the nutritional compositions are administered (or consumed) orally as needed to provide the desired level of nutrition. In certain of these embodiments, the nutritional compositions are administered (or consumed) in the form of one to two servings daily or in one or two or more divided doses daily. Typical serving sizes range about 100-500 mL, including about 100-300 mL, including about 150-250 mL, including about 190-240 mL and also including 4-10 fluid ounces, 8-10 fluid ounces and 8 fluid ounces and 10 fluid ounces). Various calorie contents may be associated with each serving of the nutritional compositions according to the first, second and third embodiments disclosed herein, typically 25-500 Kcal, including 50-250 Kcal; 100-200 Kcal or 150-180 Kcal per serving. Alternatively, a serving may be construed as any amount which is intended to be consumed in one sitting or within one hour or less.

[00026] As previously discussed, according to the first, second and third embodiments the liquid nutritional compositions include beta-glucan. In certain embodiments, the liquid nutritional compositions comprise viscous or viscous soluble fiber. Viscous fibers are characterized by their ability to form a liquid or gel solution when combined with water in the digestive tract. Viscous fibers are known to bind with fatty acids in the stomach to create a viscous mass. Examples of sub-sets of viscous fibers include pectins, such as those found in apples; beta-glucans; guar gum; and mucilages, such as psyllium husk. Beta-glucan is a natural source of soluble fiber. Soluble fiber (or viscous fiber) has been demonstrated to lower LDL cholesterol and has been identified as providing benefits for maintaining healthy blood glucose levels. Beta-glucan molecules consist of linked chains of D-glucose polysaccharides. Though similar, beta-glucans are more diverse than molecules like starch. Some beta-glucans exist as single strand chains while others have complex helical arrangements. The particular arrangement is often due to the source of beta-glucan, with some arrangements, known as $\beta(1,3)(1,4)$, showing interesting biological activity. Some known sources of beta-glucan are cereals such as barley, oat, triticale, wheat, rice, corn, amaranth and quinoa among others. Generally, beta-glucans extracted from grains are both soluble and insoluble, while beta-glucan derived from baker's yeast is mainly insoluble.

[00027] When beta-glucan is utilized in the liquid nutritional compositions disclosed herein, the beta-glucan may be provided by a single source or more than one source. In certain embodiments, the beta-glucan may be provided in its natural form. Conversely, in certain

embodiments according to the first, second and third embodiments, the beta-glucan that is utilized is in a modified form of the beta-glucan-containing cereal. The weight average molecular weight of isolated oat and barley beta-glucan has been reported to be on the order of 1,000,000 Da though the molecular weight of cereal beta-glucan has not been reported. The modified beta-glucan can have a weight average molecular weight of 50-1000 kDa, including 120-170 kDa. The weight average molecular weight range of the modified beta-glucan may be achieved by any process known to those of skill in the art including using an enzyme or combination of enzymes to perform a non-specific digestion of the cereal. The modified beta-glucan may have modified physiochemical properties including lowered viscosity, non-gelling characteristics and high solubility in water. The beta-glucan that is utilized is highly soluble in water and forms a solution having a low viscosity. For example, a solution containing 1% of the modified beta-glucan would have a viscosity of 1-1000 cps at 25°C.

[00028] As previously discussed, according to the first embodiment, the beta-glucan is present in an amount of 0.004-0.02 grams per Kcal of the liquid nutritional composition. In other embodiments according to the first embodiment, the beta-glucan is present in an amount of 0.005-0.010 grams per Kcal of the liquid nutritional composition. The particular amount of beta-glucan that is utilized can vary according to the total calories in the liquid nutritional composition. Further, in certain embodiments according to the first embodiment, the beta-glucan is present in an amount of 0.75-3 grams per serving. As previously discussed, suitable sources of beta-glucan include oat and barley. One source of barley beta-glucan is sold under the name Barliv™ by the Cargill Corporation 15407 McGinty Road West MS 110 Wayzata, MN 55391. In certain embodiments according to the first embodiment, the beta-glucan is barley-sourced.

[00029] As previously discussed, according to the second and third embodiments disclosed herein, the beta-glucan is present in an amount of 0.75-3 grams per serving. In certain embodiments disclosed herein, the beta-glucan is present in an amount of 0.75-1.5 grams per serving. In certain embodiments according to the second and third embodiments disclosed herein, the beta-glucan is barley-sourced. In certain embodiments according to the second and third embodiments disclosed herein, the beta-glucan is provided by more than one source such as barley and oat with barley comprising 0.75-3 grams per serving.

[00030] As previously discussed, according to the first and second embodiments disclosed herein, the liquid nutritional compositions are clear. Furthermore, in certain embodiments according to the third embodiment disclosed herein, the liquid nutritional compositions are clear. The term clear as used herein, unless otherwise specified, refers to a non-emulsified or similar other liquid having a visibly clear or translucent appearance. In certain embodiments according to the first, second and third embodiments disclosed herein, the clear liquid nutritional compositions are in the form of a clear liquid. Clearness or clarity in this context is measured by formazin nephelometric unit (FNU) at 90 degree light scattering and 860 nm with a Nephla reader. A clear liquid nutritional composition, as used herein, refers to a clear liquid nutritional composition with a FNU of less than 50 (*i.e.*, 3 to 50), less than 40 (*i.e.*, 3 to 40) and in other embodiments less than 30 (*i.e.*, 3 to 30).

[00031] In certain embodiments according to the first, second and third embodiment the liquid nutritional compositions contain one or more sources of fiber (in addition to the beta-glucan). In certain of these embodiments, the nutritional compositions comprise 1-6 grams of total fiber per serving and the fiber included comprises at least 0.75 grams of beta-glucan, with the remainder of the fiber made up of one or more additional sources of fiber. An exemplary source of fiber (other than the beta-glucan) that is useful in the liquid nutritional compositions is a resistant starch sold under the name Nutriose® by the Roquette Company, 62136 Lestrem France.

[00032] As previously discussed, according to the first and third embodiment, the nutritional compositions include at least one source of protein in an amount sufficient to provide protein in a total amount of between 6.25 and 20 grams per serving and according to the second embodiment, the nutritional compositions include at least one source of protein in an amount sufficient to provide protein in a total amount of 9-15 grams per serving. Depending on the total amount of protein in the liquid nutritional compositions according to the first, second and third embodiments, the protein may be provided by a single source of protein or a combination of protein sources. In certain embodiments of the liquid nutritional compositions according to the first, second and third embodiments disclosed herein, soy protein comprises 30-100 weight % of the total protein and whey protein isolate comprises 0-70 weight % of the total protein.

[00033] When soy protein is utilized in the liquid nutritional compositions according to the first and third embodiments disclosed herein and in the liquid nutritional compositions according to the second embodiment disclosed herein (which contain at least 6.25 grams of soy protein), the soy protein may be provided by one or more sources of soy protein. Common forms of soy protein include soy protein concentrates, soy protein isolates (including acidified soy protein isolates) and soy protein hydrolysates. As previously discussed, the amount of soy protein utilized in the liquid nutritional compositions is up to 100 weight % of the total protein in certain embodiments (*i.e.*, 0-100 weight %) of the total protein, in certain other embodiments the amount of soy protein is 30-70 weight % of the total protein. In certain embodiments according to the first, second and third embodiments, the soy protein is soy protein isolate. In certain embodiments according to the first, second and third embodiments where the total protein is present in an amount of 6.25 grams per serving it is preferred that the soy protein make up 100% of the total protein. In certain embodiments according to the first, second and third embodiments, the soy protein is a soy protein isolate processed for use in liquid nutritional compositions having a pH of less than 4.6. In order to achieve this level of processing, the soy protein isolate may be isolated by ultrafiltration. Commercial sources of soy protein are well known in the nutrition art, non-limiting examples of which include a soy protein isolate distributed by ADM Specialty Products 4666 East Faries Parkway Decatur, IL 62526, under the trade designation Clarisoy.

[00034] When whey protein is utilized in the liquid nutritional compositions according to the first, second and third embodiments disclosed herein, the whey may be provided by one or more than one source. Common forms of whey protein include whey protein concentrate, whey protein hydrolysate, and whey protein isolate. Preferably, the whey protein is present as whey protein isolate. Various commercial sources of whey protein exist, containing varying concentrations of protein such as about 75 weight % protein (w/w, based on the total weight of the protein source). As previously discussed, the amount of whey protein utilized in the liquid nutritional compositions can be up to 70 weight % (*i.e.*, 0-70 weight %) of the total protein in certain embodiments. In embodiments according to the first, second and third embodiments where the total protein content of the liquid nutritional composition is higher such as closer to 20 grams or 20 grams, the amount of whey protein may be as much as 70% of the total protein, for example 1-13 grams per serving. In embodiments according to the first, second and third

embodiments where the total protein content of the liquid nutritional composition is lower (*e.g.*, around 6.25 grams), it is preferred that whey make up less than 1% of the total protein.

[00035] In addition to the protein sources discussed above, in certain embodiments, the liquid nutritional compositions according to the first, second and third embodiments disclosed herein may also contain protein from one or more other sources, in an amount or amounts that is in accordance with the guidance on the amounts of soy protein and whey protein, discussed above. Generally according to the first, second and third embodiments, the other protein source(s) (when present) will not comprise (in total) more than 40 weight % of the total protein (*i.e.*, 0-40 weight %), no more than 30 weight %, no more than 20 weight % or no more than 10 weight %. In those embodiments where the liquid nutritional composition is clear, suitable additional sources of protein (*i.e.*, in addition to the soy protein) include certain casein-based proteins such as casein hydrolysates; certain pea-based proteins such as pea hydrolysates; and the like. The at least one source of protein can include any individual or combination of the various sources of protein listed above. In those embodiments of the third embodiment disclosed herein where the liquid nutritional composition is not clear, one or more other sources of protein (in an amount of not more than 40% by weight (*i.e.*, 0-40% by weight), alternatively not more than 30% by weight, not more than 20% by weight or even no more than 10% by weight of the total protein, taking into account the specified amounts of soy protein and whey protein discussed above) include milk protein concentrate, soy protein concentrate, casein from milk, animal products (*e.g.*, meat, fish, egg albumen, collagen), cereals (*e.g.*, rice, corn), vegetable (*e.g.*, soy, pea, potato, quinoa), collagen protein or combinations thereof. The additional protein sources can also include, free amino acids known for use in nutritional compositions, non-limiting examples of which include tryptophan, glutamine, tyrosine, L-methionine, cysteine, taurine, L-arginine, carnitine, and combinations thereof.

[00036] As previously discussed, the liquid nutritional compositions according to the first, second and third embodiments disclosed herein contain at least one source of carbohydrates, in certain embodiments more than one source. The particular amount of carbohydrates present in the liquid nutritional composition may vary depending upon the nutritional needs of the intended user. The total amount of carbohydrates present in liquid nutritional compositions according to the first, second and third embodiments disclosed herein will usually fall within the range of 5-40 weight % (percentages are weight percentages based upon the total weight of the liquid

nutritional composition), 7-30 weight %, or 10-20 weight %. The amount of carbohydrates present in liquid nutritional compositions according to the first, second and third embodiments disclosed herein can also be characterized as a percentage of total calories in the liquid nutritional composition and may vary widely. In certain embodiments according to the first, second and third embodiments disclosed herein, the at least one source of carbohydrate comprises 10-85% of the total calories of the liquid nutritional composition and in other embodiments 20-60% of the total calories. In certain embodiments, the liquid nutritional composition includes at least one source of carbohydrates in an amount sufficient to provide a total of 100-200 grams of carbohydrate per liter of liquid nutritional composition.

[00037] Various commercial sources of carbohydrates exist and may be utilized in the liquid nutritional compositions disclosed herein. Non-limiting examples of suitable carbohydrates or sources thereof for use in the liquid nutritional compositions disclosed herein include maltodextrin, hydrolyzed or modified starch or cornstarch, glucose polymers, corn syrup, corn syrup solids, rice-derived carbohydrates, glucose, fructose, lactose, high fructose corn syrup, honey, sugar alcohols (*e.g.*, malitol, erythritol, sorbitol), slow digesting carbohydrates (*e.g.*, sucromalt, isomaltulose alpha cyclodextrin, gamma cyclodextrin, pullulan, tapioca dextrin, galacto-oligosaccharide, isomalto-oligosaccharide, green bean carbohydrate, green pea carbohydrate, and peach carbohydrate among others) and combinations thereof.

[00038] In certain embodiments according to the first, second and third embodiments disclosed herein, the amount of sugars utilized for the at least one carbohydrate component is limited. In certain of these embodiments, the total amount of sugars is less than 18 grams per serving or less than 18 grams per 8 ounce serving, and even as low as 13 grams per serving or less than 13 grams per 8 ounce serving.

[00039] As previously discussed, the amount of fat that is contained within the nutritional compositions according to the first, second and third embodiments disclosed herein, is relatively small (*i.e.*, not more than 1 gram of fat per 100 grams of nutritional composition according to the first and third embodiments and not more than 1 weight % fat based on the total weight of the nutritional composition according to the second embodiment). In other embodiments according to the first, second and third embodiments disclosed herein, the total amount of fat contained within the liquid composition is 0.5% by weight or less, or 0.1% by weight or less based upon

the total weight of the liquid nutritional composition. Generally, when a liquid nutritional composition is formulated to be clear, the amount of fat that can be added to the composition is limited. The amount of fat present can also be characterized as a percentage of total calories in the liquid nutritional composition and may vary depending upon the total number of calories in the liquid nutritional composition but (taking into account the fat parameters discussed above) is generally less than 10% of the total calories or even less than 5% the total calories of the liquid nutritional composition.

[00040] In those embodiments of the first, second and third embodiments disclosed herein, where some amount of fat is present, the fat may be present as a result of being inherently present in another ingredient (*e.g.*, a source of protein) or may be present as a result of being added as one of more separate sources of fat. Various commercial sources of fat exist and may be utilized in the liquid nutritional compositions disclosed herein. Non-limiting examples of suitable fats or sources thereof suitable for use in the liquid nutritional compositions disclosed herein include coconut oil, fractionated coconut oil, soy oil, corn oil, olive oil, safflower oil, high oleic safflower oil, MCT oil (medium chain triglycerides), sunflower oil, high oleic sunflower oil, palm and palm kernel oils, palm olein, canola oil, marine oils, cottonseed oils and combinations thereof.

[00041] In certain embodiments according to the first, second and third embodiments the liquid nutritional compositions include L-carnitine. L-carnitine is a biologically active compound implicated in the conversion of fats to energy in the body. In certain of these embodiments, the L-carnitine is present in an amount of 50-250 mg per serving. In certain embodiments according to the first, second and third embodiments disclosed herein, L-carnitine is present in an amount of between 75-150 mg per serving or 100-125 mg per serving. In other embodiments according to the first, second and third embodiments disclosed herein, L-carnitine is present in an amount of at least 100 mg per serving.

[00042] In certain embodiments according to the first, second and third embodiments, the nutritional compositions include curcumin. The ingestion of curcumin has been associated with the reduction of blood triglycerides, however, curcumin generally exhibits poor bioavailability in human subjects when in its naturally occurring form.. When present in the nutritional

compositions according to the first, second and third embodiments disclosed herein, curcumin is present in an amount of 5-150 mg per serving.

[00043] Additionally, in certain embodiments according to the first, second and third embodiments disclosed herein, the nutritional compositions disclosed herein contain polyphenols including polyphenols from green tea. In certain such embodiments, the amount of polyphenols is 100-500 mg per serving of the nutritional composition. Green tea and extracts therefrom are known to contain EGCg. EGCg is a polyphenol, specifically a catechin, that is desirable for many therapeutic and nutritional benefits. EGCg is the most abundant polyphenol present in green tea. The green tea extracts used with the shelf-stable, clear liquid nutritional compositions disclosed herein may also contain other polyphenols including other catechins such as catechin (*i.e.*, (+)-catechin, also known as “C”), epicatechin (“EC”), gallocatechin (“GC”), epigallocatechin (“EGC”), and epicatechin gallate (“ECg”); flavones such as apigenin, isoviloxin, sapotarin, and vicenin-2; flavonols such as kaempferol, quercetin, myricetin; condensed flavanoids, and tannin glycosides. Furthermore, the disclosed embodiments may also contain polyphenols from other sources such as fruit (*e.g.*, plums/prunes or plum/prune extract) or cocoa powder.

[00044] In certain embodiments according to the first, second and third embodiments, the liquid nutritional compositions have a pH of between 2 and 4.6. Generally, liquid nutritional compositions having a pH of more than 4.6 are required to undergo more significant heat processing prior to being marketed to the public. The reduced amount of heat processing makes acidic formulations attractive for certain applications.

[00045] In certain embodiments according to the first, second and third embodiments disclosed herein, the liquid nutritional compositions include fruit juice. In certain such embodiments, the fruit juice is used as a replacement for a portion of the plain water, as a replacement for all or a portion of sweetener(s), or both, that would otherwise be present in the liquid nutritional composition. The fruit juice, depending upon type and amount, will provide a certain amount of water and sweetness. The fruit juice may come from one or more sources. Some non-limiting examples of fruit sources for the fruit juices useful in the liquid nutritional compositions disclosed herein include: grape, apple, cranberry, orange, peach, blueberry, pomegranate, pineapple juice, berry juice blend, and combinations thereof whether from

conventional or organic sources and whether concentrated or non-concentrated. Juice blends useful with the disclosed embodiments should be compatible with the prior discussion regarding clarity of the nutritional compositions.

[00046] In certain embodiments according to the first, second and third embodiments disclosed herein, the liquid nutritional compositions contain other ingredients, non-limiting examples of which include preservatives, antioxidants, emulsifying agents, buffers, pharmaceutical actives, additional nutrients, colorants, flavors, thickening agents and stabilizers.

[00047] In certain embodiments according to the first, second and third embodiments disclosed herein, the liquid nutritional compositions contain vitamins or related nutrients, non-limiting examples of which include vitamin A, vitamin E, vitamin K, thiamine, riboflavin, pyridoxine, vitamin B12, carotenoids, niacin, folic acid, pantothenic acid, biotin, vitamin C, choline, inositol, salts, and derivatives thereof, and combinations thereof.

[00048] In certain embodiments according to the first, second and third embodiments disclosed herein, the liquid nutritional compositions contain minerals, non-limiting examples of which include phosphorus, magnesium, iron, zinc, manganese, copper, sodium, potassium, molybdenum, chromium, selenium, chloride, and combinations thereof.

[00049] Although certain of the examples presented above include formulations of nutritional compositions that are for ready-to-drink liquid nutritional compositions, other product forms such as concentrated liquids, liquids (*e.g.*, suspensions, solutions, emulsions, clear solutions), reconstitutable powders, bars, semi-solids, yogurts, puddings *etc.* may be suitable for the nutritional compositions in various embodiments disclosed herein. Further, in certain embodiments the compositions may be in the form of a jello or gel matrix. Additionally, in certain embodiments the liquid nutritional compositions according to the first, second and third disclosed embodiments may be in the form of a frozen liquid nutritional composition (*i.e.*, a popsicle) or may be packaged in a form suitable for freezing by the consumer (*e.g.*, such as a freezer pop). A particular advantage of packaging the liquid nutritional compositions of the first, second and third embodiments into a popsicle or freezer pop form is that when packaged and including 0.75-1.5 grams of beta-glucan and 6.25 grams of soy protein, the frozen nutritional composition does not form ice crystals, thus, providing a more slushy-like texture instead of an icy or crystalline texture.

[00050] In particular, in certain embodiments, the nutritional composition is still clear but is in the form of a semi-solid, such as a gel or other gelatin-like form; the nutritional composition comprises 0.004-0.02 grams of beta-glucan per Kcal of the nutritional composition, 6.25-20 grams of protein per serving at least one source of carbohydrates, and not more than 1 gram of fat per 100 grams of the nutritional composition (*i.e.*, not more than 1 weight % fat). In certain embodiments of the gel or gelatin-like form, at least 6.25 grams of the protein is soy protein. Generally, a gel or gelatin-like form of the liquid nutritional composition can be formed by adding a thickener such as gelatin, alginate, carrageenan, pectins, carboxymethylcellulose, gum Arabic and beta-glucans among others.

[00051] The liquid nutritional compositions according to the first, second and third embodiments disclosed herein may also optionally include one or more masking agents to reduce or otherwise obscure the development of any residual bitter flavors and after taste in the emulsions over time. Suitable masking agents include natural and artificial sweeteners, sodium sources such as sodium chloride, and hydrocolloids, such as guar gum, xanthan gum, carrageenan, gellan gum, and combinations thereof. The amount of masking agent in the nutritional emulsion may vary depending upon the particular masking agent selected, other ingredients in the formulation, and other formulation or product target variables. Such amounts, however, most typically are at least about 0.1%, including 0.1-3%, including 0.15-3%, and also including about 0.18-2.5%, by weight of the nutritional emulsion.

[00052] The liquid nutritional compositions described herein are useful to provide nutrition, and or to provide individuals one or more benefits as described herein. In accordance with such methods, the liquid nutritional compositions may be administered orally as needed to provide the desired level of nutrition, most typically in the form of one to two servings daily, in one or two or more divided doses daily.

Methods of Manufacturing

[00053] The liquid nutritional compositions according to the first, second and third embodiments disclosed herein can be manufactured by any process or suitable method (now known or known in the future) for making nutritional emulsions. In one suitable manufacturing process, at least two separate slurries are prepared. These slurries include: a protein-in-water (PIW) slurry and a carbohydrate-mineral (CHO-MIN) slurry. The PIW slurry is formed by first

making a fiber pre-blend of Nutriose (resistant starch) and Barliv (beta-glucan source). The fiber pre-blend is then added slowly into 150 °F water. The required quantity of Clarisoy (soy protein isolate) is then added to the fiber water blend. The blend is then cooled to 130 °F and any whey protein required is then added to the protein fiber blend. The CHO-MIN slurry is formed by adding to water, minerals (*e.g.*, potassium citrate, dipotassium phosphate, sodium citrate, *etc.*), trace and ultra trace minerals (often as pre-mix(es)), thickening-type or suspending agents L-carnitine, sucrose, maltodextrin, colors, flavors, sweeteners, folic acid and potassium iodide among others are all added into the slurry.

[00054] The two slurries are blended together with liquid sucrose, final water and agitation and the pH is adjusted to the desired range (typically below 4.6), after which the composition is subjected to high-temperature short-time (HTST) processing during which time the composition is heat treated, emulsified and homogenized and allowed to cool.

Examples

[00055] The following examples illustrate specific and exemplary embodiments and features of the liquid nutritional compositions disclosed herein. The examples are provided solely for the purposes of illustration and should not be construed as limitations of the present disclosure. Numerous variations over these specific examples are possible without departing from the spirit and scope of the presently disclosed liquid nutritional compositions. All amounts indicated within the tables below are weight percentages based upon the total weight of the composition, unless indicated otherwise.

[00056] **Example 1:** A 1000 kg batch of a fruit-flavored clear liquid nutritional composition having a protein content of about 9 grams of total protein of which 6.25 grams is soy protein and the remainder of which is whey protein isolate, 0.75 grams of beta-glucan and 100 mg of L-carnitine, all per 10 fluid ounce serving was prepared according to the bill of materials provided in Table 1 below. The clear liquid nutritional composition contains 0 grams of fat, 13 grams of sugar, 9 grams of protein, has 152 calories per 10 ounce serving and a measured osmolality of 253 mOSM/kg H₂O. When preparing the product, the manufacturing method described above (*i.e.*, preparation of PIW, CHO-MIN and subsequent blending) was generally followed. The final pH of the composition (after sterilization) was adjusted to 3.2 using citric acid.

Table 1				
Ingredients	Approximate Amount			
	per 1000 Kg			
Ingredient Water	Q.S.			
Maltrin M200	79.2	Kg		
Sucrose	34.5	Kg		
Soy Protein Isolate (Clarisoy from ADM)	21.2	Kg		
Provon A-190 whey protein isolate	10.9	Kg		
Wheat Dextrins (Nutriose from Roquette)	7.48	Kg		
Barley Beta Fiber (Barliv from Cargill)	3.69	Kg		
Citric Acid	1.55	Kg		
Natural Fruit WONF flavoring	1.2	Kg		
Natural Orange WONF flavoring	1	Kg		
Ascorbic Acid	535	g		
L-Carnitine	321	g		
Liquid Sucralose (25%) Ross	275	g		
Sucralose			68.75	g
UTM/TM Premix	230	g		
Zinc Sulfate, Monohydrate			52.1	g
Ferrous Sulfate, Dried			40.8	g
Citric Acid, Anhydrous (Processing Aid)			14.2	g
Manganese Sulfate, monohydrate			13	g

Copper Sulfate, monohydrate			7.1	g
Chromium Chloride, hexahydrate			339	mg
Sodium Molybdate, dihydrate			146	mg
Sodium Selenate, anhydrous				
Water Soluble ADEK Premix	178	g		
dl-Alpha Tocopheryl Acetate				
Vitamin A Palmitate				
Phylloquinone				
Vitamin D3				
Acesulfame Potassium	110	g		
FD&C Red #40	75	g		
XFO-380 non-silicone antifoam (Processing Aid)	60	g		
WSV Premix	37.9	g		
Niacinamide			14.2	g
d-Calcium Pantothenate			9.2	g
Thiamin Chloride Hydrochloride			2.4	g
Pyridoxine Hydrochloride			2.3	g
Riboflavin			1.8	g
Folic acid			350	mg
Biotin			277	mg
Cyanocobalamin			6.3	mg
Folic Acid	3.3	g		
Potassium iodide	204	mg		

[00057] **Example 2:** A 1000 kg batch of a fruit-flavored clear liquid nutritional composition having a protein content of about 9 grams of total protein of which 100 % is soy protein, 0.75 grams of beta-glucan and 100 mg of L-carnitine, all per 10 fluid ounce serving was prepared according to the bill of materials provided in Table 2 below. When preparing the product, the manufacturing method described above (*i.e.*, preparation of PIW, CHO-MIN and subsequent blending) was generally followed. The clear liquid nutritional composition contains 0 grams of fat, 13 grams of sugar, 9 grams of protein, has 157 calories per 10 fluid ounce serving and a measured osmolality of 269 mOSM/kg H₂O.

Table 2				
Ingredients	Approximate Amount per 1000			
	Kg			
Ingredient Water	Q.S.			
Maltrin M200	79.2	Kg		
Sucrose	34.5	Kg		
Soy Protein Isolate (Clarisoy from ADM)	30.2	Kg		
Provon A-190 Whey protein isolate	0	Kg		
Wheat Dextrins (Nutriose from Roquette)	7.48	Kg		
Barley Beta Fiber (Barliv from Cargill)	3.69	Kg		
Citric Acid	1.55	Kg		
Natural Fruit WONF	1.2	Kg		
Natural Orange WONF	1	Kg		
Ascorbic Acid	535	g		
L-Carnitine	321	g		

Liquid Sucralose (25%) Ross	275	g		
Sucralose			68.75	g
UTM/TM Premix	230	g		
Zinc Sulfate, Monohydrate			52.1	g
Ferrous Sulfate, Dried			40.8	g
Citric Acid, Anhydrous (Processing Aid)			14.2	g
Manganese Sulfate, monohydrate			13	g
Copper Sulfate, monohydrate			7.1	g
Chromium Chloride, hexahydrate			339	mg
Sodium Molybdate, dihydrate			146	mg
Sodium Selenate, anhydrous				
Water Soluble ADEK Premix	178	g		
dl-Alpha Tocopheryl Acetate				
Vitamin A Palmitate				
Phylloquinone				
Vitamin D3				
Acesulfame Potassium	110	g		
FD&C Red #40	75	g		
XFO-380 non-silicone antifoam (Processing Aid)	60	g		
WSV Premix	37.9	g		
Niacinamide			14.2	g
d-Calcium Pantothenate			9.2	g
Thiamin Chloride Hydrochloride			2.4	g

Pyridoxine Hydrochloride			2.3	g
Riboflavin			1.8	G
Folic acid			350	Mg
Biotin			277	Mg
Cyanocobalamin			6.3	Mg
Folic Acid	3.3	g		
Potassium iodide	204	mg		

[00058] Four separate formulations of liquid nutritional compositions according to the disclosed embodiments were prepared for hedonic testing. The formulations comprised the following: 601: 9 g of protein with a 70/30 soy/whey blend; 602: 9 g of protein with 100% soy; 605: 9 g total protein with 70/30 soy/whey with added 50% K citrate and 50% KCl; 606: 9 g total protein with 100% soy with added 50% K citrate and 50% KCl. The formulations were stored for 1 month prior to testing. A total of 41 individuals were asked to rate the overall acceptability of the four formulations on a 9-point Hedonic scale (1 = Dislike Extremely, 9 = Like Extremely). Panelists ranked the samples and then comments were then collected. Samples were served at room temperature. Panelists were served approximately 3/4 ounce of each sample, in 5 oz. plastic cups coded with 3-digit random numbers. Red lights were used to mask color differences among the samples. Analysis of Variance and the Fisher LSD test were used to analyze the hedonic data. Rank preference was determined using Friedman's Analysis of Rank. Significance was determined at the 95% confidence level. The results of the panel are shown in Table 3 below.

Table 3		
Samples	Overall Acceptability	Rank Preference
601	5.32	1.90
602	4.66	2.66

605	4.49	2.49
605	4.34	2.95
Statistical information	p=0.0101; LSD=0.588	p=0.002; LSD=0.559
scales	4=dislike slightly 5=neither like nor dislike	1=most preferred 4=least preferred

[00059] To the extent that the term “includes” or “including” is used in the specification or the claims, it is intended to be inclusive in a manner similar to the term “comprising” as that term is interpreted when employed as a transitional word in a claim. Furthermore, to the extent that the term “or” is employed (*e.g.*, A or B) it is intended to mean “A or B or both.” When the applicants intend to indicate “only A or B but not both” then the term “only A or B but not both” will be employed. Thus, use of the term “or” herein is the inclusive, and not the exclusive use. *See* Bryan A. Garner, *A Dictionary of Modern Legal Usage* 624 (2d. Ed. 1995). Also, to the extent that the terms “in” or “into” are used in the specification or the claims, it is intended to additionally mean “on” or “onto.” Furthermore, to the extent the term “connect” is used in the specification or claims, it is intended to mean not only “directly connected to,” but also “indirectly connected to” such as connected through another component or components.

[00060] While the present application has been illustrated by the description of embodiments thereof, and while the embodiments have been described in considerable detail, it is not the intention of the applicants to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. Therefore, the application, in its broader aspects, is not limited to the specific details, the representative apparatus, and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of the applicant’s general inventive concept.

What is claimed is:

1. A clear, liquid nutritional composition for improving the heart health of an individual, comprising: at least one source of viscous soluble fiber providing 0.004-0.02 grams of beta-glucan per Kcal of the nutritional composition; at least one source of protein in an amount sufficient to provide 6.25-20 grams of protein per serving, at least one source of carbohydrates, and at most 1 gram of fat per 100 grams of the nutritional composition.
2. The composition of claim 1 wherein the protein comprises at least 6.25 grams of soy protein per serving.
3. The composition of claim 1 or 2, wherein the liquid nutritional composition is reconstituted from a powder.
4. The composition of any one of claims 1-3 comprising 0.75-3 grams of barley beta-glucan, at least 6.25 grams of soy protein and 50-250 mg of L-carnitine per serving.
5. The composition of any one of claims 1-4 wherein the calorie content of the nutritional composition is 150-180 Kcal.
6. A clear, shelf-stable liquid nutritional composition with heart health benefits comprising:
 - at least one source of protein in an amount sufficient to provide 9-15 grams protein per serving,
 - at least one source of carbohydrates,
 - 0.75 grams-3 g of beta-glucan fiber per serving, and
 - at most 1 weight % fat based on total weight of the liquid nutritional composition,
 - wherein at least 6.25 grams of the protein is soy protein.
7. The composition of any one of claims 1 to 6 wherein the pH of the composition is 2-4.6.
8. The composition of any one of claims 1 to 7 wherein the beta-glucan is barley-sourced.
9. The composition of any one of claims 1 to 8 further comprising L-carnitine.
10. The composition of any one of claims 1 to 9, further comprising fruit juice.
11. The composition of claim 6 further comprising 5-150 mg of curcumin per serving.

12. A liquid nutritional composition for use in improving the cardiovascular health of an individual in need thereof wherein the liquid nutritional composition comprises: at most 1 gram fat per 100 grams of the nutritional composition; at least one source of protein in an amount sufficient to provide 6.25-20 grams of protein per serving; at least one source of carbohydrates; vitamins and minerals; and at least one source of viscous soluble fiber providing 0.75-3 grams of beta-glucan per serving.
13. The composition of claim 12, wherein the liquid nutritional composition further comprises a source of resistant starch.
14. The composition of claim 12 or 13, wherein the beta-glucan is barley-sourced.
15. The composition of any one of claims 12 to 14, wherein the liquid nutritional composition further comprises water and is in the form of a clear liquid.
16. The composition of any one of claims 12 to 15, wherein the liquid nutritional composition has a pH of 2-4.6.
17. The composition of any one of claims 12 to 16, wherein the liquid nutritional composition further comprises 50-250 mg L-carnitine.
18. The composition of any one of claims 12 to 17, wherein the liquid nutritional composition has at least 3 grams of total fiber per serving.
19. The composition of any one of claims 12 to 18, wherein the nutritional composition comprises at least 6.25 grams of soy protein per serving.
20. The composition of any one of claims 12 to 19, wherein the cardiovascular health that is improved is a heart condition, heart-related condition, heart disease or heart defect.