

Title: FOOD SUPPLEMENT FOR INCREASING LEAN MASS AND STRENGTH**FIELD OF INVENTION**

The present invention is directed to food supplements which comprise nitric oxide or derivatives thereof, and a source of amino acids or derivatives thereof; supplements which stimulate nitric oxide in the body, and a source of amino acids; supplements which enhance and mimic insulin activity; and to methods for supplementing the diet of an athlete and methods for enhancing an athlete's muscle size and/or strength, which methods employ these food supplements.

BACKGROUND OF INVENTION

Food supplements for enhancing an athlete's muscle size and strength have become popular substitutes for steroids and other drugs in various sports and body building regimes. However, as athletes continually strive for improved performance, there is a continuing need for non-steroid containing aids for increasing lean mass, muscle size and strength.

SUMMARY OF THE INVENTION

Nitric oxide plays an essential role in tonic and exercise-associated (e.g., recovery from exercise) regulation of vasodilation and blood flow. The present inventors have found that increased NO through supplementing the diet of an athlete with substances which increase the concentration of nitric oxide (NO) or increase its half life in the body, in combination with a source of amino acids, may provide surprising enhancement of an athlete's muscle size and/or strength when administered to an athlete's diet. Accordingly, in one broad aspect the present invention provides new food supplements to increase the delivery and duration of nitric oxide in the body. These food supplements do not themselves contain nitric oxide; rather, they act to promote the production of nitric oxide or to enhance its half life in the body. Preferably the invention provides food supplements particularly adapted for supplementing the diet of an athlete, preferably the food supplements of the present invention enhance an athlete's muscle size and/or strength.

According to one embodiment of the present invention there is provided a food supplement comprising a substance which increases nitric oxide production in the body, and, a source of amino acids.

Preferably the substance which increases nitric oxide production may act by stimulating insulin levels in the circulation, and, a source of amino acids.

According to another preferred embodiment, the supplements of the present invention include a substance which may increase insulin sensitivity, and, a source of amino acids.

- 2 -

According to yet another aspect of the present invention, there is provided a supplement which may increase nitric oxide and thereby increase nitrogen retention in the body. Preferably the supplement comprises a substance which may increase nitrogen retention in the body, in combination with a source of amino acids.

In another aspect, the present invention provides a food supplement comprising a substance which enhances and mimics insulin activity, and, a source of amino acids.

In an embodiment of the supplement of the invention the substance which increases nitric oxide production is glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, or folic acid, preferably ginseng.

In another embodiment, a food supplement of the invention comprises a substance which provides at least one function selected from the group consisting of enhancing insulin activity and mimicking insulin activity, and a source of amino acids, preferably the substance is glucomannan. In another embodiment the substance is N-acetyl cysteine, α -lipoic acid, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, or d-pinitol, in this respect, preferably the substance is myo-inositol.

In another embodiment, the present invention provides a food supplement which increases nitrogen retention in the body comprising a substance which increases nitrogen retention and a source of amino acids, preferably the substance which increases nitrogen retention in the body is glucomannan or l-arginine, most preferably glucomannan.

In another embodiment, the present invention provides a food supplement comprising one or more of a glycosidal saponin, glucomannan D-chiro-inositol, myo-inositol, and a source of amino acids.

In yet another embodiment, the present invention provides a food supplement comprising one or more of a glycosidal saponin, glucomannan myo-inositol, and a source of amino acids.

According to any of these embodiments, the source of amino acids in the supplement comprises whey protein or a whey protein derivative.

In another embodiment of the invention there is provided a food supplement comprising a substance which increases nitric oxide production in the body, and whey protein or a whey protein derivative, preferably the whey protein derivative, more preferably two or more whey protein derivatives.

According to certain embodiments of the invention, the substance which increases nitric oxide production is a glycosidal saponin, ginseng, l-arginine, N-

- 3 -

acetyl cysteine or folic acid, preferably ginseng.

In another embodiment of the invention there is provided a food supplement comprising one or more of glycosidal saponins; myo-inositol; d-chiro-inositol; or glucomannan; in concentrations of 1mg-3000mg glycosidal saponins; 1mg-2000mg myo-inositol; 1mg-2000mg d-chiro-inositol; 10mg-4000mg glucomannan; and a source of amino acids. Preferably the food supplement comprises one or more of glycosidal saponins; myo-inositol; or glucomannan in concentrations of about 150mg to 1500mg glycosidal saponins; about 100mg to 2000mg myo-inositol; and 25mg to 2000mg glucomannan, more preferably it comprises one or more of glycosidal saponins; myo-inositol; or glucomannan in concentrations of about 50mg to 500mg glycosidal saponins; about 200mg to 1000mg myo-inositol; and 50mg to 1000mg glucomannan.

According to a preferred embodiment, the supplement comprises 100mg to 500mg glucomannan and a source of amino acids, with preferably about 50mg glycosidal saponins. As stated previously the preferred source of amino acids for any supplement according to the invention comprises whey protein.

In another embodiment of the food supplement of the invention there is provided a food supplement comprising a component which increase nitric oxide production in the body, and amino acids, the food supplement being in powder or granular form. Preferably a first component is a glycosidal saponin, ginseng, l-arginine, N-acetyl cysteine, or folic acid, and mixtures thereof, and a second component consists of whey protein, wherein the whey protein is included in the food supplement in an amount of from about 0.01mg to about 1000mg per gram of food supplement. In another embodiment, the food supplement comprises from 13mg to 11,000mg of the first component, per 28g of the food supplement. In another embodiment the food supplement comprises from 275mg to 5500mg of the first component, per 28g of the food supplement.

In another broad aspect, the present invention provides methods of supplementing bodybuilding in an athlete comprising administering to the athlete an effective amount of a food supplement according to the present invention to achieve an increase in muscle size and strength.

Accordingly, in an embodiment of the invention there is provided a method for increasing an athlete's lean muscle mass and strength, comprising administering to the athlete a food supplement comprising a substance which increases nitric oxide production in the body, and a source of amino acids, preferably the substance which increases nitric oxide production is glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, or folic acid, most preferably ginseng.

- 4 -

In another embodiment there is provided a method for increasing an athlete's lean muscle mass and strength, comprising administering to the athlete a food supplement comprising a substance which provides at least one function selected from the group consisting of enhancing insulin activity and mimicking
5 insulin activity, and a source of amino acids, preferably the substance is glucomannan. In another embodiment, the substance is N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, or d-pinitol, preferably myo-inositol.

10 In another aspect, methods according to the invention preferably require that the supplement is administered to the athlete on a daily basis, and preferably the food supplement is mixed with water to provide a liquid drink.

In another embodiment there is provided a method for increasing muscle mass and/or strength of an individual, comprising administering to the
15 individual a food supplement comprising a substance which increases nitric oxide production in the body, and a source of amino acids the substance which increases nitric oxide production is glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, or folic acid, preferably the substance is ginseng.

In another embodiment of the invention there is provided a method for
20 increasing muscle mass and or strength of an individual comprising administering to the individual a food supplement comprising a substance which provides at least one function selected from the group consisting of enhancing insulin activity and mimicking insulin activity, and a source of amino acids, preferably the substance is glucomannan. In another embodiment the substance is N-acetyl
25 cysteine, α -lipoic acid, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, or d-pinitol, preferably myo-inositol.

As stated above, the methods according to the invention preferably require that the supplement is administered to the individual on a daily basis.
30 Preferably the food supplement is mixed with water to provide a liquid drink.

In another embodiment of the invention there is provided a method for increasing an athlete's lean muscle mass and strength, comprising administering to the athlete a food supplement comprising a substance which increases nitric oxide production in the body and whey protein, preferably the substance which
35 increases nitric oxide production is glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, or folic acid, more preferably ginseng.

In another embodiment there is provided a method for increasing an athlete's lean muscle mass and strength, comprising administering to the athlete

- 5 -

a food supplement comprising a substance which provides at least one function selected from the group consisting of enhancing insulin activity and mimicking insulin activity, and whey protein, preferably the substance is glucomannan. In another embodiment the substance is N-acetyl cysteine, α -lipoic acid,
5 myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, or d-pinitol, preferably myo-inositol.

In another embodiment of the invention there is provided a method for increasing an athlete's lean muscle mass and strength, comprising administering to
10 the athlete a food supplement comprising one or more of glycosidal saponins; myo-inositol; d-chiro-inositol; or glucomannan, in concentrations of about 1mg-3000mg glycosidal saponins; 1mg-2000mg myo-inositol; 1mg-2000mg d-chiro-inositol; 10mg-4000mg glucomannan; and a source of amino acids. In another embodiment the supplement comprises one or more of glycosidal saponins;
15 myo-inositol; or glucomannan in concentrations of about 150mg to 1500mg glycosidal saponins; about 100mg to 2000mg myo-inositol; and 25mg to 2000mg glucomannan. In another embodiment the supplement comprises one or more of glycosidal saponins; myo-inositol; or glucomannan in concentrations of about 50mg to 500mg glycosidal saponins; about 200mg to 1000mg myo-inositol; and 50mg to
20 1000mg glucomannan. In yet another embodiment of the method the supplement comprises about 100mg to 500mg glucomannan, and in another embodiment the supplement comprises about 50mg glucosidal saponins.

With respect to the methods of the invention herein preferably the source of amino acids comprise whey protein.

25 Other features and advantages of the present invention will become apparent from the following detailed description. It should be understood, however, that the detailed description and the specific examples while indicating preferred embodiments of the invention are given by way of illustration only. Various changes and modifications within the spirit and scope
30 of the invention will become apparent to those skilled in the art from this detailed description.

DETAILED DESCRIPTION OF THE INVENTION

The food supplements and methods of the present invention may provide further and significant muscle size and strength enhancement or improvement in
35 individuals as compared with supplements and methods employing only proteins and/or amino acids. While it is expected that the supplements and methods of the present invention will be of importance to bodybuilders and other athletes, the supplements and methods of the invention are not limited to those groups.

- 6 -

Rather, any individual may use the supplements and methods of the invention. Indeed, the supplements and methods may have applications to all animals.

Although the present invention is not to be limited by any theoretical explanation, it is believed that nitric oxide plays an essential role in tonic and exercise-associated (e.g., recovery from exercise) regulation of vasodilation and blood flow. Increased NO supports improved perfusion of skeletal muscle, which it is believed thereby stimulates oxidative metabolism, ATP and creatine phosphate biosynthesis, nutrient (e.g., amino acid) delivery and utilization for muscle (e.g., myofibrillar) protein synthesis, sarcomere addition, glucose delivery and uptake, glycogen synthesis, creatine delivery and uptake, creatine phosphate synthesis, fat loss regulation of nutrient-mediated insulin secretion, and nitrogen retention. The supplements according to the present invention are preferably based on a unique whey-protein system fortified with additional amino acids to further enhance the rapid absorption (i.e., of α -amino nitrogen) characteristics of whey which lend to its potent protein anabolic effects. Thus, combined with the metabolic effects of increased NO function, the supplements of the present invention effectively enhance the muscle protein anabolic effects of a source of amino acids, preferably any source of protein, more preferably whey.

The food supplements and methods of the present invention may provide further and significant size and strength enhancement through the role of certain substances which mimic and/or increase the sensitivity of insulin, in conjunction with a source of amino acid. Although, as already stated, the present invention is not to be limited by any theoretical explanation, it is believed that the family of substances known as the inositols, are physiological precursors to membrane protein anchors known as glycosylphatidylinositols (GPI). As used herein, "inositols" includes myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, d-pinitol and myo-inositol. Hydrolysis of GPI releases inositolphosphoglycans which are water soluble mediators of insulin signalling events. Accordingly, increased availability of these GPI precursors, increases insulin sensitivity and these GPIs can trigger insulin signalling pathways and events independent of insulin thereby mimicking the effects of insulin. The pathways and events which are mimicked include, but are not limited to amino acid transport, protein synthesis, gene transcription, mRNA translation initiation, glucose uptake, glycogen storage, steroid hormone synthesis, and can thereby increase the development of muscle cells. Consequently, supplements which comprise a substance which can enhance and/or mimic insulin activity, and a source of amino acids, preferably any source of protein, more preferably, whey, may provide

- 7 -

further and significant muscle size and strength enhancement as compared with supplements employing only proteins or amino acids.

The food supplements described herein comprise the compounds specifically identified and any derivatives thereof, for example a salt or ester.

5 Suitable salts include, but are not limited to, alkali and alkaline earth metal salts, for example sodium, potassium or calcium salts, while suitable esters include, but are not limited to, alkyl esters, for example, methyl, ethyl or propyl esters, or lactone esters.

As used herein "source of amino acid" means any peptide, polypeptides, protein or any composition of individual amino acids or individual amino acid
10 and including creatine. Throughout the present specification, as a part of the food supplement of the invention whey protein or a derivative thereof are identified as the preferred source of amino acids or protein. Commercially available whey protein derivatives include WPI 97, Whey Peptides, WPC 80, and ION
15 EXCHANGE whey protein. However, as will be readily appreciated by those skilled in the art, other sources of protein include milk protein, casein, any of the albumins including chicken egg albumin, and soy, may be used as a source of amino acids.

Supplements

20 According to one embodiment of the present invention there is provided a food supplement comprising a substance which increases nitric oxide production in the body in combination with a source of amino acids. As used herein, "a food supplement comprising a substance ... in combination with a source of amino acids" means the supplement contains both the substance which has an action as well as
25 a source of amino acids. According to one aspect, an increase in nitric oxide production may be brought about by a substance selected from the group consisting of glycosidal saponins, ginseng, L-arginine, folic acid, bioflavonoids, for example, grape seed extract, and herbs, preferably L-arginine, most preferably ginseng.

According to one aspect of the present invention a substance which
30 increases nitric oxide production may act by stimulating insulin levels in the circulation, preferably, the substance is selected from the group consisting of L-arginine, α -lipoic acid, glycosidal saponins, for example, ginseng, and N-acetyl cysteine, most preferably ginseng.

According to another embodiment of the present invention, there is
35 provided a food supplement comprising a substance which mimics and/or enhances insulin activity, the supplement also containing a source of amino acids. According to a preferred embodiment, a substance which mimics and/or enhances insulin activity is preferably selected from the group consisting of N-acetyl

cysteine, α -lipoic acid, myo-inositol, preferably d-myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, d-pinitol and glucomannan, most preferably glucomannan.

5 A source of amino acids is preferably selected from the group consisting of WPI 97, Whey Peptides, WPC 80, ION EXCHANGE, lactoferrin, whey protein, most preferably whey protein, although as indicated above, any other protein source may be used.

10 According to yet another aspect of the present invention, there is provided a supplement which may increase nitric oxide thereby increasing nitrogen retention in the body. Preferably the supplement comprises a substance which may increase nitrogen retention in the body, in combination with a source of amino acids. Preferably the substance which may increase nitrogen retention in the body is selected from the group consisting of glucomannan, glycosidal saponins, for
15 example, ginseng, l-arginine, glutamine, methionine and leucine, preferably glucomannan, most preferably ginseng. The source of amino acids is preferably selected from the group consisting of WPI 97, Whey Peptides, WPC 80, ION EXCHANGE, lactoferrin, whey protein, most preferably whey protein.

20 As will be readily appreciated by those skilled in the art, the supplement is not limited to only one substance which by itself may increase nitric oxide, insulin output, insulin secretion, insulin sensitivity, and one source of amino acids. Indeed the present invention provides for combinations of substances and sources of amino acids, in differing amounts.

25 The food supplement compositions of the present invention may be provided in a variety of formats, for example, in liquid form, powder form, or protein bar form. Powders are preferable and are prepared to be suitable for mixing with water or other liquids. The food supplement compositions in powder or granular form may be provided in accordance with customary processing techniques, for example as spray dried powders, or the like.

30 According to one embodiment, the food supplement compositions of the present invention are delivered in powder on a per one "scoop" basis. As used herein, one "scoop" is approximately 28 g of supplement. According to one embodiment, one "scoop" comprises: glycosidal saponins (such as ginseng) from 1mg-3000 mg; myo-inositol, from 1mg- 2000mg; d-chiro-inositol, from 1mg-2000mg;
35 and glucomannan, from 10mg-4000mg; and a source of amino acids, preferably protein, most preferably whey.

 According to another embodiment a food supplement composition comprises, when delivered in powder form per one "scoop": glycosidal saponins,

about 150mg to about 1500mg; myo-inositol about 100mg to about 2000mg; and glucomannan from about 25mg to about 2000mg; and a source of amino acids, preferably protein, most preferably whey.

5 According to another embodiment the food supplement composition comprises, when delivered in powder form per one "scoop": glycosidal saponins from about 50mg to about 500mg; glucomannan from about 50mg to about 1000mg; and myo-inositol, from about 200mg to about 1000mg, and a source of amino acids preferably protein, most preferably whey.

10 According to another embodiment, the food supplement composition comprises, when delivered in powder form per one "scoop": glucomannan from about 100mg to about 500mg; and a source of amino acids, preferably protein, most preferably whey.

15 According to yet another embodiment, the food supplement composition comprises, when delivered in powder form per one "scoop" glycosidal saponins at about 50mg; and a source of amino acids, preferably protein, most preferably whey.

The food supplement compositions according to the present invention may further contain additional components to further increase the speed and or ease with which the substances enter the bloodstream and subsequently possibly impact the muscle tissue, or to otherwise enhance the effects of nitric oxide in the body. For example, additional amino acids may be included in the food supplement compositions. Suitable amino acids include, but are not limited to, glutamine, alanine, taurine, carnitine, acetyl-L-carnitine, and the like. These additional amino acids may stimulate cell volumization and protein synthesis and therefore provide further advantages to increasing muscle strength and/or size. These amino acids may be employed individually or in various combinations and in amounts customary in the art, for example in the range of from about 0.01 mg to about 1000 mg per gram of food supplement depending upon the amount of protein, or peptides, derived from whey or other source of amino acid in the supplement.

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The food supplement compositions can also contain ascorbic acid (vitamin C), for example in amounts equal to or exceeding the recommended minimum daily requirements. Another component for possible use in the food supplements of the present invention comprises beta-hydroxy, beta-methyl butyrate (HMB), in amounts known in the art.

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The food supplement compositions may further comprise natural and/or artificial flavouring components, dyes or other colouring additives, preservatives and other conventional food supplement additives known in the art.

- 10 -

Methods of Use of Supplements

The food supplements according to the present invention may be employed in methods for supplementing the diet of an athlete, and/or for enhancing an athlete's muscle size or strength. The food supplement compositions of the present invention are particularly advantageous for creating an increased anabolic environment and obtaining extra growth in lean muscle mass and strength. Accordingly, the present invention provides methods of supplementing bodybuilding in an athlete comprising administering to the athlete an effective amount of a food supplement according to the present invention. Administration of an "effective amount" of the supplements and substances of the present invention is defined as an amount effective, at dosages and for periods of time necessary to achieve the desired result. The effective amount of the supplements of the invention may vary according to factors such as the age, sex, and weight of the athlete. Dosage regima may be adjusted to provide the optimum response: Several divided doses may be administered daily or the dose may be proportionally reduced as indicated by the exigencies of the individual athlete situation.

As just stated, the amount of the food supplement composition which is administered to the diet of the athlete may vary depending on the desired effect, the body weight and characteristics of the athlete, and the like. For example, in preferred methods for supplementing the diet of an athlete and/or for enhancing an athlete's muscle size or strength, from about 0.5 to about 10 scoops of a supplement according to present invention are administered to the diet of the athlete on a daily basis.

In more preferred embodiments of these methods, from about 1 to about 6 scoops of a supplement according to the present invention are administered to the diet of the athlete on a daily basis. The number of scoops and frequency per day will depend upon the composition of the scoop, as outlined in variations set out above.

As will be readily appreciated, a food supplement in accordance with the present invention may be administered in a single serving or in multiple servings spaced throughout the day. In a preferred embodiment, a food supplement in accordance with the present invention may be administered once in the morning, once immediately or shortly after training and once in the evening on a daily basis.

In order to maximize the effects of a food supplement according to the present invention, in enhancing muscle size and/or strength, it is preferred that the food supplement is administered to the diet of the athlete immediately

- 11 -

following an exercise period. On non-workout days, the food supplement may be administered anytime during the day, although administering a first amount of a food supplement upon awakening or otherwise during the morning hours is preferred.

- 5 The food supplement compositions and methods of the invention are further illustrated in the following non-limiting examples. In the examples and throughout the present specification, parts and percentages are by weight unless otherwise specified.

EXAMPLES

10 EXAMPLE 1

A muscle size and/or strength enhancing regime is initiated and established so that the athlete consumes three servings of the following food supplement daily, with each serving being 1 scoop which is approximately 28 g of the supplement and comprising:

15 Per 1 scoop:

Protein 20g

Carbohydrates 3g

Fiber 1g

Sugar 2g

20 Fat: 1.5g

These components may be comprised of the following:

INGREDIENT

AMOUNT/SERVING

SynthePro™ A blend of the following constituting 18g

WPI 97

25 WHEY PEPTIDES

WPC 80

ION EXCHANGE WHEY

LACTOFERRIN

METHIONINE

30 LEUCINE

Nitroxen™ A blend of the following constituting

ARGININE

GLYCOSIDAL SAPONINS

FOLIC ACID

400mcg

35 Insulogen™ A blend of the following constituting

200mg

MYO-INOSITOL,

CIS-INOSITOL

EPI-INOSITOL

- 12 -

	ALLO-INOSITOL	
	MUCO-INOSITOL	
	NEO-INOSITOL	
	SCYLLO-INOSITOL	
5	D-CHIRO-INOSITOL	
	L-CHIRO-INOSITOL	
	INZITOL((D-PINITOL)	
	ALPHA-LIPOIC ACID	
	GLUCOMANNAN	
10	TAURINE	100mg
	POTASSIUM PHOSPHATE	100mg
	VIT E	30IU
	NAC	25mg
	VIT B6	10.5mg
15	MAGNESIUM	50mg
	GUAR GUM	
	The rest of the volume comprising the following:	
	GLUTAMINE PEPTIDES	
	GLUTAMINE	
20	ALPHA-KETO GLUTARATE	
	PHENYLALANINE	
	Creatine is included in the composition.	

Each supplement serving is mixed with 6 ounces of cold water and the servings are administered approximately evenly spaced through the day, with a first serving in the morning, shortly after awakening, a second serving being consumed immediately after the athlete's exercise workout, and a third at a convenient time in the evening.

EXAMPLE 2

A muscle size and/or strength enhancing regime as outlined in Example 1 is established so that the athlete consumes three servings of the food supplement daily, with each serving being 2 scoops which is approximately 56 g of the supplement.

EXAMPLE 3

Where the regime in Example 1 or 2 is established, the athlete continues this regime on a day-to-day basis. As in Example 1 or 2, the serving is mixed with cold water to form a liquid drink. Alternatively, the food supplements may be combined with other liquid drinks or foods as desired. This regime is intended to last for the full term during which an athlete is working out. The servings and

- 13 -

their timing should also be consumed on non-workout days (with the second serving being taken mid-day) in order to maintain enhanced muscle size and/or strength.

5 The servings set forth in these examples are designed for a 2000 calorie diet. Daily values may be increased or decreased depending on the calorie needs of individual athletes, and/or body weights of individual athletes.

EXAMPLE 4

Thirty-six experienced weight trained males were randomly assigned (double-blind) to one of three experimental groups: 1. a dietary supplement of a
10 whey protein blend, comprising whey protein isolate 97%, creatine, glycosidal saponins, arginine, and glucomannan (WI) - 1.2 g/kg/d whey protein, and 0.1 g/kg/d creatine; pure whey protein (W) - 1.2 g/kg/d; or a placebo (P) - 1.2 g/kg/d maltodextrin. Pre and post test measures consisted of 1-RM bench press, 1-RM squat, Biodex isokinetic leg extension power (ILP), and body composition as
15 assessed by dual energy x-ray absorptiometry (DEXA). Training involved a 4-day split routine of high volume, heavy load periodized workouts with sets and reps varying from 4-5 sets and 4-10 reps. Each group experienced a significant change from baseline measure ($p < 0.05$). Post hoc analysis revealed that the WI group demonstrated greater increases in lean muscle mass (+4.0 kg), 1-RM bench press
20 (+16 kg), and ILP (+23 J/s) than W and P ($p < 0.05$). The W group had a significantly greater increase in lean mass (+2.3 kg) and ILP (+18 J/s) than the P group ($p < 0.05$). These findings indicate that whey protein supplementation when combined with resistance training for 6-weeks results in significant gains in muscular power and lean muscle mass, and when the whey protein is combined
25 with other potentially ergogenic ingredients, even larger gains in muscle mass, 1-RM strength, and power occur.

EXAMPLE 5

36 trained males resistance-trained for 42 days and were divided into three equally sized groups and the groups' diets supplemented with one of:
30 Group 1 = the Supplement of Example 1 (1.2 g/kg/d), which included creatine
Group 2 = Whey Protein [WP] (1.2 g/kg/d)
Group 3 = Placebo [PL] (1.2 g/kg/d maltodextrin)

Results

The following is illustrative of the results for individuals in Group 1: Subject 11a
35 gained 14.5 lbs total body mass and 12.8 lbs of lean mass and added 60 lbs to his bench press and 90 lbs to his squat. Finally this individual lost 2.4 lbs of bodyfat & decreased bodyfat by 2%. With respect to results as between groups, Group 1 gained 147% more total body mass than Group 2 on WP, and gained 74% more lean

- 14 -

tissue mass than Group 2. As well, Group 1 gained 270% more total body mass than placebo group Group 3. Further, Group 1 gained 344% more lean tissue mass than Group 3 and increased lean tissue mass (LTM) by 4.0 kg (8.8 lbs). The bench press strength gains of Group 1 were significantly greater than those of Group 2 after 42 days. Finally, Group 1's bench press strength was increased by approximately 16 kg (35.2 lbs) after 42 days.

Conclusion

The mass and strength gains of Group 1 were greater than those found in group 2 in weight-trained subjects.

10 EXAMPLE 6

The purpose of this study was to evaluate the effects of two different types of whey protein supplements on body mass, body composition and exercise performance over 28 days, in resistance trained adults. In a double blind trial, 24 health athletic adults males were randomized to receive either a whey protein concentrate/isolate based product (Group 1: the Supplement of Example 1 which included creatine) or whey protein concentrate (WPC 80; Group 2). Both groups ingested 120 grams of supplemental protein daily. Each subject followed a diet that restricted food protein intake to 2.0 gm/kg/d. Total protein intake was ~3.3 gm/kg/d with supplementation. In addition, all participants engaged in hypertrophy resistance exercise under the guidance of an exercise physiologist. At baseline, day 14 and 28, each subject underwent body composition and exercise testing. By day 28, Group 1 gained a statistically significant amount of body mass compared to Group 2 [1.28 vs. - 0.02 kg; p=0.043]. In terms of lean body mass (LBM) by day 14, Group 1 increased significantly compared to Group 2 (1.49 vs. -0.31 kg; p=0.01). By day 28 the intragroup change for Group 1 was significant [1.25 kg; p<0.01], while the change for Group 2 was insignificant. On day 14 Group 1 experienced a greater reduction in body fat compared to Group 2 (-1.06% vs. 0.53%; p=0.04). For exercise, there were no significant differences between the two groups however, both groups improved significantly over the 28 days (bench and leg press 1 rep maximum and repetitions until failure both at 1x and 2x body weight respectively). The results of this study indicate Group 1 gained more mass over 28 days than Group 2.

EXAMPLE 7

For this study 24 trained males followed a control diet (2.0g protein/day) and resistance-trained for 28 days and supplemented with one of:
Group 1 = Supplement of Example 1 which included creatine (120g/day)
Group 2 = Whey Protein Concentration [WPC] (120g/day).

Results

- 15 -

The lean body mass (LBM) gains of Group 1 were significantly greater than those of Group 2 on WPC as determined after 14 days (1.49 vs. -0.31 kg). It was also observed that Group 1 had significantly increased lean body mass (LBVM)(by 1.25 kg) after 28 days. Indeed, Group 1 had gained 2400% more LBM than WPC after 5 28 days. In addition to these gains, the total body mass gains (TBM) of Group 1 were significantly greater than Group after 28 days (1.28 vs. -0.02 kg). Finally, the % body fat loss was significantly greater in Group 1 than found for Group 2 after 14d (-1.06 vs. +0.53%). Three individual results exemplify the results of members from Group 1: After 14 days subject SV had an increase in LBM of 8.6 lbs; 10 subject DK had an increase in 1 RM bench press of 25.3 lbs; and subject RB had an increase in 1 RM leg press of 90.2 lbs.

Conclusion

Group 1 individuals experienced greater mass gains than those members of Group 2 (weight-trained subjects of both Groups).

15 The examples and embodiments set forth in the present application are provided only to illustrate various aspects of the invention and additional embodiments and advantages of the food supplements and methods of the present invention will be apparent to those skilled in the art.

- 16 -

WE CLAIM:

1. A food supplement comprising a substance which increases nitric oxide production in the body, and, a source of amino acids.
2. A food supplement according to claim 1 wherein the substance which
5 increases nitric oxide production is glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, or folic acid.
3. A food supplement according to claim 2 wherein the substance is ginseng.
4. A food supplement which comprises a substance which provides at least one function selected from the group consisting of enhancing insulin activity and
10 mimicking insulin activity, and a source of amino acids.
5. A food supplement according to claim 4 wherein the substance is glucomannan.
6. A food supplement according to claim 4 or 5 wherein the substance is N-acetyl cysteine, α -lipoic acid, myo-inositol, cis-inositol, epi-inositol,
15 allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, or d-pinitol.
7. A food supplement according to claim 6 wherein the substance is myo-inositol.
8. A food supplement which increases nitrogen retention in the body
20 comprising a substance which increases nitrogen retention and a source of amino acids.
9. A supplement according to claim 8 wherein the substance which increases nitrogen retention in the body is glucomannan or l-arginine.
10. A supplement according to claim 9 wherein the substance is glucomannan.
- 25 11. A food supplement comprising one or more of a glycosidal saponin, glucomannan D-chiro-inositol, myo-inositol, and a source of amino acids.



- 17 -

12. A food supplement comprising one or more of a glycosidal saponin, glucomannan myo-inositol, and a source of amino acids.
13. A supplement according to any one of claims 1-12 wherein the source of amino acids comprise whey protein or a whey protein derivative.
- 5 14. A food supplement comprising a substance which increases nitric oxide production in the body, and whey protein or a whey protein derivative.
15. A supplement according to claim 14 comprising a whey protein derivative.
16. A supplement according to claim 14 comprising a combination of two or more whey protein derivatives.
- 10 17. A food supplement according to any one of claims 14-16 wherein the substance which increases nitric oxide production is a glycosidal saponin, ginseng, l-arginine, N-acetyl cysteine or folic acid.
18. A food supplement according to claim 17 wherein the substance is ginseng.
- 15 19. A food supplement comprising one or more of glycosidal saponins; myo-inositol; d-chiro-inositol; or glucomannan; in concentrations of 1mg-3000mg glycosidal saponins; 1mg-2000mg myo-inositol; 1mg-2000mg d-chiro-inositol; 10mg-4000mg glucomannan; and a source of amino acids.
- 20 20. A food supplement according to claim 19 comprising one or more of glycosidal saponins; myo-inositol; and glucomannan in concentrations of about 150mg to 1500mg glycosidal saponins; about 100mg to 2000mg myo-inositol; and 25mg to 2000mg glucomannan.
- 25 21. A food supplement according to claim 19 or 20 comprising one or more of glycosidal saponins; myo-inositol; or glucomannan in concentrations of about 50mg to 500mg glycosidal saponins; about 200mg to 1000mg myo-inositol; and 50mg to 1000mg glucomannan.
22. A food supplement according to claim 19 comprising 100mg to 500mg glucomannan.



- 18 -

23. A food supplement according to claim 19 comprising about 50mg glycosidal saponins.
24. A food supplement according to anyone of claims 19-23 wherein the source of amino acids comprise whey protein.
- 5 25. A method for increasing an athlete's lean muscle mass and strength, comprising administering to the athlete a food supplement comprising a substance which increases nitric oxide production in the body, and a source of amino acids.
26. A method according to claim 25 wherein the substance which increases nitric oxide production is glycosidal saponins, ginseng, l-arginine, N-acetyl
10 cysteine, or folic acid.
27. A method according to claim 26 wherein the substance is ginseng.
28. A method for increasing an athlete's lean muscle mass and strength, comprising administering to the athlete a food supplement comprising a substance which provides at least one function selected from the group consisting of
15 enhancing insulin activity and mimicking insulin activity, and a source of amino acids.
29. A method according to claim 28 wherein the substance is glucomannan.
30. A method according to claim 28 wherein the substance is N-acetyl cysteine, α -lipoic acid, myo-inositol, cis-inositol, epi-inositol, allo-inositol,
20 muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, or d-pinitol.
31. A method according to claim 30 wherein the substance is myo-inositol.
32. A method according to any one of claims 25-31, wherein the supplement is administered to the athlete on a daily basis.
- 25 33. A method according to anyone of claims 25-32, wherein the food supplement is mixed with water to provide a liquid drink.
34. A method for increasing muscle mass and/or strength of an individual,



- 19 -

comprising administering to the individual a food supplement comprising a substance which increases nitric oxide production in the body, and a source of amino acids.

35. A method according to claim 34 wherein the substance which increases
5 nitric oxide production is glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, or folic acid.

36. A method according to claim 35 wherein the substance is ginseng.

37. A method for increasing muscle mass and or strength of an individual
comprising administering to the individual a food supplement comprising a
10 substance which provides at least one function selected from the group consisting of enhancing insulin activity and mimicking insulin activity, and a source of amino acids.

38. A method according to claim 37 wherein the substance is glucomannan.

39. A method according to claim 37 wherein the substance is N-acetyl
15 cysteine, α -lipoic acid, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, or d-pinitol.

40. A method according to claim 39 wherein the substance is myo-inositol.

41. A method according to anyone of claims 37-40 wherein the supplement is
20 administered to the individual on a daily basis.

42. A method according to anyone of claims 37-41 wherein the food supplement is mixed with water to provide a liquid drink.

43. A method for increasing an athlete's lean muscle mass and strength,
comprising administering to the athlete a food supplement comprising a substance
25 which increases nitric oxide production in the body and whey protein.

44. A method according to claim 43 wherein the substance which increases nitric oxide production is glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, or folic acid.



- 20 -

45. A method according to claim 44 wherein the substance is ginseng.
46. A method for increasing an athlete's lean muscle mass and strength, comprising administering to the athlete a food supplement comprising a substance which provides at least one function selected from the group consisting of
5 enhancing insulin activity and mimicking insulin activity, and whey protein.
47. A method according to claim 46 wherein the substance is glucomannan.
48. A method according to claim 46 wherein the substance is N-acetyl cysteine, α -lipoic acid, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, or
10 d-pinitol.
49. A method according to claim 48 wherein the substance is myo-inositol.
50. A method according to any one of claims 43-49, wherein the supplement is administered to the athlete on a daily basis.
51. A method according to any one of claims 43-50, wherein the food
15 supplement is mixed with water to provide a liquid drink.
52. A method for increasing an athlete's lean muscle mass and strength, comprising administering to the athlete a food supplement comprising one or more of glycosidal saponins; myo-inositol; d-chiro-inositol; or glucomannan, in concentrations of about 1mg-3000mg glycosidal saponins; 1mg-2000mg
20 myo-inositol; 1mg-2000mg d-chiro-inositol; 10mg-4000mg glucomannan; and a source of amino acids.
53. A method according to claim 52 wherein the supplement comprises one or more of glycosidal saponins; myo-inositol; or glucomannan in concentrations of about 150mg to 1500mg glycosidal saponins; about 100mg to 2000mg myo-inositol; and 25mg to 2000mg glucomannan.
25
54. A method according to claim 52 wherein the supplement comprises one or more of glycosidal saponins; myo-inositol; or glucomannan in concentrations of about 50mg to 500mg glycosidal saponins; about 200mg to 1000mg myo-inositol; and



- 21 -

50mg to 1000mg glucomannan.

55. A method according to claim 52 wherein the supplement comprises about 100mg to 500mg glucomannan.

56. A method according to claim 52 wherein the supplement comprises about
5 50mg glucosidal saponins.

57. A method according to any one of claims 52-56 wherein the source of amino acids comprise whey protein.

58. A food supplement comprising a component which increase nitric oxide production in the body, and amino acids, the food supplement being in powder or
10 granular form.

59. A food supplement comprising a first component selected from the group consisting of glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, and folic acid, and mixtures thereof, and a second component consisting whey protein, wherein the whey protein is included in the food supplement in an amount of from
15 about 0.01mg to about 1000mg per gram of food supplement.

60. A food supplement according to claim 59, comprising from 13mg to 11,000mg of the first component, per 28g of the food supplement.

61. A food supplement according to claim 59, comprising from 275mg to 5500mg of the first component, per 28g of the food supplement.

